| Case ID | WW Identifier | Narrative |
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| 4.1(b) | 4.1(b) | This case was received via 4.1(b) (Reference number: 4.1(b) ) on 21-Sep-2021 and was forwarded to Moderna on 21-Sep-2021.<br>This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (Myocarditis) in a 27-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 14-Sep-2021, the patient received second dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 20-Sep-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criterion medically significant). At the time of the report, MYOCARDITIS (Myocarditis) had not resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On an unknown date, SARS-CoV-2 test: negative (Negative) Negative.<br><br>The action taken with mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown) was unknown.<br><br>No concomitant medication details were reported.<br>No treatment medication details was reported.<br>Completely sound medical history, no conditions. Patient has not had symptoms associated with COVID-19.<br><br>Company Comment:<br>This case concerns a 27-year-old, male patient with no relevant medical history, who experienced the unexpected event of Myocarditis. The event occurred approximately 7 days after the second dose of Spikevax . The rechallenge was not applicable, as the event happened after the second dose and no additional dose will be given.The benefit-risk relationship of Spikevax is not affected by this report. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 21-Sep-2021 and was forwarded to Moderna on 21-Sep-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myocarditis) in a 26-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination.<br><br>Concurrent medical conditions included Asthma.<br><br>In July 2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form.<br>On 10-Aug-2021, received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to 1 dosage form. On 14-Aug-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Myocarditis) had not resolved. |

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| | | For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.<br><br>Concomitant medication was not provided.<br><br>Treatment medication was not provided.<br><br>Company comment: This case concerns a 26 year old male patient with no relevant medical history, who experienced the expected event of Myocarditis. The event Myocarditis occurred approximately 4 days after the second dose of the Moderna COVID-19 vaccine. The rechallenge was not applicable. The benefit-risk relationship of the Moderna COVID-19 vaccine is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 21-Sep-2021: Translation Document Received on 28-Sep-2021, containing no new information |
| 4.1(b) | 4.1(b) | This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (4.1(b)) in a 21-year-old female patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 24-Jul-2021, the patient received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 100 microgram. On 26-Jul-2021, after starting mRNA-1273 (COVID-19 Vaccine Moderna), the patient experienced MYOCARDITIS (4.1(b)) (seriousness criterion medically significant). On 09-Aug-2021, MYOCARDITIS (4.1(b)) had resolved with sequelae.<br><br>For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered MYOCARDITIS (4.1(b)) to be possibly related.<br><br>Concomitant product use was not provided by the reporter.<br><br>The patient was non-smoker and alcohol consumption rare.<br><br>No treatment information was provided.<br><br>This case concerns a 21 year old female patient with no medical history reported, who experienced the expected serious event of MYOCARDITIS, within 2 days after the second dose of mRNA-1273 vaccine. Limited information regarding the event have been provided at this time. The HCP reporter considered MYOCARDITIS to be possibly related. Rechallenge is not applicable. The benefit-risk relationship of the vaccine is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 23-Sep-2021: Translation received on 27 Sep 2021 contains dose number was added and other relevant history was added in narrative. |

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| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 22-Sep-2021 and was forwarded to Moderna on 22-Sep-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (4.1(b) in a 28-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3004224) for Vaccination. The occurrence of additional non-serious events is detailed below.<br><br>Co-suspect product included non-company product TOZINAMERAN (COMIRNATY) for Vaccination.<br><br>The patient's past medical history included Smoker (2 cigarettes daily for 16 years.).<br>Family history included Heart disease, unspecified (but not among first degree relatives).<br><br>On 30-Jul-2021, the patient received first dose of TOZINAMERAN (COMIRNATY) (Intramuscular) 1 dosage form.<br>On 28-Aug-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 31-Aug-2021, after starting mRNA-1273 (Spikevax), the patient experienced MYOCARDITIS (4.1(b) (seriousness criteria hospitalization and medically significant). On an unknown date, the patient experienced COVID-19 IMMUNISATION (Revaccination with different covid-19 vaccine). At the time of the report, MYOCARDITIS (4.1(b) was resolving and COVID-19 IMMUNISATION (Revaccination with different covid-19 vaccine) outcome was unknown.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 31-Aug-2021, C-reactive protein: abnormal (abnormal) 14-3.5 mg/L-.<br>On 31-Aug-2021, Chest X-ray: normal (normal) Normal.<br>On 31-Aug-2021, Computerised tomogram: normal (normal) No abnormal heart findings..<br>On 31-Aug-2021, Echocardiogram: normal (normal) Normal.<br>On 31-Aug-2021, Electrocardiogram: abnormal (abnormal) Inferolateral ST elevation without resiprocal changes..<br>On 31-Aug-2021, N-terminal prohormone brain natriuretic peptide: normal (normal) 60-56 ng/L.<br>On 31-Aug-2021, Troponin I: abnormal (abnormal) 4729-130 ng/L..<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered MYOCARDITIS (4.1(b) and COVID-19 IMMUNISATION (Revaccination with different covid-19 vaccine) to be possibly related.<br><br>Treatment medications were not reported.<br>Concomitant medications were not reported.<br>The reporter states that the patient had Some history of heart disease in the family, but not among first degree relatives.<br><br>Company Comment : This is a case of revaccination with different Covid-19 vaccine for this 28-year-old, male patient with relevant medical history of receiving different brand of Covid-19 vaccine (Comirnaty) as the first |

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| | | dose, who experienced the expected event of perimyocarditis. The event perimyocarditis occurred 4 days after the "second dose" of mRNA-1273 vaccine administration. The rechallenge was not applicable since the patient received different brand of Covid-10 vaccine (Comirnaty) as the first dose. The events were considered possibly related to the product per the reporter's assessment. The medical history of first dose with other brand of Covid-19 vaccine (Comirnaty) remain confounder for this case report. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. The RA SD report captured the dosage interval as 33 days while it is 29 days.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 23-Sep-2021: Translation document received on 24 Sep 2021 contain no new information. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 22-Sep-2021 and was forwarded to Moderna on 22-Sep-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (4.1(b) ) in an 18-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 214020 and 3002921) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 31-Jul-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form.<br>On 30-Aug-2021, received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to 1 dosage form. On 30-Aug-2021, the patient experienced MYOCARDITIS (4.1(b) ) (seriousness criteria hospitalization and medically significant). On 08-Sep-2021, MYOCARDITIS (4.1(b) ) had resolved.<br><br>mRNA-1273 (Spikevax) (Intramuscular) was withdrawn on 31-Jul-2021.<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.<br><br>The concomitant medications were not reported. The treatment information was not provided.<br><br>Lab details were not provided.<br><br>Company Comment : This case concerns a 18 year-old male subject with no relevant medical history reported ., who experienced the serious expected event of MYOCARDITIS. The event occurred approximately 1 day after receiving the second dose of spikevax. Time to onset from the first dose was 1 month. Rechallenge was not applicable since the event occurred after the second dose. The benefit-risk relationship of spikevax is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 22-Sep-2021: Translation document received on 27 Sep 2021 contains no new information |

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| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 22-Sep-2021 and was forwarded to Moderna on 22-Sep-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of COVID-19 IMMUNISATION (REVACCINATION WITH DIFFERENT COVID-19 VACCINE), IMPAIRED WORK ABILITY (INABILITY TO WORK) and PERICARDITIS (PERICARDITIS) in a 24-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3004224) for Vaccination.<br><br>Previously administered products included for Vaccination: Comirnaty.<br>Concurrent medical conditions included Migraine.<br><br>On 01-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 03-Sep-2021, the patient experienced COVID-19 IMMUNISATION (REVACCINATION WITH DIFFERENT COVID-19 VACCINE) (seriousness criterion medically significant), IMPAIRED WORK ABILITY (INABILITY TO WORK) (seriousness criterion medically significant) and PERICARDITIS (PERICARDITIS) (seriousness criterion medically significant). At the time of the report, COVID-19 IMMUNISATION (REVACCINATION WITH DIFFERENT COVID-19 VACCINE), IMPAIRED WORK ABILITY (INABILITY TO WORK) and PERICARDITIS (PERICARDITIS) had not resolved.<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered COVID-19 IMMUNISATION (REVACCINATION WITH DIFFERENT COVID-19 VACCINE), IMPAIRED WORK ABILITY (INABILITY TO WORK) and PERICARDITIS (PERICARDITIS) to be possibly related.<br><br>No treatment details were provided.<br>Concomitant information was not provided.<br>Company comment: This case concerns a 24-year-old, male patient with no relevant medical history, who experienced the unexpected events of COVID-19 immunisation and impaired work ability, and the expected event of pericarditis. The events occurred 2 days after administration of the second dose of Spikevax. The rechallenge was not applicable as no additional dosing will be given. The events pericarditis and impaired work ability were considered possibly related to Spikevax per the reporter's assessment. The event pericarditis is consistent with the current understanding of the mechanism of action of Spikevax. The benefit-risk relationship of Spikevax is not affected by this report. Event seriousness was assessed as per Regulatory Authority reporting; however, there was no information in the source document supporting that the events COVID-19 immunisation and impaired work ability are medically significant.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 22-Sep-2021: Translation Received on 29-SEP-2021 contains No new information (NNI). |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 22-Sep-2021 and was forwarded to Moderna on 22-Sep-2021. |

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| | | This regulatory authority case was reported by a physician and describes the occurrence of CHEST PAIN (4.1(b) and MYOCARDITIS (4.1(b) in an 18-year-old male patient who received mRNA-1273 (Spikevax) for Vaccination.<br><br>Previously administered products included for Vaccination: COMIRNATY.<br><br>On 28-Aug-2021 at 12:41 PM, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 31-Aug-2021, the patient experienced CHEST PAIN (4.1(b) (seriousness criterion hospitalization) and MYOCARDITIS (4.1(b) (seriousness criteria hospitalization and medically significant). At the time of the report, CHEST PAIN (4.1(b) and MYOCARDITIS (4.1(b) was resolving.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 31-Aug-2021, Echocardiogram: normal (normal) Normal.<br>On 31-Aug-2021, Troponin: 250 (High) 250 ng/L (nanogram per litre).<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered CHEST PAIN (4.1(b) and MYOCARDITIS (4.1(b) to be possibly related.<br><br>No concomitant medications reported by reporter.<br>No treatment medications provided by the reporter.<br><br>Company comment:<br>This case concerns a 18 year old male patient with no relevant medical history ,who experienced the serious unexpected event of Chest pain and expected event of Myocarditis . The events occurred 2 days after second dose of Spikevax . The rechallenge was unknown since no information about the first dose was disclosed.The reporter assessed the events as related to the product.The benefit-risk relationship of Spikevax is not affected by this report. Case awaiting translation.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 22-Sep-2021: Translation Received on 29-SEP-21 and contain no new information. |
| 4.1(b) | 4.1(b) | This case was initially received via European Medicines Agency (Reference number:4.1(b) ) on 21-Sep-2021.<br>The most recent information was received on 29-Sep-2021 and was forwarded to Moderna on 29-Sep-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of EJECTION FRACTION DECREASED (4.1(b) ) and MYOCARDITIS (4.1(b) ) in a 20-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3004224) for Vaccination. The occurrence of additional non-serious events is detailed below.<br><br>Previously administered products included for Vaccination: Comirnaty. |

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| | | Past adverse reactions to the above products included No adverse event with Comirnaty.<br><br>On 06-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 06-Sep-2021, the patient experienced COVID-19 IMMUNISATION (REVACCINATION WITH DIFFERENT COVID-19 VACCINE). On 08-Sep-2021, the patient experienced EJECTION FRACTION DECREASED (4.1(b) [redacted] (seriousness criterion hospitalization) and MYOCARDITIS (4.1(b) [redacted]) (seriousness criteria hospitalization and medically significant). On an unknown date, the patient experienced INTERCHANGE OF VACCINE PRODUCTS (Interchange of vaccine products). On 06-Sep-2021, COVID-19 IMMUNISATION (REVACCINATION WITH DIFFERENT COVID-19 VACCINE) outcome was unknown. At the time of the report, EJECTION FRACTION DECREASED (4.1(b) [redacted]) and MYOCARDITIS (4.1(b) [redacted]) was resolving and INTERCHANGE OF VACCINE PRODUCTS (Interchange of vaccine products) had resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 08-Sep-2021, Echocardiogram: 40 % (abnormal) Ejection fraction ca 40 %.<br>On 08-Sep-2021, Ejection fraction: 40% (Low) 40 %.<br>On 08-Sep-2021, N-terminal prohormone brain natriuretic peptide: 2246 (abnormal) 2246.<br>On 08-Sep-2021, Troponin: 3537 - 3932 - 4109 (High) 3537 - 3932 - 4109.<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered EJECTION FRACTION DECREASED (4.1(b) [redacted]) and MYOCARDITIS (4.1(b) [redacted]) to be possibly related. No further causality assessments were provided for COVID-19 IMMUNISATION (REVACCINATION WITH DIFFERENT COVID-19 VACCINE) and INTERCHANGE OF VACCINE PRODUCTS (Interchange of vaccine products).<br><br>Concomitant medications was not provided by the reporter.<br>Treatment information was not provided.<br><br>On 08 Sep 2021 patient had undergone Echocardiogram and the result was Ejection fraction ca 40 %.<br><br>Patient experienced Severe perimyocarditis with transient left ventricular failure.<br><br>Company Comment: This case concerns a 20-year-old, male patient with a history of previously administered products for vaccination with |

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| | | Comirnaty, who experienced the expected serious AESI event of myocarditis. The event occurred approximately 2 days after the first dose of Spikevax. COVID-19 immunisation (revaccination with different COVID-19 vaccine) and interchange of vaccine products were considered additional events. The rechallenge was not applicable for myocarditis as the event happened after the second dose and no additional dosing will be given. The medical history of history of previously administered products for vaccination with Comirnaty (at an unknown date) remains a confounder. The benefit-risk relationship of Spikevax is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 29-Sep-2021: Event added, event outcome myocarditis unknown to recovering , vaccine anatomical region added and lab data were added .(Ejection fraction).<br>On 29-Sep-2021: Translation received on 04-Oct-2021 and Translated event verbatim is updated in I-narrative. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 21-Sep-2021 and was forwarded to Moderna on 21-Sep-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myocarditis) in a 21-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3004233) for Prophylactic vaccination. The occurrence of additional non-serious events is detailed below.<br><br>No Medical History information was reported.<br><br>On 02-Jul-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form.<br>On 14-Aug-2021, received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. On 14-Aug-2021, the patient experienced INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (Inappropriate schedule of vacciine administered). On 16-Aug-2021, after starting mRNA-1273 (Spikevax), the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). On 14-Aug-2021, INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (Inappropriate schedule of vacciine administered) had resolved. At the time of the report, MYOCARDITIS (Myocarditis) had not resolved.<br><br>For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.<br><br>No concomitant medications were provided by the reporter.<br>No treatment information was provided by the reporter.<br><br>This case concerns a 21-year-old, male patient with no relevant medical history, who experienced the expected event of myocarditis. Myocarditis occurred two days after the second dose of Spikevax. The rechallenge was not applicable. The event is consistent with the current understanding of the mechanism of action of the vaccine. The benefit-risk relationship of Spikevax is not affected by this report. Event term, onset date, outcome and seriousness captured per SD from Regulatory Authority reporting. |

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| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 21-Sep-2021 and was forwarded to Moderna on 21-Sep-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (4.1(b) in a 28-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3003604) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 30-Aug-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to 1 dosage form.<br>On an unknown date, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 01-Sep-2021, the patient experienced MYOCARDITIS (4.1(b) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (4.1(b) was resolving.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 01-Sep-2021, Troponin T: 1600 (High) 1600 nanogram per litre.<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered MYOCARDITIS (4.1(b) to be possibly related.<br><br>No concomitant medication was reported.<br>Treatment medication was not provided by the reporter.<br><br>This case concerns a 28-year-old, male patient with no relevant medical history, who experienced the expected event of Myocarditis. The event occurred approximately 3 days after the second dose of Spikevax. The rechallenge was not applicable, as the event happened after the second dose as no additional dosing is expected. The benefit-risk relationship of Spikevax is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 21-Sep-2021: Translated document received on 26 Sep 2021 included no new information. |
| 4.1(b) | 4.1(b) | This case was initially received via European Medicines Agency (Reference number: 4.1(b) ) on 21-Sep-2021. The most recent information was received on 18-Oct-2021 and was forwarded to Moderna on 18-Oct-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Perimyocarditis) in a 19-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination.<br><br>The patient's past medical history included Anaphylaxis (Developed anaphylaxis upon intake of nuts).<br>Concurrent medical conditions included Allergy to nuts.<br><br>On 30-Aug-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 08-Sep-2021, the patient experienced MYOCARDITIS (Perimyocarditis) (seriousness criteria |

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| | | hospitalization and medically significant). At the time of the report, MYOCARDITIS (Perimyocarditis) was resolving.<br><br>For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.<br><br>Concomitant product use was not provided by the reporter.<br>Treatment information was not provided.<br><br>Company comment: This case concerns a 19-year-old, male patient with no relevant medical history, who experienced the expected event of Myocarditis. The event occurred approximately 10 days after the first dose of Spikevax. The rechallenge was not applicable, as the event happened after the first dose. The event was considered related to the product per the reporter's assessment. The benefit-risk relationship of Spikevax is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 18-Oct-2021: Follow-Up received and Medical history - Anaphylaxis and Allergy to nuts were updated.<br>On 18-Oct-2021: Translation Received on 19-Oct-2021 included translated event verbatim and medical history notes updated. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 21-Sep-2021 and was forwarded to Moderna on 21-Sep-2021.<br>This regulatory authority case was reported by a pharmacist and describes the occurrence of MYOCARDITIS (Myopericarditis) in an 18-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 3005703 and 3004672) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 24-Jul-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form.<br>On 21-Aug-2021, received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to 1 dosage form. On 26-Aug-2021, the patient experienced MYOCARDITIS (Myopericarditis) (seriousness criteria hospitalization and medically significant). On 29-Aug-2021, MYOCARDITIS (Myopericarditis) had resolved.<br><br>mRNA-1273 (Spikevax) (Intramuscular) was withdrawn on 24-Jul-2021.<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.<br><br>Concomitant product use was not provided by the reporter.<br>No treatment information was provided.<br><br>Company comment<br>This case concerns a 18-year-old, male patient with no relevant medical history, who experienced the expected event of Myocarditis. The event occurred approximately 6 days after the second dose of Spikevax. The rechallenge was not applicable, as the event happened after the second |

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| | | dose. The benefit-risk relationship of Spikevax is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 21-Sep-2021: Translation uploaded on 27-SEP-2021 in which event verbatim and dose information was translated. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 23-Sep-2021 and was forwarded to Moderna on 23-Sep-2021.<br>This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (Myocarditis) in a 25-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 3003603 and 3001945) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 12-May-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form.<br>On 23-Jun-2021, received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. On 30-Jun-2021, after starting mRNA-1273 (Spikevax), the patient experienced MYOCARDITIS (Myocarditis) (seriousness criterion medically significant). At the time of the report, MYOCARDITIS (Myocarditis) had not resolved.<br><br>No relevant concomitant medications were reported.<br><br>Treatment information was not provided.<br><br>Laboratory details included, N-terminal pro b-type natriuretic peptide positive on 17-JUL-2021. On 17-AUG-2021, Echocardiography was done and results were not provided at the time of the report.<br><br>Company comment -This case concerns a 25-years-old, male patient with no reported medical history. The patient experienced serious (medically significant) event of and Myocarditis 7 days after the second dose of Spikevax. The events causality was not provided by reporter. Patient experienced AEs after second dose rechallenge is not applicable. The benefit-risk relationship of Spikevax is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 23-Sep-2021: Translation received on 27-SEP-2021 contains laboratory details of the patient. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 23-Sep-2021 and was forwarded to Moderna on 23-Sep-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of CEREBRAL INFARCTION (Middle cerebral artery infarct) and MYOCARDITIS (Acute myocarditis) in a 36-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 214007) for Prophylactic vaccination.<br><br>The patient's past medical history included Obesity. |

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| | | On 20-Jul-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form.<br>On 31-Aug-2021, received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. On 07-Sep-2021, the patient experienced CEREBRAL INFARCTION (Middle cerebral artery infarct) (seriousness criteria hospitalization and medically significant) and MYOCARDITIS (Acute myocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, CEREBRAL INFARCTION (Middle cerebral artery infarct) and MYOCARDITIS (Acute myocarditis) outcome was unknown.<br><br>For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.<br><br>Concomitant product use was not provided by the reporter.<br><br>No treatment information was provided.<br><br>company comment: This case concerns a 36-year-old, male patient with relevant medical history of obesity, who experienced the unexpected event of Cerebral infarction and the expected event of Myocarditis. The events cerebral infarction and myocarditis both occurred approximately 8 days after the second dose of Spikevax. The rechallenge was not applicable as events occurred after second dose. The benefit-risk relationship of Spikevax is not affected by this report. |
| 4.1(b) | 4.1(b) | This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (4.1(b) in a 36-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) (batch nos. 3002918 and 3001942) for COVID-19 vaccination.<br><br>The patient's past medical history included H1N1 influenza (last time sick, 2009 swine flu;) in 2009.<br><br>On 18-May-2021, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form.<br>On 18-Jun-2021, received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) dosage was changed to 1 dosage form. On 14-Aug-2021, after starting mRNA-1273 (COVID-19 Vaccine Moderna), the patient experienced MYOCARDITIS (4.1(b) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (4.1(b) ) was resolving.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>In 2021, SARS-CoV-2 test: negative (Negative) Negative.<br><br>No concomitant medication details were reported. |

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| | | No treatment medication details was reported.<br>After a latency period of almost two months, perimyocarditis that required hospitalization Pericarditis, myocarditis, pressure on the chest. Admission to Insel hospital.<br>The adverse reaction is described as improved and was perceived, by the patient, as severe.<br><br>Company Comment: This case concerns a 36-year-old, male patient with no relevant medical history, who experienced the expected, serious, AESI event of Myocarditis. The event occurred approximately 1 month and 28 days after second dose of Spikevax. The rechallenge is unknown since no information was disclosed from first dose. The benefit-risk relationship of Spikevax is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 23-Sep-2021: Translation received on 30-SEP-2021. Updated information in inarrative and Sender's comments. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) on 23-Sep-2021 and was forwarded to Moderna on 23-Sep-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of CHEST PAIN (4.1(b) and MYOCARDITIS (4.1(b) in a 33-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3004224) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below.<br><br>Co-suspect product included non-company product TOZINAMERAN (COMIRNATY) for Vaccination.<br><br>No Medical History information was reported.<br><br>On 19-Jul-2021, the patient started TOZINAMERAN (COMIRNATY) (Intramuscular) 1 dosage form.<br>On 31-Aug-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 03-Sep-2021, the patient experienced CHEST PAIN (4.1(b) (seriousness criterion hospitalization). On 04-Sep-2021, the patient experienced MYOCARDITIS (4.1(b) (seriousness criteria hospitalization and medically significant). On an unknown date, the patient experienced COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine) and INTERCHANGE OF VACCINE PRODUCTS (interchange of vaccines). At the time of the report, CHEST PAIN (4.1(b) and MYOCARDITIS (4.1(b) had not resolved and COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine) and INTERCHANGE OF VACCINE PRODUCTS (interchange of vaccines) outcome was unknown.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 03-Sep-2021, C-reactive protein: 40 (abnormal) 40 mg/L (milligram per litre).<br>On 03-Sep-2021, Electrocardiogram: abnormal (abnormal) Global ST-elvations and global st-elvations (abnormal) Global ST-elvations.<br>On 03-Sep-2021, Magnetic resonance imaging heart: abnormal (abnormal) Findings compatible with myocarditis. |

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| | | On 03-Sep-2021, Troponin I: 2000 - 3000 - 2000 ng/l (abnormal) 2000 - 3000 - 2000 ng/L.<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.<br><br>No concomitant medication listed<br>No treatment medications provided<br><br>It was originally reported perimyocarditis, but the after receiving results from cardiac MRI, the diagnosis was changed to myocarditis.<br><br>This case concerns a 33-year-old male patient with no relevant medical history, who experienced the unexpected serious events of Chest pain and Myocarditis. The events occurred 1 month 17 days after the second dose of (Spikevax). The patient received interchange of vaccine products (Pfizer vaccine for the first dose) and hence the rechallenge for Spikevax was not applicable. The benefit-risk relationship of Spikevax is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 23-Sep-2021: Translated document received on 29-sep-2021 contain no new information<br>On 29-Sep-2021: Significant follow up received on 29-Sep-2021, Comirnanty updated from historical vaccine to suspect vaccine and event perimyocarditis updated to myocarditis.<br>On 29-Sep-2021: Translation received on 01 OCT 2021 contains no new information. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) on 23-Sep-2021 and was forwarded to Moderna on 23-Sep-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Perimyocarditis) in a 24-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3004498) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below.<br><br>The patient's past medical history included Childhood asthma.<br>Previously administered products included for Vaccination: COMIRNATY.<br><br>On 09-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 09-Sep-2021, the patient experienced COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine). On 11-Sep-2021, the patient experienced MYOCARDITIS (Perimyocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Perimyocarditis) was resolving and COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine) outcome was unknown.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 11-Sep-2021, C-reactive protein: 100 (Inconclusive) 100. |

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| | | On 11-Sep-2021, Echocardiogram: small amount of pericardial fluid (abnormal) Small amount of pericardial fluid.<br>On 11-Sep-2021, Electrocardiogram: no distinct abnormality (normal) No distinct abnormality.<br>On 11-Sep-2021, Pain assessment: nrs 3 (Inconclusive) NRS 3.<br>On 11-Sep-2021, Troponin T: 620 (Inconclusive) 620.<br>On 12-Sep-2021, Echocardiogram: no pericardial fluid (Inconclusive) Done by cardiologist. No pericardial fluid. Fine contractility..<br>On 12-Sep-2021, White blood cell count: slight leucopenia, monocytopenia and neutropenia. (abnormal) Slight leucopenia, monocytopenia and neutropenia..<br>On 14-Sep-2021, Troponin T: 709 (High) 709 (highest value).<br>On 15-Sep-2021, C-reactive protein: 18 (Inconclusive) 18.<br>On 15-Sep-2021, Magnetic resonance imaging heart: sparse perimyocarditis changes basal inferolateral (abnormal) Sparse perimyocarditis changes basal inferolateral..<br>On 15-Sep-2021, Troponin T: 498 (Low) 498 (lowest value).<br>On 16-Sep-2021, Electrocardiogram: global st-elevations during on of the episodes (abnormal) Normal at first, but development of global ST-elevations during one of the episodes with chest pain.(New reporter, duplicate report).<br>On 16-Sep-2021, Magnetic resonance imaging heart: perimyocarditis changes; reduced contractility (abnormal) Perimyocarditis changes detected as well as reduced contractility in affected myocardium (New reporter, duplicate report).<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered MYOCARDITIS (Perimyocarditis) to be possibly related. No further causality assessment was provided for COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine).<br><br>No concomitant medications were provided by the reporter.<br><br>No treatment information was provided by the reporter.<br><br>This is a case of revaccination with different Covid-19 vaccine for this 24-year-old, male patient with no relevant medical history, who experienced the expected event of myocarditis. The event myocarditis occurred 2 days after the administration of labeled dose number two of mRNA-1273 vaccine. The rechallenge was not applicable because the patient previously received other brand of Covid-19 vaccine (Comirnaty). The patient's age, gender and vaccine history of receiving of other brand of Covid-19 vaccine (Comirnaty) remains confounders. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. The RA SD captured the onset latency of the event myocarditis as 3 days instead of 2 days, RA SD coding was captured and maintained.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 23-Sep-2021: Translation received on 30-Sep-2021 for initial; Sender's comments translated.<br>On 24-Sep-2021: Follow-up received on 24-SEP-2021 contained significant information: additional lab/diagnostic studies.<br>On 24-Sep-2021: Translation received for FU on 30-Sep-2021 contained no new information. |

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| 4.1(b) | 4.1(b) | This case was received via an unknown source (no reference has been entered for a health authority or license partner) on 23-Sep-2021 and was forwarded to Moderna on 23-Sep-2021.<br>This regulatory authority case was reported by a consumer and describes the occurrence of PERICARDITIS (4.1(b)) in a 21-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) (batch nos. 3003185 and 3002918) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 07-Jun-2021, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (unknown route) 1 dosage form.<br>On 09-Jul-2021, received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (unknown route) dosage was changed to 1 dosage form. On 11-Jul-2021, the patient experienced PERICARDITIS (4.1(b)) (seriousness criteria hospitalization and medically significant). At the time of the report, PERICARDITIS (4.1(b)) had not resolved.<br><br>Concomitant product use was not provider by the reporter.<br><br>Treatment information was not provided by the reporter.<br><br>This case concerns a 21-year-old, male patient with no relevant medical history, who experienced the expected event of Pericarditis. The event Pericarditis occurred around 2 days after second dose of Moderna vaccine. The rechallenge is not applicable as a third dose is not expected. The event was considered possibly related to the product per the reporter's assessment. The event is consistent with the current understanding of the mechanism of action of the vaccine. The benefit-risk relationship of Moderna vaccine is not affected by this report. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b)) on 23-Sep-2021 and was forwarded to Moderna on 23-Sep-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of CHEST PAIN (4.1(b)) and MYOCARDITIS (4.1(b)) in a 24-year-old male patient who received mRNA-1273 (Spikevax) for Vaccination. The occurrence of additional non-serious events is detailed below.<br><br>The patient's past medical history included Vaccination (Dose number 1. Vaccination site: Right arm; Intramuscular.) on 07-Jul-2021.<br><br>On 11-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 12-Sep-2021, the patient experienced GENERAL PHYSICAL HEALTH DETERIORATION (Reduced general condition), ARTHRALGIA (Arthralgia), HEADACHE (Headache) and PYREXIA (Fever). On 14-Sep-2021, the patient experienced CHEST PAIN (4.1(b)) (seriousness criterion hospitalization) and |

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| | | MYOCARDITIS (4.1(b) (seriousness criteria hospitalization and medically significant). On an unknown date, the patient experienced COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine). On 14-Sep-2021, PYREXIA (Fever) was resolving. At the time of the report, CHEST PAIN (4.1(b) ), MYOCARDITIS (4.1(b) and COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine) outcome was unknown and GENERAL PHYSICAL HEALTH DETERIORATION (Reduced general condition), ARTHRALGIA (Arthralgia) and HEADACHE (Headache) was resolving.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 14-Sep-2021, C-reactive protein: 55 (High) 55 milligram per litre High.<br>On 14-Sep-2021, Echocardiogram: normal (normal) Normal findings. Good heart pumping function..<br>On 14-Sep-2021, Troponin: 659 (High) 659 nanogram per litre.<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered CHEST PAIN (4.1(b) ), MYOCARDITIS (4.1(b) COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine), GENERAL PHYSICAL HEALTH DETERIORATION (Reduced general condition), ARTHRALGIA (Arthralgia), HEADACHE (Headache) and PYREXIA (Fever) to be possibly related.<br><br>Concomitant product use was not provided by the reporter.<br><br>Treatment information was not provided.<br><br>This case concerns a 24 year-old, male subject, with no relevant medical history, who experienced the unexpected event of Chest pain, and the expected serious and AESI event of Myocarditis. Additional event of Revaccination with different COVID-29 vaccine was captured. The events occurred approximately 4 days after a dose of Spikevax. The rechallenge was not applicable since the first dose was different from Spikevax. The benefit-risk relationship of Spikevax is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 23-Sep-2021: Translation document received on 27-Sep-2021 included drug information and sender's comments. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 23-Sep-2021 and was forwarded to Moderna on 23-Sep-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of CHEST PAIN (4.1(b) and MYOCARDITIS (4.1(b) in a 29-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3004670) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 09-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 10-Sep-2021, the patient |

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| | | experienced CHEST PAIN (4.1(b) (seriousness criterion medically significant) and MYOCARDITIS (4.1(b) (seriousness criterion medically significant). At the time of the report, CHEST PAIN (4.1(b) and MYOCARDITIS (4.1(b) was resolving.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>In September 2021, C-reactive protein: 66 (High) 66.<br>In September 2021, Troponin: 109 (High) 109.<br>In September 2021, White blood cell count: 11.05 (High) 11.05.<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered CHEST PAIN (4.1(b) and MYOCARDITIS (4.1(b) to be possibly related.<br><br>No concomitant medications reported by reporter.<br><br>No treatment medications provided by the reporter.<br><br>Follow-up received on 23-SEP-2021 included no new information<br><br>Company comment - This case concerns a 29-year-old, male patient with no relevant medical history, who experienced the unexpected event of chest pain and the expected event of myocarditis. The events occurred 2 days after the second dose of Spikevax. The rechallenge was not applicable, as no additional dosing will be given. The event myocarditis is consistent with the current understanding of the mechanism of action of the vaccine. The benefit-risk relationship of Spikevax is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 23-Sep-2021: Translation Document received on 27-SEP-2021 and does not contain any new information. |
| 4.1(b) | 4.1(b) | This case was received via 4.1(b) (Reference number: 4.1(b) ) on 22-Sep-2021 and was forwarded to Moderna on 22-Sep-2021.<br>This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (Myopericarditis) in a 30-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) (batch no. 3003651) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 02-Aug-2021, the patient received second dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 04-Aug-2021, the patient experienced MYOCARDITIS (Myopericarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Myopericarditis) had not resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On an unknown date, SARS-CoV-2 test: no - negative covid-19 test (Negative) No - Negative COVID-19 test. |

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| | | The action taken with mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown) was unknown.<br><br>Concomitant product was not provided by the reporter<br>Treatment product was not provided by the reporter<br><br>Company comment:<br>This case concerns a 30 year-old male patient with no reported medical history of who experienced the expected event of myocarditis. The event occurred approximately 3 days after the second dose of mRNA-1273. The rechallenge was not applicable as no additional dosing will be given. The event myocarditis is consistent with the current understanding of the mechanism of action of the vaccine. The benefit-risk relationship of mRNA-1273 is not affected by this report. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 23-Sep-2021 and was forwarded to Moderna on 23-Sep-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (MYO-PERICARDITIS - CHEST DISCOMFORT), LOSS OF PERSONAL INDEPENDENCE IN DAILY ACTIVITIES (COULD NOT TAKE PART IN CONTACT SPORTS. HE CAN RETURN TO HIS USUAL ACTIVITIES IN ABOUT 2 WEEKS / AVOIDING EXTREMES OF EXERTION) and IMPAIRED WORK ABILITY (SHOULD STAY OFF WORK UNTIL MONDAY WEEK) in a 22-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 3004218 and 3003604) for COVID-19 vaccination.<br><br>None.<br><br>On 28-Jul-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form.<br>On 26-Aug-2021, received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. On 27-Aug-2021, the patient experienced MYOCARDITIS (MYO-PERICARDITIS - CHEST DISCOMFORT) (seriousness criteria hospitalization and medically significant). On an unknown date, the patient experienced LOSS OF PERSONAL INDEPENDENCE IN DAILY ACTIVITIES (COULD NOT TAKE PART IN CONTACT SPORTS. HE CAN RETURN TO HIS USUAL ACTIVITIES IN ABOUT 2 WEEKS / AVOIDING EXTREMES OF EXERTION) (seriousness criteria hospitalization and medically significant) and IMPAIRED WORK ABILITY (SHOULD STAY OFF WORK UNTIL MONDAY WEEK) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (MYO-PERICARDITIS - CHEST DISCOMFORT) was resolving and LOSS OF PERSONAL INDEPENDENCE IN DAILY ACTIVITIES (COULD NOT TAKE PART IN CONTACT SPORTS. HE CAN RETURN TO HIS USUAL ACTIVITIES IN ABOUT 2 WEEKS / AVOIDING EXTREMES OF EXERTION) and IMPAIRED WORK ABILITY (SHOULD STAY OFF WORK UNTIL MONDAY WEEK) outcome was unknown. |

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| | | DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>In August 2021, Electrocardiogram: inconclusive (Inconclusive) ECG wide spread concave upwards ST elevation.<br>On 27-Aug-2021, C-reactive protein: 66 (abnormal) Admission CRP 66.<br>On 27-Aug-2021, Echocardiogram: normal (normal) No pericardial effusion. Normal LV function.<br>On 27-Aug-2021, Troponin: 893 (abnormal) Admission Troponin 893.<br>On 30-Aug-2021, C-reactive protein: 10 (normal) normal.<br><br>For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.<br><br>No treatment information was provided.<br>No relevant concomitant medications were reported.<br><br>Company comment: This case concerns a 22-year-old, male patient with no relevant medical history, who experienced the unexpected events of impaired work ability, loss of personal independence in daily activities, and the expected event of Myocarditis. The event Myocarditis occurred 1 day after the second dose of Spikevax. The rechallenge was not applicable, as no additional dosing will be given. The event myocarditis is consistent with the current understanding of the mechanism of action of the vaccine. The benefit-risk relationship of Spikevax is not affected by this report. Events term, onset date, outcome and seriousness captured per SD from Regulatory Authority reporting. |
| 4.1(b) | 4.1(b) | This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (4.1(b) in a 32-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below.<br><br>Concurrent medical conditions included Alcohol use and Tobacco user.<br><br>On 10-Jun-2021, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 200 microgram.<br>On 08-Jul-2021, received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) dosage was changed to 200 microgram. On 10-Jun-2021, the patient experienced the first episode of INCORRECT DOSAGE ADMINISTERED (Dose 200 microgram). On 08-Jul-2021, the patient experienced the second episode of INCORRECT DOSAGE ADMINISTERED (Dose 200 microgram). On 19-Aug-2021, after starting mRNA-1273 (COVID-19 Vaccine Moderna), the patient experienced MYOCARDITIS (4.1(b) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (4.1(b) had not resolved and last episode of INCORRECT DOSAGE ADMINISTERED (Dose 200 microgram) outcome was unknown.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>In 2021, Angiogram: normal (normal) normal.<br>In 2021, Blood creatine phosphokinase: 1506 peak: 1707 (High) 1506 peak: 1707. |

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| | | In 2021, Electrocardiogram: abnormal (abnormal) abnormal.<br>In 2021, Troponin T: 2251 peak: 4441 (High) 2251 peak: 4441.<br>On 20-Aug-2021, Echocardiogram: abnormal (abnormal) abnormal.<br><br>For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered MYOCARDITIS (4.1(b) to be possibly related. No further causality assessments were provided for INCORRECT DOSAGE ADMINISTERED (Dose 200 microgram) and INCORRECT DOSAGE ADMINISTERED (Dose 200 microgram).<br><br>Patient had complained of left thoracic pain without any previous symptoms of infection.<br>Concomitant product use was not provided by the reporter.<br>No treatment information was provided.<br><br>Company Comment: This is a case of incorrect dosage administered for this 32-year-old, male patient with no relevant medical history, who experienced the expected event of myocarditis. The event myocarditis occurred 42 days after the second dose of mRNA-1273 vaccine. The rechallenge was not applicable, as the event occurred after the second dose of mRNA-1273 vaccine administration. The patient's age, gender and the event incorrect dosage administered remains confounders. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. The incorrect dosage administered was an added event. According to the RA SD structured field the patient received 200 microgram of mRNA-1273 vaccine for dose 1 and dose 2. The correct dosage for mRNA-1273 is 100 microgram per dose.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 23-Sep-2021: Translation received on 28-SEP-2021 contains significant information ECG, transthoracic echocardiogram, coronary angiography added in lab data.In history alcohol use, tobacco use added, narrative updated. |
| 4.1(b) | 4.1(b) | This regulatory authority case was reported by a physician and describes the occurrence of CHEST PAIN (4.1(b) PYREXIA (4.1(b) 4.1(b) ), HEADACHE (4.1(b) LIMB DISCOMFORT (4.1(b) ABDOMINAL PAIN (4.1(b) and MYOCARDITIS (4.1(b) in a 37-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) (batch nos. 30380777700688 and 3002541) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 03-May-2021, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form.<br>On 31-May-2021, received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) dosage was changed to 1 dosage form. On 31-May-2021, the patient experienced PYREXIA (4.1(b) ) (seriousness criteria hospitalization and medically significant), HEADACHE (4.1(b) (seriousness criteria hospitalization and medically significant), LIMB DISCOMFORT (4.1(b) (seriousness criteria hospitalization and medically significant) and ABDOMINAL PAIN (4.1(b) (seriousness criteria hospitalization and medically significant). On 02-Jun-2021, the patient experienced |

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| | | CHEST PAIN (4.1(b) (seriousness criteria hospitalization and medically significant). On 04-Jun-2021, the patient experienced MYOCARDITIS (4.1(b) (seriousness criteria hospitalization and medically significant). On 02-Jun-2021, PYREXIA (4.1(b) ), HEADACHE (4.1(b) LIMB DISCOMFORT (4.1(b) and ABDOMINAL PAIN (4.1(b) had resolved. At the time of the report, CHEST PAIN (4.1(b) and MYOCARDITIS (4.1(b) was resolving.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 04-Apr-2021, Angiocardiogram: abnormal (abnormal) Bland coronary arteries with smooth walls,Apical hypokinesia, LVEF 45-50%.<br>On 04-Jun-2021, Electrocardiogram: abnormal (abnormal) Sinus rhythm with normal heart rate (68bpm)heart axis between +30degrees and +60 degrees PQ interval (146 ms ) narrow QRS, R/S transition V3/V4,Diffuse ST segment elevation , no other repolarization abnormalities.<br><br>For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered PYREXIA (4.1(b) ) and HEADACHE (4.1(b) to be probably related and CHEST PAIN (4.1(b) LIMB DISCOMFORT (4.1(b) ABDOMINAL PAIN (4.1(b) and MYOCARDITIS (4.1(b) to be possibly related.<br><br>Concomitant products were not provided. Treatment medication were not reported.<br><br>Post second dose patient developed body ache, headache, abdominal cramps, fever. On 02-JUN-2021 patient developed chest pain in the middle , with radiation into left upper arm and also in the right arm. The event got recovered and reoccurred on 03-JUN- 2021 and 04-JUN-2021.Later the patient was taken to emergency room and upon admission the vitals were observed as blood pressure 124/93 mmHg, pulse 77 bpm, O2 100% and body temperature of 36.3 degree Celsius. The patient was hospitalized on 04-JUN-2021. At the time of reporting the condition of the patient was reported as improving.<br><br>The patient had a family history of myocarditis for his uncle at age of 60.<br><br>Company Comment: This case concerns a 37 year old male patient with no medical history reported, who experienced the unexpected serious events of PYREXIA, HEADACHE, LIMB DISCOMFORT and ABDOMINAL PAIN within the same day after the second dose of mRNA-1273 vaccine and experienced the unexpected serious event of CHEST PAIN, within 2 days after the second dose of mRNA-1273 vaccine and experienced the expected serious event of MYOCARDITIS, within 4 days after the second dose of mRNA-1273 vaccine. The HCP reporter considered PYREXIA and HEADACHE to be probably related and CHEST PAIN, LIMB DISCOMFORT, ABDOMINAL PAIN and MYOCARDITIS to be possibly related. Rechallenge is not applicable. The benefit-risk relationship of the vaccine is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes: |

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| | | On 22-Sep-2021: Translation received on 28-Sep-2021 and had significant information. Updated lab data investigation and narrative. |
| 4.1(b) | 4.1(b) | This regulatory authority case was reported by a physician and describes the occurrence of PERICARDITIS (4.1(b) ) in a 28-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for SARS-CoV-2 immunisation.<br><br>No Medical History information was reported.<br><br>On 12-Jul-2021, the patient received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) .5 milliliter. On 13-Jul-2021, after starting mRNA-1273 (COVID-19 Vaccine Moderna), the patient experienced PERICARDITIS (4.1(b) ) (seriousness criterion medically significant). At the time of the report, PERICARDITIS (4.1(b) ) outcome was unknown.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 14-Jul-2021, Chest X-ray: normal (normal) no infected site.<br>On 14-Jul-2021, Electrocardiogram: normal (normal) Regular sinus rhythm.<br>On 14-Jul-2021, Electrocardiogram ST segment: normal (normal) normal.<br>On 14-Jul-2021, Sinus rhythm: 70 (normal) 70 bpm.<br>On 14-Jul-2021, Troponin: high (High) High sensitive.<br>On 15-Jul-2021, Troponin: high (High) High sensitive.<br>On an unknown date, Blood pressure measurement: 122/71 (abnormal) 122/71 mmHg.<br>On an unknown date, C-reactive protein: 38.6 mg/l (abnormal) 38.6 mg/L.<br>On an unknown date, Heart rate: 75 (abnormal) 75 bpm.<br>On an unknown date, Oxygen saturation: 98 (abnormal) 98%.<br><br>For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered PERICARDITIS (Douleur thoracique) to be probably related.<br><br>Concomitant medications were not provided.<br>Treatment medications included were NSAIDs for one week<br>Patient had received second dose after that 13-JUL-2021 with respire-dependent retrosternal pain, of sudden onset, radiating to the jaw, evaluated at 5/10, increased with exertion, not relieved in anteversion.<br>Patient was received second dose after few hr later chills without a measured fever.<br>On 14-JUL-2021patient has a mild inflammatory syndrome (CRP 38.6 mg/L) and the ultrasensitive troponin assay is negative (troponin I 11.6 ng/L, normal <60 ng/L). The ECG shows a regular sinus rhythm at 70/min, an isoelectric PR and ST segment and the absence of depolarization or repolarization disorders. Physical examination BP 122/71mmhg, pulse 75bpm, saturation 98% on room air<br><br>On 14-Jul-2021, patient undergone High sensitive troponin I, C-reactive protein, Leukocyte count, Electrocardiogram, Thorax X-ray and results were unknown. |

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| | | On 15-Jul-2021, patient undergone C-reactive protein, High sensitive troponin I, Creatine kinase and results were unknown.<br><br>Company comment: This case concerns a 28 year-old male patient with no reported medical history who experienced the expected event of pericarditis. The event occurred approximately 1 day after the second dose of mRNA-1273. The rechallenge was not applicable as no additional dosing will be administered. The event was considered related to mRNA-1273 per the reporter's assessment. The benefit-risk relationship of mRNA-1273 is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes: On 23-Sep-2021: Translation Document received on 28-Sep-2021 significant information that include lab data added, narrative updated. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 24-Sep-2021 and was forwarded to Moderna on 24-Sep-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myopericarditis) in a 20-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 300005695 and 3004672) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 26-Jul-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form.<br>On 22-Aug-2021, received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. On 23-Aug-2021, the patient experienced MYOCARDITIS (Myopericarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Myopericarditis) was resolving.<br><br>mRNA-1273 (Spikevax) (Unknown) was withdrawn on 26-Jul-2021.<br><br>For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.<br><br>Concomitant product use was not provided by the reporter. No treatment information was provided.<br><br>Company Comment:<br>This case concerns a 20-year-old male patient with no relevant medical history, who experienced serious, AESI, listed, events of myocarditis. The event occurred 2 days after 2nd dose of Moderna COVID-19 Vaccine. The rechallenge was not applicable as the events occurred after the 2nd dose of Moderna COVID-19 Vaccine. The benefit-risk relationship of Moderna COVID-19 Vaccine is not affected by this report. |
| 4.1(b) | 4.1(b) | This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) ) on 14-Sep-2021 and was forwarded to Moderna on 27-Sep-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myocarditis) in a 28-year-old male patient who received mRNA-1273 (COVID 19 Vaccine Moderna) (batch nos. 3003653 and 3004501) for COVID-19 vaccination. |

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| | | No Medical History information was reported.<br><br>On 24-Jul-2021, the patient received first dose of mRNA-1273 (COVID 19 Vaccine Moderna) (Intramuscular) 1 dosage form.<br>On 21-Aug-2021, received second dose of mRNA-1273 (COVID 19 Vaccine Moderna) (Intramuscular) dosage was changed to 1 dosage form. On 23-Aug-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). The patient was hospitalized from 24-Aug-2021 to 29-Aug-2021 due to MYOCARDITIS. At the time of the report, MYOCARDITIS (Myocarditis) was resolving.<br><br>For mRNA-1273 (COVID 19 Vaccine Moderna) (Intramuscular), the reporter considered MYOCARDITIS (Myocarditis) to be possibly related.<br><br>No concomitant medications were reported.<br><br>No treatment information was provided.<br><br>This case concerns a 28 year old male patient with no medical history reported, who experienced the expected serious event of myocarditis, within 2 days after the second dose of mRNA-1273 vaccine. Rechallenge is not applicable. The benefit-risk relationship of the vaccine is not affected by this report. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 24-Sep-2021 and was forwarded to Moderna on 24-Sep-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myopericarditis) in a 24-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 3005790 and 214020) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 13-Aug-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) .5 milliliter.<br>On 10-Sep-2021, received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to .5 milliliter. On 13-Sep-2021, the patient experienced MYOCARDITIS (Myopericarditis) (seriousness criteria hospitalization and medically significant). The patient was hospitalized on 13-Sep-2021 due to MYOCARDITIS. At the time of the report, MYOCARDITIS (Myopericarditis) was resolving.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 13-Sep-2021, C-reactive protein (0-5): 55 (High) 55 ng/L.<br>On 13-Sep-2021, Electrocardiogram: abnormal (abnormal) patient ECG on admission (no pain): Sinus rhythm 75 lpm, axis 40°, decreased PR in V3-V6 peri cordials, incomplete RBBB, early repolarization.<br>On 13-Sep-2021, Troponin T (0-5): 318 (High) units: ng/L Increased. |

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| | | For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.<br><br>Concomitant medications was not provided by the reporter<br>Treatment information was not provided.<br><br>Action taken with mRNA-1273 (Spikevax) was not applicable.<br><br>Company Comment:<br>This case concerns a 24-year-old, male patient with no relevant medical history, who experienced the unexpected event of Myocarditis. The event occurred approximately 4 days after the first dose of Spikevax. The rechallenge was not applicable, as the event happened after the first dose. The benefit-risk relationship of Spikevax is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 24-Sep-2021: Translation received on 29-Sep-2021 and included patient lab data. |
| 4.1(b) | 4.1(b) | This case was initially received via Takeda Pharmaceuticals (Reference number: 4.1(b) ) on 14-Sep-2021. The most recent information was received on 07-Jan-2022 and was forwarded to Moderna on 07-Jan-2022.<br>This case, initially reported to the 4.1(b) by a (physician), was received via the 4.1(b) (Ref, 4.1(b) ). On 05-Jan-2022, follow-up information was received from a physician. The patient had hyperuricaemia as a comorbidity, which had been in a good control as the patient was under treatment with oral benzbromarone 50 mg once daily. On 17-Aug-2021, the patient received the 1st dose of the vaccine. On 07-Sep-2021, the patient received the 2nd dose of the vaccine. On 08-Sep-2021, body temperature went up to 38.5 degrees Celsius. On 09-Sep-2021, body temperature went down to 37.0 degrees Celsius. On 10-Sep-2021, chest pain suddenly developed while the patient was sleeping. Although the patient saw the course of the symptom, there was few improvements and thus the patient called an ambulance. The patient was transported to the reporting hospital. On arrival at the hospital, chest pain was persisting. A blood test found increases in CK, CK-MB, troponin T, and CRP level while no increase in D-dimer level was found. Electrocardiogram showed ST-elevation in leads I, II, III, aVF, and V4 to 6. Echocardiography showed hypokinesis of the inferior lateral wall. Coronary angiography which was performed on the same day showed no significant stenosis of the coronary arteries. In addition, left ventriculography was performed to show hypokinesis in the posterolateral wall. The patient was hospitalized with a diagnosis of myocarditis. Only conservative treatments were performed. Chest pain improved over time. On 12-Sep-2021, a blood test found decreases in CK, CK-MB, troponin T, and CRP level. The echocardiography showed no pericardial fluid and no further hypokinesis of the wall. As chest pain disappeared, it was considered that the patients condition was improving. Based on the course of the disease, it was considered highly possible that the patient experienced myocarditis. On 13-Sep-2021, relief of the symptom was confirmed. On 18-Sep-2021, myocarditis disappeared. The chest pain disappeared, and the patient was discharged from the hospital with resolving symptoms. The outcome of myocarditis was reported as resolving. No follow-up investigation will be made. [Physical finding] No |

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| | | pulsus paradoxus No pericardial friction rub No other abnormal findings [Chest X-ray] (Date of exam: 10-Sep-2021) No special note. [Electrocardiogram] (Date of exam: 10-Sep-2021) I, II, III, aVF, and V4-V6: ST elevated. [Echocardiography] (Date of exam: 10-Sep-2021) There was a hypokinesis in inferolateral wall. [Pericardial and endomyocardial biopsies] (Date of exam: 10-Sep-2021) There was a mild lymphocyte and neutrophil infiltration. [Electrocardiogram] (Date of exam: 14-Sep-2021) Within the normal range. [Magnetic resonance imaging (MRI)] (Date of exam: 14-Sep-2021) There was myocardial edema on the posterior lateral wall. [Chest X-ray] (Date of exam: 16-Sep-2021) No special note. Reporter comments continuation: The patient had no significant stenoses in the coronary arteries and had wall hypokinesis limited to the inferior wall, which was one of characteristics of myocarditis associated with the vaccine reported to date. In addition, the patient was a young man who received the 2nd dose, had localized hypokinesis of the wall, and experienced increases in CK, CK-MB, troponin T, and CRP level. Based on the above, it was considered as highly possible that the patient experienced myocarditis. The patient was a young male with normal growth history and had received the 2nd vaccination, which was consistent with previous reports of myocarditis after vaccination with this vaccine, so the onset of adverse events was temporally related to the timing of administration of this vaccine. Since the uric acid level had been well controlled and there was no significant stenosis in the coronary artery, the occurrence of the adverse event was not related to pathological factors of underlying disease or complications. Follow-up received on 05-JAN-2022 Updated: Reporter Information, Patient Information, Other Relevant History, Lab Data, Product Information, Event Information, Narrative, Reporter Comments Company Comment: The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. |
| 4.1(b) | 4.1(b) | This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) ) on 15-Sep-2021 and was forwarded to Moderna on 27-Sep-2021.<br><br>This case, initially reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref, 4.1(b)<br><br>On an unknown date, the patient received 1st dose of the vaccine.<br><br>On an unknown date, body temperature before vaccination: 36.2 degrees Celsius.<br><br>On 11-Sep-2021, at 11:30, the patient received 2nd dose of the vaccine.<br><br>On 12-Sep-2021, at 08:00, the patient visited a nearby hospital with a complaint of chest pain on inspiration. Electrocardiogram showed that elevated ST was seen in wide range of leads, and blood test showed no elevated cardiac enzymes. The diagnosis of acute pericarditis was made.<br><br>On 13-Sep-2021, the patient was hospitalized due to acute pericarditis.<br><br>On 14-Sep-2021, it was confirmed that the symptom resolved.<br><br>The outcome of acute pericarditis was reported as resolved. |

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| | | Follow-up investigation will be made.<br><br>Company Comment:<br><br>The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. |
| 4.1(b) | 4.1(b) | This case was initially received via 4.1(b) (Reference number: 4.1(b) ) on 24-Sep-2021. The most recent information was received on 26-Oct-2021 and was forwarded to Moderna on 26-Oct-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of CHEST PAIN (Chest pain), VACCINATION SITE PAIN (Vaccination site pain), PYREXIA (High temperature)), MYOCARDITIS (Myocarditis) and BUNDLE BRANCH BLOCK RIGHT (Bundle branch block right) in a 21-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for COVID-19 immunisation.<br><br>No Medical History information was reported.<br><br>On 19-Sep-2021, the patient received second dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form.<br>On an unknown date, the patient received first dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 19-Sep-2021, the patient experienced VACCINATION SITE PAIN (Vaccination site pain) (seriousness criterion hospitalization) and PYREXIA (High temperature)) (seriousness criterion hospitalization). On 20-Sep-2021, the patient experienced CHEST PAIN (Chest pain) (seriousness criterion hospitalization). On 22-Sep-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). On an unknown date, the patient experienced BUNDLE BRANCH BLOCK RIGHT (Bundle branch block right). On 20-Sep-2021, VACCINATION SITE PAIN (Vaccination site pain) and PYREXIA (High temperature)) had resolved. At the time of the report, CHEST PAIN (Chest pain), MYOCARDITIS (Myocarditis) and BUNDLE BRANCH BLOCK RIGHT (Bundle branch block right) outcome was unknown.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 19-Sep-2021, Body temperature: 39 (High) 39 degree Celsius.<br>On an unknown date, Electrocardiogram: abnormal (abnormal) Sinus rhythm, abnormal (abnormal) Partial RBBB and abnormal (abnormal) Tall T on lateral chest leads.<br>On an unknown date, Troponin: abnormal (abnormal) 7070.<br><br>For mRNA-1273 (Moderna CoviD-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments.<br><br>Reportedly, after receiving dose 2 of Moderna COVID-19 Vaccine, Patient experienced Pain on injection site arm and Body temperature of 39 Degree Celsius at night, had resolved on the next day. Patient had woke up with severe chest pain (sharp/pressure like) across upper chest more |

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| | | on left side, exacerbated by breathing and lying supine, radiating pain to both arm at upper arms down to below elbows.<br><br>Patient was admitted to hospital for further investigation and monitoring.<br><br>Concomitant product use was not provided.<br><br>Treatment product information was not provided.<br><br>Company comment: This case concerns a 21 -year-old, male patient with no relevant medical history, who experienced the expected and serious event of MYOCARDITIS and the unexpected serious events of VACCINATION SITE PAIN, PYREXIA, CHEST PAIN, BUNDLE BRANCH BLOCK RIGHT. The events VACCINATION SITE PAIN and PYREXIA occurred on the same day of the second dose of Spikevax. The event CHEST PAIN occurred the following day of the second dose of Spikevax. The event MYOCARDITIS occurred three days after the second dose of Spikevax, and on an unknown date the event BUNDLE BRANCH BLOCK RIGHT occurred. The rechallenge was not applicable as no information about additional dosing was disclosed. The benefit-risk relationship of Spikevax is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 26-Oct-2021: Significant Follow-up was received on 26-OCT-2021. Lab data and information were. Outcome of events were updated. Narrative was updated |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 24-Sep-2021 and was forwarded to Moderna on 24-Sep-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myopericarditis) in a 19-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 300005695 and 3004672) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 26-Jul-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form.<br>On 22-Aug-2021, received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. On 25-Aug-2021, the patient experienced MYOCARDITIS (Myopericarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Myopericarditis) was resolving.<br><br>mRNA-1273 (Spikevax) (Unknown) was withdrawn on 26-Jul-2021.<br><br>For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.<br><br>No concomitant medications reported by reporter.<br>No treatment medications provided by the reporter.<br><br>Company Comment: |

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| | | This case concerns a 19- year-old, male patient with no relevant medical history, who experienced the expected serious AESI event of myocarditis. The event occurred approximately 4 days after the second dose of Spikevax. The rechallenge was not applicable as the event happened after the second dose and the vaccine was withdrawn. The benefit-risk relationship of Spikevax is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 24-Sep-2021: Translated document received on 30-Sep-21 and contain no new information. |
| 4.1(b) | 4.1(b) | This case was initially received via European Medicines Agency (Reference number: 4.1(b) ) on 24-Sep-2021. The most recent information was received on 04-Oct-2021 and was forwarded to Moderna on 04-Oct-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myocardiopericarditis) in a 19-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3005294) for COVID-19 immunisation.<br><br>No Medical History information was reported.<br><br>On 11-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) .5 milliliter. On 11-Sep-2021, the patient experienced MYOCARDITIS (Myocardiopericarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Myocardiopericarditis) had not resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 14-Sep-2021, C-reactive protein: 29.5 (High) 29.5 mg.<br>On 14-Sep-2021, Troponin T: 14.5 (High) 14.5 nanogram.<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.<br><br>No concomitant medications were provided by the reporter.<br>No treatment information was provided by the reporter.<br><br>Laboratory data included Echocardiogram conducted on 14SEP2021 result were not provided. The first dose was administered on 06-AUG-2021, batch number 30044992.<br><br>Patient received the first dose on 06 Aug 2021 with batch number 3004492.<br><br>Company Comment : This case concerns a 19-year-old, male patient with no relevant medical history, who experienced the expected event of Myocarditis. The events occurred the same day after the second dose of Spikevax. The rechallenge was unknown since no information about the first dose was disclosed. No causality assessment was provided by the reporter. The benefit-risk relationship of Spikevax is not affected by this report. Event seriousness assessed as per Regulatory Authority reporting, |

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| | | however there was no information in the source document supporting that the events resulted in a persistent or permanent incapacity<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 04-Oct-2021: Follow Up information was received on 04-Oct-2021 and contains new laboratory test Troponin T added, laboratory test result was added.<br>On 04-Oct-2021: FU Translation received on 07-Oct-2021 Include no new information.<br>On 28-Oct-2021: Follow up received contains No new information.<br>On 29-Oct-2021: Follow up received contains No new information |
| 4.1(b) | 4.1(b) | This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 16-Sep-2021 and was forwarded to Moderna on 28-Sep-2021.<br><br>This case, initially reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref, 4.1(b)<br><br>On an unknown date, the patient received 1st dose of the vaccine.<br><br>On 04-Sep-2021, the patient received 2nd dose of the vaccine.<br><br>On 05-Sep-2021, the patient experienced pyrexia of 38.0 degrees Celsius. Chest pain was noted at night.<br><br>On 06-Sep-2021, the patient made an emergency outpatient visit and was hospitalized with a diagnosis of epicarditis. WBC 10,300/mcL, CRP 1.94 mg/dL, CK/CK・MB 98/1 IU/L, Trop T 0.004 ng/mL, coronavirus PCR test negative.<br><br>On 07-Sep-2021, WBC 4,600/mcL, CRP 3.26 mg/dL, CK/CK・MB 87/1 IU/L, Trop T 0.005 ng/mL.<br><br>On 10-Sep-2021, WBC 5,300/mcL, CRP 0.50 mg/dL, CK/CK・MB 69/2 IU/L, Trop T 0.005 ng/mL.<br><br>On an unknown date, the symptom was resolving with oral medication.<br><br>On 11-Sep-2021, the patient was discharged from the hospital.<br><br>The outcome of epicarditis was reported as resolving.<br><br>Follow-up investigation will be made.<br><br>Company Comment:<br><br>The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 27-Sep-2021 and was forwarded to Moderna on 27-Sep-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of PERICARDITIS (Acute pericarditis) in a 31-year-old |

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| | | female patient who received mRNA-1273 (Spikevax) (batch nos. 3003610 and 3002919) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 09-Jun-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form.<br>On 08-Jul-2021, received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to 1 dosage form. On 15-Jul-2021, the patient experienced PERICARDITIS (Acute pericarditis) (seriousness criterion medically significant). At the time of the report, PERICARDITIS (Acute pericarditis) was resolving.<br><br>mRNA-1273 (Spikevax) (Intramuscular) was withdrawn on an unknown date.<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.<br><br>No concomitant medication were reported. The treatment information were unknown.<br><br>Company comment: This case concerns a 31-year-old female patient with no reported medical history who experienced the event of Acute pericarditis. The event occurred 7 days after the administration of the second dose of mRNA-1273 (Spikevax). The re-challenge was unknown as no information about the first dose was disclosed. Causality for the reported was not provided by the reporter. The benefit-risk relationship of the vaccine is not affected by this report. Percarditis is an adverse event of special interest and is consistent with the current understanding of the mechanism of action of mRNA-1273. The event was assessed as serious per Regulatory Authority reporting as event is an important medical event.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 27-Sep-2021: Translation document received on 29-Sep-2021: dose 1 and 2 information added. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 24-Sep-2021 and was forwarded to Moderna on 24-Sep-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myopericarditis) in a 31-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 214020) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>In July 2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form.<br>On 27-Aug-2021, received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to .5 milliliter. On 30-Aug-2021, the patient experienced MYOCARDITIS (Myopericarditis) (seriousness criteria hospitalization and medically significant). On 02-Sep-2021, MYOCARDITIS (Myopericarditis) had resolved. |

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| | | mRNA-1273 (Spikevax) (Intramuscular) was withdrawn on 27-Aug-2021.<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.<br><br>Concomitant medication was not provided<br>Treatment medication was not provided<br>Company Comment: This case concerns a 31-year-old, male patient with no relevant medical history, who experienced the unexpected event of Myocarditis. The event occurred approximately 4 days after the second dose of Spikevax The rechallenge was not applicable, as the event happened after the second dose and the for another dose. The event was considered related to the product per the reporter's assessment. The benefit-risk relationship of Spikevax is not affected by this report. |
| 4.1(b) | 4.1(b) | This case was initially received via European Medicines Agency (Reference number: 4.1(b) ) on 24-Sep-2021. The most recent information was received on 07-Oct-2021 and was forwarded to Moderna on 07-Oct-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (4.1(b) in a 22-year-old male patient who received mRNA-1273 (Spikevax) for Vaccination.<br><br>Previously administered products included for Vaccination: COMIRNATY (Substance / Specified Substance Name - 5'capped mRNA encoding full length SARS-CoV-2 spike protein).<br><br>On 11-Sep-2021 at 12:00 PM, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 14-Sep-2021, the patient experienced MYOCARDITIS (4.1(b) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (4.1(b) had not resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 14-Sep-2021, Electrocardiogram: normal (normal) Normal.<br>On 14-Sep-2021, Troponin T: 352 (abnormal) 352 nanogram per litre.<br>In September 2021, Magnetic resonance imaging heart: pericarditis (abnormal) Signs of pericarditis..<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered MYOCARDITIS (4.1(b) to be possibly related.<br><br>Concomitant product use was not provided by the reporter.<br>No treatment information was provided.<br><br>Company comment: This case concerns interchange of vaccine products in a 22 year-old male patient with no reported medical history, who experienced the expected serious event of myocarditis. The event occurred 3 days after the second dose of mRNA vaccine (Spikevax). The patient previously received Comirnaty vaccine, which was followed by a dose of Spikevax. ECG was reported to be normal and troponin T was reported to be 352 nanogram per litre (abnormal) and Magnetic |

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| | | resonance imaging heart showed signs of pericarditis. Rechallenge is not applicable. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 07-Oct-2021: FollowUp received contains Lab test ECG and Cardiac MRI are updated.<br>On 07-Oct-2021: Translated document received on 11-Oct-2021 Contains No new information |
| 4.1(b) | 4.1(b) | This case was initially received via Takeda Pharmaceuticals (Reference number: 4.1(b) ) on 17-Sep-2021. The most recent information was received on 24-Dec-2021 and was forwarded to Moderna on 29-Dec-2021.<br>This case, initially reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref, 4.1(b) On 24-Dec-2021, follow-up information was received from a physician. On an unknown date, the patient received the 1st dose of this vaccine. On an unknown date, body temperature before the vaccination: 36.6 degrees Celsius. On 18-Aug-2021, the patient received the 2nd dose of this vaccine. Chest pain developed. On 19-Aug-2021, acute myocarditis developed. On 21-Aug-2021, the patient visited local doctor, and myocardial abnormalities were pointed out. The patient visited an emergency outpatient at this hospital. Blood test showed elevated myocardial prolapse enzymes including troponin T of 0.308 ng/mL, CK-MB of 27 IU/L, CRP of 10.02 mg/dL, and D-dimer of 1.26 mcg/mL. Electrocardiography showed chest lead ST elevation, and the patient was diagnosed with myocarditis and hospitalized. Contrast-enhanced MRI showed LGE in the lateral wall and high signal intensities in T2. On 24-Aug-2021, magnetic resonance imaging (MRI) showed positive LGE with high signal intensities in T2. On 25-Aug-2021, chest pain disappeared. The patient was discharged from the hospital because resolving of symptoms was confirmed. The outcome of acute myocarditis was reported as resolving. No follow-up investigation will be made. Follow-up received on 24-DEC-2021 Updated: Patient Information, Lab Data, Event Information, Narrative, Reporter Comments Company Comment: The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. |
| 4.1(b) | 4.1(b) | This case was initially received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 17-Sep-2021. The most recent information was received on 23-Dec-2021 and was forwarded to Moderna on 28-Dec-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Acute myocarditis) and ATRIAL FIBRILLATION (AF) in a 20-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna Intramuscular Injection) (batch no. 3005286) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 27-Jul-2021, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna Intramuscular Injection) (Intramuscular) 1 dosage form. On 27-Aug-2021, received second dose of mRNA-1273 (COVID-19 Vaccine Moderna Intramuscular Injection) (Intramuscular) dosage was changed to 1 dosage form. On 29-Aug-2021, the patient experienced |

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| | | MYOCARDITIS (Acute myocarditis) (seriousness criteria hospitalization and medically significant). On 30-Aug-2021, the patient experienced ATRIAL FIBRILLATION (AF) (seriousness criterion medically significant). At the time of the report, MYOCARDITIS (Acute myocarditis) and ATRIAL FIBRILLATION (AF) was resolving.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 29-Aug-2021, Electrocardiogram: st elevation (abnormal) ST elevation.<br>On 29-Aug-2021, Myocardial necrosis marker: elevated (High) elevated.<br>On 30-Aug-2021, Angiocardiogram: no significant stenosis (normal) No significant stenosis.<br>On 30-Aug-2021, Aspartate aminotransferase (8-40): 144 (High) 144 iU/L (international unit per litre) and 135 (High) 135 iU/L (international unit per litre).<br>On 30-Aug-2021, Biopsy heart: edematous myocardium (abnormal) Edematous myocardium.<br>On 30-Aug-2021, Blood creatine phosphokinase (60-250): 1488 (High) 1488 iU/L (international unit per litre) and 1211 (High) 1211 iU/L (international unit per litre).<br>On 30-Aug-2021, Blood creatine phosphokinase MB (Unknown-12.0): 99.7 (High) 99.7 iU/L (international unit per litre) and 78.5 (High) 78.5 iU/L (international unit per litre).<br>On 30-Aug-2021, Blood lactate dehydrogenase (124-222): 349 (High) 349 iU/L (international unit per litre) and 389 (High) 389 iU/L (international unit per litre).<br>On 30-Aug-2021, C-reactive protein (Unknown-0.50): 5.33 (High) 5.33 mg/dl (MILLIGRAM PER DECILITRE).<br>On 30-Aug-2021, Chest X-ray: normal (normal) Normal.<br>On 30-Aug-2021, Echocardiogram: abnormal (abnormal) Posterior wall severe hypokinesis, regional wall motion abnormalities (plus), hypokinesia (plus), pericardial effusion (plus), delayed imaging inconsistent with vascular distribution, such as on the epicardial side of the inferior wall is noted, consistent with myocarditis. DB-T2 is difficult to detect abnormalities, but T2map shows an elevated T2 value, which may reflect edema..<br>On 30-Aug-2021, Ejection fraction: 42.4 42.4 percent and 38.3 38.3 percent.<br>On 30-Aug-2021, Electrocardiogram: persistent st elevations (abnormal) Persistent ST elevations (I, aVL, 2-aVF, and V3-6).<br>On 30-Aug-2021, Fibrin D dimer (Unknown-0.99): 0.27 0.27 ug/mL (microgram per milliliter.<br>On 30-Aug-2021, Imaging procedure: no abnormalities (normal) No abnormalities.<br>On 30-Aug-2021, Magnetic resonance imaging: lge plus LGE plus.<br>On 30-Aug-2021, N-terminal prohormone brain natriuretic peptide (Unknown-125): 595 (High) 595 pg/mL (picogram per milliliter).<br>On 30-Aug-2021, Troponin I (Unknown-0.028): 76.81 (High) 76.81 ng/mL (nanogram per millliiter).<br>On 30-Aug-2021, White blood cell count (3.9-9.8): 6.9 (normal) 6.9 x 10e3/uL (thousand per microlitre).<br>On 31-Aug-2021, Aspartate aminotransferase (8-40): 77 (High) 77 iU/L (international unit per litre). |

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| | | On 31-Aug-2021, Blood creatine phosphokinase (60-250): 412 (High) 412 iU/L (international unit per litre).<br>On 31-Aug-2021, Blood creatine phosphokinase MB (Unknown-12.0): 27.6 (High) 27.6 iU/L (international unit per litre).<br>On 31-Aug-2021, Blood lactate dehydrogenase (124-222): 326 (High) 326 iU/L (international unit per litre).<br>On 31-Aug-2021, C-reactive protein (Unknown-0.50): 2.36 (High) 2.36 mg/dl (MILLIGRAM PER DECILITRE).<br>On 31-Aug-2021, White blood cell count (3.9-9.8): 5.5 (normal) 5.5 x 10e3/uL (thousand per microlitre).<br>On 02-Sep-2021, Aspartate aminotransferase (8-40): 24 (normal) 24 iU/L (international unit per litre).<br>On 02-Sep-2021, Blood creatine phosphokinase (60-250): 80 (normal) 80 iU/L (international unit per litre).<br>On 02-Sep-2021, Blood creatine phosphokinase MB (Unknown-12.0): 9.8 9.8 iU/L (international unit per litre).<br>On 02-Sep-2021, Blood lactate dehydrogenase (124-222): 269 (High) 269 iU/L (international unit per litre).<br>On 02-Sep-2021, C-reactive protein (Unknown-0.50): 0.55 (High) 0.55 mg/dl (MILLIGRAM PER DECILITRE).<br>On 02-Sep-2021, Troponin I (Unknown-0.028): 23.03 (High) 23.03 ng/mL (nanogram per millliiter).<br>On 02-Sep-2021, White blood cell count (3.9-9.8): 5.0 (normal) 5.0 x 10e3/uL (thousand per microlitre).<br>On 03-Sep-2021, Echocardiogram: improvement (abnormal) Improvement in the wall motion, pericardial effusion(plus, small quantity).<br>On 03-Sep-2021, Ejection fraction: 61.4 61.4 percent.<br>On 22-Sep-2021, Aspartate aminotransferase (8-40): 23 (normal) 23 iU/L (international unit per litre).<br>On 22-Sep-2021, Blood creatine phosphokinase (60-250): 68 (normal) 68 iU/L (international unit per litre).<br>On 22-Sep-2021, Blood creatine phosphokinase MB (Unknown-12.0): 8.4 8.4 iU/L (international unit per litre).<br>On 22-Sep-2021, Blood lactate dehydrogenase (124-222): 160 (normal) 160 iU/L (international unit per litre).<br>On 22-Sep-2021, C-reactive protein (Unknown-0.50): 0.01 0.01 mg/dl (MILLIGRAM PER DECILITRE).<br>On 22-Sep-2021, Troponin I (Unknown-0.028): 0.014 0.014 ng/mL (nanogram per millliiter).<br>On 22-Sep-2021, White blood cell count (3.9-9.8): 9.1 (normal) 9.1 x 10e3/uL (thousand per microlitre).<br>On an unknown date, Body temperature: 36.0 36.0 Cel (degree Celsius).<br><br>For mRNA-1273 (COVID-19 Vaccine Moderna Intramuscular Injection) (Intramuscular), the reporter considered MYOCARDITIS (Acute myocarditis) and ATRIAL FIBRILLATION (AF) to be possibly related.<br><br>This is a regulatory case concerning a 20-year-old male patient with no relevant medical history, who experienced the serious expected AESI event of myocarditis and serious unexpected AESI event of atrial fibrillation. The events occurred approximately on 3-4 days after the second dose of mRNA-1273 vaccine administration. The events were assessed as related, per temporal association with the product administration. The rechallenge was not applicable since the events |

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| | | occurred after the second dose and no further dosing is expected. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes: On 23-Dec-2021: Follow-up contains significant information, patient initials and demographics updated, event (Atrial fibrillation), lab data and reporters comment added. |
| 4.1(b) | 4.1(b) | This case was initially received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 17-Sep-2021. The most recent information was received on 23-Dec-2021 and was forwarded to Moderna on 28-Dec-2021.<br>This case was initially received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 17-Sep-2021. The most recent information was received on 23-Dec-2021 and was forwarded to Moderna on 28-Dec-2021.<br>This case, initially reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref, 4.1(b) On 09-Oct-2021, follow-up information, reported to the 4.1(b) by a physician, was received via the PMDA (Ref, 4.1(b) On 23-Dec-2021, follow-up information was received from a physician. On 18-Jul-2021, the patient received the 1st dose of this vaccine. On 22-Aug-2021, the patient received the 2nd dose of this vaccine. Pyrexia developed at night. On 25-Aug-2021, pyrexia had persisted until the morning. At 04:00, the patient noticed chest pain and cold sweat and visited the reporting hospital in the morning. In the blood test, troponin T was found to be positive, and elevated cardiac enzymes and inflammatory reaction of CRP of 3.29 mg/dL were found. Chest X-ray showed CTR of 51.1%, and electrocardiogram showed ST elevation in I, II, aVF, and V4-6. Echocardiography showed LVDd of 51 mm and EF of 64%. There was no coronary artery lesion in coronary CT, and the diagnosis of acute myocarditis was made. The patient was hospitalized and was placed on bedrest. At 23:00, the patient complained of chest pain and took two tablets of acetaminophen 200 mg orally. On 25-Aug-2021, chest pain disappeared. On 26-Aug-2021, MRI revealed that LGE was positive in a part of the myocardia. On 30-Aug-2021, ST levels in electrocardiogram improved. On 31-Aug-2021, the symptoms were resolving. The patient was discharged from the hospital. The outcome of acute myocarditis was reported as resolving. No follow-up investigation will be made. Follow-up received on 09-OCT-2021 Updated: Lab Data, Narrative, Reporter Comments Follow-up received on 23-DEC-2021 Updated: Patient Information, Other Relevant History, Lab Data, Narrative, Reporter Comments Company Comment: The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. |
| 4.1(b) | 4.1(b) | This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 17-Sep-2021 and was forwarded to Moderna on 28-Sep-2021.<br><br>This case, reported by a physician, was received by Takeda via Moderna's adverse reaction reporting site 4.1(b) and reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref, 4.1(b) |

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| | | On 09-Jul-2021, at 11:00, the patient received the 1st dose of this vaccine.<br><br>On 07-Aug-2021, at 11:00, the patient received the 2nd dose of this vaccine.<br><br>On 08-Aug-2021, at 17:00, peripheral nerve disorder and chest pain developed.<br><br>On 09-Aug-2021, the patient visited the reporting hospital and was admitted to the hospital due to elevated troponin and electrocardiographic changes. The steroid therapy was started as myopericarditis.<br><br>On an unknown date, the patient received detailed examination for coronary artery during hospitalization, but there were no abnormalities.<br><br>On 16-Aug-2021, the patient was discharged from the hospital.<br><br>On 17-Sep-2021, the symptom recovery was confirmed.<br><br>The outcome of myopericarditis and peripheral nerve disorder was reported as recovered.<br><br>Follow-up investigation will be made.<br><br>Company Comment:<br><br>The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 24-Sep-2021 and was forwarded to Moderna on 24-Sep-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Chest pain, increase in troponin,ECG compatible with pericarditis.final diagnosis:onset of myopericarditis 4 days after the administration of the second dose of moderna vaccine), PERICARDITIS (Chest pain, increase in troponin,ECG compatible with pericarditis.final diagnosis:onset of myopericarditis 4 days after the administration of the second dose of moderna vaccine) and CHEST PAIN (Chest pain, increase in troponin,ECG compatible with pericarditis.final diagnosis:onset of myopericarditis 4 days after the administration of the second dose of moderna vaccine) in a 22-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 214024) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 03-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) .5 milliliter in total. On 07-Sep-2021, the patient experienced MYOCARDITIS (Chest pain, increase in troponin,ECG compatible with pericarditis.final diagnosis:onset of myopericarditis 4 days after the administration of the second dose of moderna vaccine) (seriousness criteria hospitalization prolonged and medically significant), PERICARDITIS (Chest pain, increase in |

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| | | troponin,ECG compatible with pericarditis.final diagnosis:onset of myopericarditis 4 days after the administration of the second dose of moderna vaccine) (seriousness criteria hospitalization prolonged and medically significant) and CHEST PAIN (Chest pain, increase in troponin,ECG compatible with pericarditis.final diagnosis:onset of myopericarditis 4 days after the administration of the second dose of moderna vaccine) (seriousness criterion hospitalization prolonged). On 13-Sep-2021, MYOCARDITIS (Chest pain, increase in troponin,ECG compatible with pericarditis.final diagnosis:onset of myopericarditis 4 days after the administration of the second dose of moderna vaccine), PERICARDITIS (Chest pain, increase in troponin,ECG compatible with pericarditis.final diagnosis:onset of myopericarditis 4 days after the administration of the second dose of moderna vaccine) and CHEST PAIN (Chest pain, increase in troponin,ECG compatible with pericarditis.final diagnosis:onset of myopericarditis 4 days after the administration of the second dose of moderna vaccine) had resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 07-Sep-2021, Troponin: increase (High) Increase.<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.<br><br>No concomitant product was provided by the reporter.<br>No treatment medication was provided.<br>Case history includes a previous episode of Pericarditis.<br>Lab data included C reactive protein on 07 Sep 2021 no results were provided and electrocardiogram compatible with Pericarditis. Final diagnosis was onset of Myopericarditis 4 days after the administration of the second dose of the Moderna vaccine.<br><br>Company comment: This case concerns a 22-year-old, male patient with no relevant medical history, who experienced the unexpected event of chest pain and the expected events of myocarditis and pericarditis. The events occurred 5 days after the second dose of Spikevax. The rechallenge was not applicable as the events occurred after the second dose. The event chest pain is an intercurrent event. The events myocarditis and pericarditis are consistent with the current understanding of safety profile of the vaccine. The benefit-risk relationship of Spikevax is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 24-Sep-2021: Translation received on 30 Sep 2021: lab data added, event verbatim & Reporter's comment translated, added reporter comment and generated narrative accordingly.<br>On 27-Oct-2021: Follow-up received on 27-Oct-2021 contain no new information |
| 4.1(b) [redacted] | 4.1(b) [redacted] | This case was received via 4.1(b) [redacted] (Reference number: 4.1(b) [redacted]) on 26-Sep-2021 and was forwarded to Moderna on 26-Sep-2021.<br>This regulatory authority case was reported by a pharmacist and describes the occurrence of MYOCARDITIS (Perimyocarditis), DYSPNOEA (Shortness of breath), CHEST PAIN (Chest pain), |

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| | | TROPONIN I INCREASED (Troponin I increased) and ELECTROCARDIOGRAM CHANGE (Change in ECG) in a 19-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 23-Jul-2021, the patient received first dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form.<br>On 20-Sep-2021, received second dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 21-Sep-2021, the patient experienced MYOCARDITIS (Perimyocarditis) (seriousness criteria hospitalization and medically significant), DYSPNOEA (Shortness of breath) (seriousness criterion hospitalization), CHEST PAIN (Chest pain) (seriousness criterion hospitalization), TROPONIN I INCREASED (Troponin I increased) (seriousness criterion hospitalization) and ELECTROCARDIOGRAM CHANGE (Change in ECG) (seriousness criterion hospitalization). At the time of the report, MYOCARDITIS (Perimyocarditis), DYSPNOEA (Shortness of breath), CHEST PAIN (Chest pain) and TROPONIN I INCREASED (Troponin I increased) was resolving and ELECTROCARDIOGRAM CHANGE (Change in ECG) had resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 29-Jun-2021, SARS-CoV-2 test: positive (Positive) Positive COVID-19 test.<br><br>The action taken with mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown) was unknown.<br><br>For mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown), the reporter did not provide any causality assessments.<br><br>Concomitant medications were not provided by the reporter.<br>Treatment information was not provided.<br><br>Company Comment: This case concerns a 19 year old male with no relevant medical history who experienced serious expected AESI of myocarditis one day after receiving the second dose of the Mooderna Covid 19 Vaccine. Rechallenge is unknown. The benefit-risk relationship is not affected by this report. |
| 4.1(b) | 4.1(b) | This case was received via 4.1(b) (Reference number: 4.1(b) on 28-Sep-2021 and was forwarded to Moderna on 28-Sep-2021.<br>This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCARDITIS (Myocarditis) in a 26-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination.<br><br>Concurrent medical conditions included Penicillin allergy and Drug allergy (amoxicillin). |

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| | | On 10-Sep-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 11-Sep-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criterion medically significant). At the time of the report, MYOCARDITIS (Myocarditis) had not resolved.<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments.<br><br>on 11-SEP-2021. patient underwent Echocardiogram, Electrocardiogram, Troponin and results were unknown.<br>Concomitant medication were not provided<br>Treatment information was not provided<br>It was reported that patient experienced Post Covid vaccination associated myopericarditis<br><br>Company Comment:<br>This case concerns a 26 year-old, female patient, with no relevant medical history, who experienced the expected event of Myocarditis. The event occurred the day after the second dose of the MODERNA COVID-19 VACCINE. Rechallenge is not applicable as no additional dosing is expected to be given. The benefit-risk relationship of MODERNA COVID-19 VACCINE is not affected by this report. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 28-Sep-2021 and was forwarded to Moderna on 28-Sep-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of PERICARDITIS (4.1(b) and COVID-19 IMMUNISATION (4.1(b) in a 20-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3004952) for Vaccination.<br><br>Previously administered products included for Vaccination: Comirnaty. Concomitant products included LISDEXAMFETAMINE MESILATE (ADUVANZ) for Attention deficit hyperactivity disorder.<br><br>On 11-Aug-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. In 2021, the patient experienced COVID-19 IMMUNISATION (4.1(b) (seriousness criterion hospitalization). On 05-Sep-2021, the patient experienced PERICARDITIS (4.1(b) (seriousness criteria hospitalization and medically significant). At the time of the report, PERICARDITIS (4.1(b) and COVID-19 IMMUNISATION (4.1(b) had not resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>In September 2021, C-reactive protein: high (High) Elevated.<br>In September 2021, Echocardiogram: abnormal (abnormal) detected pericardial fluid, receive treatment for this. Also detected on the left side small amounts of pleural fluid and loose saturated basodorsalt in the left lower lobe that fits with infectious etiology and therefore also receive antibiotics for pneumonia..<br>In September 2021, White blood cell count: elevated (High) Elevated. |

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| | | For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered PERICARDITIS (4.1(b)) to be possibly related. No further causality assessment was provided for COVID-19 IMMUNISATION (4.1(b)).<br><br>No treatment information was reported.<br><br>Company comment: This case of interchange of vaccine products concerns a 20-year-old male patient with no relevant medical history, who experienced the unexpected serious event of Pericarditis (adverse event of special interest). The event occurred 26 days following the second dose of Spikevax. The re-challenge was not applicable as the patient received a different vaccine previously. The event is consistent with the current understanding of safety profile of the vaccine. The benefit-risk relationship of Spikevax in not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes: On 28-Sep-2021: Translation received on 30-SEP-2021, contains Suspect vaccine dose details updated. |
| 4.1(b) | 4.1(b) | This case was received via United States FDA VAERS (Reference number: 4.1(b)) on 28-Sep-2021 and was forwarded to Moderna on 28-Sep-2021.<br>This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCARDITIS (Myocarditis), CARDIOGENIC SHOCK (Cardiogenic shock), ASCITES (Ascites), CARDIAC ARREST (Cardiac arrest), CARDIAC FAILURE (Cardiac failure), CONGESTIVE HEPATOPATHY (Congestive hepatopathy), HEPATIC FAILURE (Hepatic failure), PERICARDIAL EFFUSION (Pericardial effusion), PNEUMONIA (Pneumonia) and RENAL FAILURE (Renal failure) in a 26-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below.<br><br>Concurrent medical conditions included Suspected COVID-19 since 10-Sep-2021.<br><br>On 13-Sep-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 15-Sep-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria death and medically significant), CARDIOGENIC SHOCK (Cardiogenic shock) (seriousness criteria death and medically significant), ASCITES (Ascites) (seriousness criterion medically significant), CARDIAC ARREST (Cardiac arrest) (seriousness criterion medically significant), CARDIAC FAILURE (Cardiac failure) (seriousness criterion medically significant), CONGESTIVE HEPATOPATHY (Congestive hepatopathy) (seriousness criterion medically significant), HEPATIC FAILURE (Hepatic failure) (seriousness criterion medically significant), PERICARDIAL EFFUSION (Pericardial effusion) (seriousness criterion medically significant), PNEUMONIA (Pneumonia) (seriousness criterion medically significant), RENAL FAILURE (Renal failure) (seriousness criterion medically significant), HYPERVENTILATION (Hyperventilation), CARDIOMEGALY (Cardiomegaly), HEPATOMEGALY (Hepatomegaly), METABOLIC ACIDOSIS (Metabolic acidosis), INFLAMMATION |

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| | | (Inflammation) and RENAL DISORDER (Renal disorder). 15-Sep-2021, the patient experienced COVID-19 (COVID-19). The patient died on 15-Sep-2021. The reported cause of death was Cardiogenic shock and Myocarditis. It is unknown if an autopsy was performed. At the time of death, ASCITES (Ascites), CARDIAC ARREST (Cardiac arrest), CARDIAC FAILURE (Cardiac failure), CONGESTIVE HEPATOPATHY (Congestive hepatopathy), HEPATIC FAILURE (Hepatic failure), PERICARDIAL EFFUSION (Pericardial effusion), PNEUMONIA (Pneumonia), RENAL FAILURE (Renal failure), HYPERVENTILATION (Hyperventilation), CARDIOMEGALY (Cardiomegaly), HEPATOMEGALY (Hepatomegaly), METABOLIC ACIDOSIS (Metabolic acidosis), INFLAMMATION (Inflammation), RENAL DISORDER (Renal disorder) and COVID-19 (COVID-19) outcome was unknown.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 14-Sep-2021, SARS-CoV-2 test: positive (Positive) SARS-CoV-2 detected.<br>On 15-Sep-2021, Anion gap: 30 (High) Anion gap increased - 30.<br>On 15-Sep-2021, Blood bicarbonate: 9 (Low) Blood bicarbonate decreased - 9.<br>On 15-Sep-2021, Blood chloride: 96 (Low) Blood chloride decreased - 96.<br>On 15-Sep-2021, Blood creatinine: 2.97 (High) Blood creatinine increased - Renal failure with a creatinine of 2.97.<br>On 15-Sep-2021, Blood glucose: 144 (normal) Blood glucose normal - 144.<br>On 15-Sep-2021, Blood lactic acid: 14.0 (High) Blood lactic acid increased - Lactate was 14.0.<br>On 15-Sep-2021, Blood pH: 7.124 (Low) Blood pH decreased - significant metabolic acidosis with a pH of 7.124.<br>On 15-Sep-2021, Blood potassium: 4 (normal) Blood potassium normal - 4.<br>On 15-Sep-2021, Blood sodium: 135 (Low) Blood sodium decreased - 135.<br>On 15-Sep-2021, Blood urea: 22 (High) Blood urea increased - BUN 22.<br>On 15-Sep-2021, Computerised tomogram abdomen: abnormal (abnormal) CTA abdomen and pelvis: No evidence of bowel ischemia. The enlargement of the liver and of mild ascites suggest hepatic congestion. This could reflect either heart failure or liver failure. Heterogeneous appearance of the kidneys, suggesting possible pyelonephritis, but this appearance could also be the result of some other inflammatory process.<br>On 15-Sep-2021, Computerised tomogram thorax: abnormal (abnormal) CTA chest: Small to moderate relatively hyperdense pericardial effusion, nonspecific. Mild cardiomegaly. Evidence of heart failure. These findings collectively would be compatible with inflammatory disease. Consider myocarditis or pericarditis. No evidence of pulmonary thromboembolism. Bilateral pneumonia.<br>On 15-Sep-2021, Electrocardiogram ST segment: elevation (abnormal) EKG showing diffuse ST elevations concerning for myocarditis.<br>On 15-Sep-2021, Fibrin D dimer: 1.25 (High) D-dimer was elevated at 1.25 without any obvious pulmonary embolism according to the CT.<br>On 15-Sep-2021, Glomerular filtration rate: 26 (Low) Glomerular filtration rate decreased - Renal failure with a GFR of 26. |

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| | | In September 2021, Oxygen saturation: 96.8 (normal) O2 sat 96.8 percentage on room air.<br>On 15-Sep-2021, PCO2: 15.4 (Low) PCO2 decreased to 15.4.<br>On 15-Sep-2021, SARS-CoV-2 test: positive (Positive) Positive.<br>On 15-Sep-2021, Troponin: 113.793 (High) Troponin increased - Troponin was elevated at 113.793.<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments.<br><br>No relevant concomitant medications were reported.<br>On 10-Sep-2021, Active COVID-19 infection was suspected based on symptom onset, tested positive on 14 Sep 2021 and was confirmed in Emergency Department, on 15-Sep-2021.<br><br>Cardiologist did not feel that transfer to a higher level care center immediately for cardiac catheterization indicated. The patient was presented to the emergency department with diffuse ST elevations concerning for myocarditis. Upon presentation he was hyperventilating, not complaining of chest pain. Labs demonstrate a significant metabolic acidosis with a pH of 7.124, PCO2 of 15.4. O2 sat 96.8% on room air. The patient unfortunately went into cardiac arrest and was unable to be revived. Cause of death suspected to be myocarditis and cardiogenic shock in the setting of active COVID-19 infection.<br><br>No treatment information was reported.<br><br>Company Comment: This is a fatal case that concerns a 26-year-old male patient, with no reported medical history, who experienced the unexpected events of ascites, cardiac arrest, cardiac failure, cardiogenic shock, congestive hepatopathy, hepatic failure, hyperventilation, myocarditis, pericardial effusion, pneumonia, renal failure, cardiomegaly, hepatomegaly, metabolic acidosis, inflammation, renal disorder and unexpected serious and aesi covid-19 . The events occurred two days after receiving the second dose of spikevax. Fatal outcome occurred two days after second dose of spikevax. Cause of death was reported as myocarditis and cardiogenic shock. The rechallenge was not applicable as no additional dose is going to be administered. The benefit-risk relationship of spikevax is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 12-Oct-2021: Follow up information received does not contain any new information.. |
| 4.1(b) | 4.1(b) | This case was received via 4.1(b) (Reference number: 4.1(b) on 28-Sep-2021 and was forwarded to Moderna on 28-Sep-2021.<br>This regulatory authority case was reported by an other health care professional and describes the occurrence of DIARRHOEA (Diarrhoea), LOSS OF CONSCIOUSNESS (Loss of consciousness), NAUSEA (Nausea), NECK PAIN (Neck pain), PAIN (Pain), PYREXIA (Pyrexia) and MYOCARDITIS (Myocarditis) in a 24-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 049G21A and 010M20A) for COVID-19 vaccination. |

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| | | No Medical History information was reported.<br><br>On 21-Jun-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form.<br>On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 27-Aug-2021, the patient experienced NAUSEA (Nausea) (seriousness criteria hospitalization and life threatening), NECK PAIN (Neck pain) (seriousness criteria hospitalization and life threatening), PAIN (Pain) (seriousness criteria hospitalization and life threatening) and MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization, medically significant and life threatening). On 28-Aug-2021, the patient experienced DIARRHOEA (Diarrhoea) (seriousness criteria hospitalization and life threatening) and PYREXIA (Pyrexia) (seriousness criteria hospitalization and life threatening). On 29-Aug-2021, the patient experienced LOSS OF CONSCIOUSNESS (Loss of consciousness) (seriousness criteria hospitalization, medically significant and life threatening). At the time of the report, DIARRHOEA (Diarrhoea), LOSS OF CONSCIOUSNESS (Loss of consciousness), NAUSEA (Nausea), NECK PAIN (Neck pain), PAIN (Pain), PYREXIA (Pyrexia) and MYOCARDITIS (Myocarditis) had resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 29-Aug-2021, Blood pressure measurement: decreased (Low) Blood pressure decreased.<br>On 29-Aug-2021, Heart rate: increased (High) Heart rate increased.<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments.<br><br>No relevant concomitant medications were reported.<br><br>The patient began to have neck pain and feel achy and nauseous on 27-Aug-2021. The patient had bloodwork, cat scan, ultrasounds, and MRI on 27-AUG-2021 with unknown results. When the patient woke up on 28-Aug-2021, he had a fever, more neck pain and diarrhea. On 29-Aug-2021, the patient visited urgent care. While there the patient's blood pressure dropped and heart rate increased and the patient went unconscious, he was transferred to a hospital where they believed something was abnormal with heart. Once they stabilized the patient, he was transferred to hospital to the critical care into on the cardiology department where he was diagnosed with Myocarditis. The patient was in the cardiology department for 5 days.<br><br>Treatment medication was not provided by the reporter.<br><br>Company Comment: This case concerns a 24-year-old, male subject, with no relevant medical history who experienced the serious, life-threatening events of myocarditis, diarrhea, and loss of consciousness, among others. The events occurred approximately 2 months, 7 days after the 2nd dose of Spikevax (receipt date for 1st dose not specified). The rechallenge was not applicable as there were no details post first dose). |

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| | | Causality was not provided by the reporter. The benefit-risk relationship of the vaccine is not affected by this report. Event seriousness assessed as per Regulatory Authority reporting. |
| 4.1(b) | 4.1(b) | This case was received via 4.1(b) (Reference number: 4.1(b) on 28-Sep-2021 and was forwarded to Moderna on 28-Sep-2021.<br>This regulatory authority case was reported by an other health care professional and describes the occurrence of ANGINA PECTORIS (Angina pectoris), CARDIAC FLUTTER (Cardiac flutter), MYOCARDITIS (Myocarditis) and PERICARDITIS (Pericarditis) in a 28-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below.<br><br>The patient's past medical history included Arrhythmia.<br>Concurrent medical conditions included Psoriasis.<br>Concomitant products included CLOBETASOL for Psoriasis.<br><br>On 14-May-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 16-May-2021, the patient experienced ANGINA PECTORIS (Angina pectoris) (seriousness criterion medically significant), CARDIAC FLUTTER (Cardiac flutter) (seriousness criterion medically significant), MYOCARDITIS (Myocarditis) (seriousness criterion medically significant), PERICARDITIS (Pericarditis) (seriousness criterion medically significant) and CARDIAC DISORDER (Cardiac disorder). At the time of the report, ANGINA PECTORIS (Angina pectoris), CARDIAC FLUTTER (Cardiac flutter), MYOCARDITIS (Myocarditis), PERICARDITIS (Pericarditis) and CARDIAC DISORDER (Cardiac disorder) had resolved.<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments.<br><br>Patient had, heart pain, fluttering, felt like heart was too big for chest, likely myocarditis or pericarditis<br>Treatment information was not provided.<br><br>Company Comment: This case concerns a 28 year old male with medical history of Arrhythmia and Psoriasis, who experienced unexpected events of Angina Pectoris, Cardiac flutter, myocarditis, pericarditis and Cardiac disorder. The events occurred approximately 2 days after the second dose of Moderna COVID-19 Vaccine. Re-challenge is not known due lack of information about the first doses. The mechanism of action is not understood for myocarditis and pericarditis cases. The Benefit-risk relationship of Spikevax is not affected by this report. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 28-Sep-2021 and was forwarded to Moderna on 28-Sep-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of PERICARDITIS (POST-VACCINE PERICARDITIS, SECOND DOSE) in a 21-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 214024) for COVID-19 vaccination. |

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| | | No Medical History information was reported.<br><br>On 02-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) .5 ml. On 03-Sep-2021, the patient experienced PERICARDITIS (POST-VACCINE PERICARDITIS, SECOND DOSE) (seriousness criteria hospitalization and medically significant). At the time of the report, PERICARDITIS (POST-VACCINE PERICARDITIS, SECOND DOSE) was resolving.<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.<br><br>No concomitant medication were provided by the reporter.<br><br>No treatment medication were provided by the reporter.<br><br>It was reported that the patient experienced event pericarditis, post second dose of Moderna vaccine.<br><br>Company Comment:<br>This case concerns a 21-year-old, male patient with no relevant medical history, who experienced the serious expected AESI event of Pericarditis. The event occurred around 2 days after the second dose of Spikevax. The rechallenge was not applicable since the event occurred after the second dose and no details were provided about the first dose. The benefit-risk relationship of Spikevax is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 28-Sep-2021: Translation document received on 30-Sep-2021 included dose number of suspect drug.<br>On 27-Oct-2021: Non-significant Follow Up Appended: NNI |
| 4.1(b) | 4.1(b) | This case was initially received via European Medicines Agency (Reference number: 4.1(b) ) on 28-Sep-2021. The most recent information was received on 12-Nov-2021 and was forwarded to Moderna on 12-Nov-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (4.1(b) in a 20-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3005242) for COVID-19 vaccination.<br><br>The patient's past medical history included Myocarditis in 2018.<br><br>On 08-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 10-Sep-2021, the patient experienced MYOCARDITIS (4.1(b) (seriousness criteria hospitalization, disability, medically significant and life threatening). At the time of the report, MYOCARDITIS (4.1(b) was resolving.<br><br>For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. |

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| | | Concomitant information was not provided by the reporter. No treatment information was provided.<br><br>Company comment: This case concerns a 20-year-old, male patient with previous relevant medical history of Myocarditis, who experienced the serious expected event of Myocarditis. The event occurred around 5 days after the dose of mRNA-1273 . The medical history of Myocarditis remains a confounder. The benefit-risk relationship of mRNA-1273 is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 12-Nov-2021: Added seriousness criteria to event - Life threatening and disabling. Updated mRNA-1273 onset date to 08-SEP-2021. Added reporter - consumer. |
| 4.1(b) | 4.1(b) | This case was initially received via European Medicines Agency (Reference number: 4.1(b) ) on 28-Sep-2021. The most recent information was received on 04-Oct-2021 and was forwarded to Moderna on 04-Oct-2021.<br>This regulatory authority case was reported by a consumer and describes the occurrence of PERICARDITIS (4.1(b) ) in a 25-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 3002622A) for COVID-19 immunisation.<br><br>No Medical History information was reported.<br><br>On 18-May-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form.<br>On 23-Jun-2021, received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to .5 milliliter. On 16-Jul-2021, the patient experienced PERICARDITIS (4.1(b) ) (seriousness criteria hospitalization and medically significant). At the time of the report, PERICARDITIS 4.1(b) ) had not resolved.<br><br>Concomitant medication use information was not provided by reporter.<br>Treatment medication use information was not provided by reporter.<br><br>Company Comment:<br>This case concerns a 25 year old female patient with no relevant medical history, who experienced the expected event of pericarditis which required hospitalization. The event occurred 23 days after the second dose of the Moderna COVID-19 vaccine. The rechallenge was not applicable as events occurred after second dose and no further dosing was reported or planned, based on information provided. Very limited information was provided in regards to patient's symptoms and diagnostic findings. The benefit-risk relationship of the Moderna COVID-19 vaccine is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 28-Sep-2021: Translation Document received on 30-SEP-2021 that contains No New Information. |

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| | | On 04-Oct-2021: Follow up received contains significant information. Product information added for 2nd dose. First dose added. |
| 4.1(b) | 4.1(b) | This case was received via 4.1(b) (Reference number: 4.1(b) on 28-Sep-2021 and was forwarded to Moderna on 28-Sep-2021.<br>This regulatory authority case was reported by an other health care professional and describes the occurrence of ASTHMA (Asthma) and PERICARDITIS (Pericarditis) in a 23-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 042L20A and 011J20A) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 25-Jan-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form.<br>On 25-Jan-2021, received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 23-Aug-2021, the patient experienced ASTHMA (Asthma) (seriousness criteria hospitalization, disability and life threatening) and PERICARDITIS (Pericarditis) (seriousness criteria hospitalization, disability, medically significant and life threatening). At the time of the report, ASTHMA (Asthma) and PERICARDITIS (Pericarditis) had not resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 23-Aug-2021, Electrocardiogram: st segment depression (abnormal) ST segment depression, Electrocardiogram abnormal.<br>On 23-Aug-2021, Ultrasound scan: abnormal (abnormal) abnormal.<br>On an unknown date, Electrocardiogram: pr depression (abnormal) PR depression.<br>On an unknown date, Ultrasound scan: hyperechoic pericardium (abnormal) Hyperechoic pericardium.<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments.<br><br>Patient developed pericarditis and asthma 8 months after vaccine, requiring medication and hospitalizations.<br>Concomitant medication use was unknown<br>Treatment information was unknown<br><br>Company Comment: This case concerns a 23 year old female patient, with no medical history reported who experienced serious unexpected event of asthma and serious expected AESI of pericarditis. The events occurred 8 months after second dose of mRNA-1273. Dose dates retained per RA report despite this being unlikely. The rechallenge is not applicable. The benefit-risk relationship of Spikevax is not affected by this report. |
| 4.1(b) | 4.1(b) | This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 21-Sep-2021 and was forwarded to Moderna on 29-Sep-2021. |

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| | | This case, initially reported to the 4.1(b) by a pharmacist, was received via the 4.1(b) (Ref, 4.1(b)<br><br>The patient had an underlying condition of hemophilia B and an history of cedar pollen allergy. The patient was under treatment with eftrenonacog alfa for intravenous injection, sublingual tablet containing cedar pollen extract, ephedra, aconite and manchurian wildginger decoction, ambroxol hydrochloride, and mequitazine.<br><br>On an unknown date, the patient received the 1st dose of the vaccine.<br><br>On 01-Sep-2021, in the morning, the patient received the 2nd dose of the vaccine. The patient received 4000 U of eftrenonacog alfa on the same day.<br><br>On 02-Sep-2021, in the morning, pyrexia and breathlessness developed. The patient was considered to experience acute myocarditis.<br><br>On 03-Sep-2021, around noon, the patient noticed obvious chest pain and was transported to another hospital. An electrocardiogram showed ST elevation in the leads of I and aVL and ST depression in III. Blood sampling found increases in myocardial biomarkers. The patient was emergently transported to the reporting hospital for detailed examinations and was hospitalized. On arrival, chest pain remained. BP (systolic) was 100-160 mmHg with HR of 80s and SpO2 of 98% (room). A blood test was performed to find CK of 1,238 mU/L, and an ECG was performed to show ST elevation in the leads of lateral and anterior wall and ST depression in III and aVF. UCG: eyeball EF was around 30% with akinesis in the basal inferior wall. Pericardial fluid was not apparently detected. An arterial line was placed, and the patient was placed on a care in ICU. Regarding nourishment, the patient was placed on fluid replacement with fasting.<br><br>On 04-Sep-2021, UCG: eyeball EF was around 40%. No marked change was shown by ECG. There was a change in the blood tests that CK of 2,689 mU/L (the 1st time on the day) decreased to CK of 2,216 mU/L (the 2nd time), which was considered to have passed a peak. Acetaminophen (oral and drip infusion) was used for the treatment of chest pain. The patient began to have meals.<br><br>On 05-Sep-2021, BP: 112/58 mmHg, HR: 75-85, and SpO2: 100% (O2: 2 L). ECG: ST in V4-6 move to the side of baseline with LI of around 1 mm, and ST itself returned to the baseline in I and aVF leads and changed to negative T wave. UCG: no change in EF, no pericardial fluid, and marked right ventricular enlargement.<br><br>On 06-Sep-2021, UCG: eyeball EF was 40%-50% with mild mitral regurgitation (MR), and IVC was 10 mm in diameter with RC +. The result of a blood test showed CK decreased to the standard value. Chest pain was relieved. As the patient was permitted to have meals, fluid replacement was finished. The course of the condition was favorable, and the patient was transferred to the general ward after the arterial line was removed. |

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| | | On 07-Sep-2021, chest pain disappeared. BP: 104/58 mmHg, HR: 62, and SpO2: 98% (room) without cardiac murmur.<br><br>On 09-Sep-2021, BP: 105/59 mmHg, HR: 64, and SpO2: 99% (room). The result of a blood test found CK decreased to the standard value. MRI was performed to show high signal intensities in the inferior wall and septum in T2, and delayed image was found in the same region. Since FIXu was as decreased as 4.8%, administration of 4000 U of eftrenonacog alfa was ordered by a hematologic physician.<br><br>On 10-Sep-2021, BP: 120/61 mmHg, HR: 68, and UCG: eyeball EF was 61%.<br><br>On 11-Sep-2021, as cardiac function recovered and the clinical course was good, the patient was discharged from the hospital.<br><br>On 16-Sep-2021, a coronary CT was performed to show no significant stenosis.<br><br>On 17-Sep-2021, the patient visited the hospital as an outpatient, and there was no worsening of the symptom. No appreciable abnormalities were also found in a blood test. Resolution of the symptoms was confirmed, and treatments and follow-up were completed.<br><br>The outcome of acute myocarditis was reposted as resolved.<br><br>Follow-up investigation will be made.<br><br>Company Comment:<br><br>The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. |
| 4.1(b) | 4.1(b) | This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) ) on 21-Sep-2021 and was forwarded to Moderna on 29-Sep-2021.<br>This case was reported by a physician via the Drug Information Center.<br><br>On 30-Aug-2021, the patient received the 1st dose of this vaccine. The patient experienced pyrexia.<br><br>On an unknown date, pyrexia went down, and the patient recovered from pyrexia.<br><br>On 15-Sep-2021, the patient received the 2nd dose of this vaccine.<br><br>On 17-Sep-2021, the patient experienced pyrexia and chest pain. At 16:00, the patient visited the hospital. No detailed examination was possible. At 22:30, the patient visited the hospital. Chest pain, elevated ECG, and increase in CT883, CKMB66, and troponin I were observed. Myocardial infarction was ruled out by catheterization, and myocarditis was diagnosed.<br><br>On an unknown date, the patient was hospitalized. |

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| | | On 21-Sep-2021, the patient's chest pain disappeared without medication.<br><br>On 22-Sep-2021, the patient was scheduled to be discharged.<br><br>The outcome of pyrexia after the 1st dose of this vaccine was reported as resolved.<br><br>The outcome of pyrexia and myocarditis after the 2nd dose of this vaccine was unknown.<br><br>Follow-up investigation will be made.<br><br>Company Comment:<br><br>The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) on 28-Sep-2021 and was forwarded to Moderna on 28-Sep-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Perimyocarditis) in a 22-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 16-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 18-Sep-2021, after starting mRNA-1273 (Spikevax), the patient experienced MYOCARDITIS (Perimyocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Perimyocarditis) was resolving.<br><br>For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.<br><br>Concomitant medications were not reported.<br>Treatment medications were not reported.<br><br>Company Comment:<br>This case concerns a 22 year old male patient with no medical history reported who experienced serious AESI of myocarditis after second dose of mRNA-1273. The event occurred 3 days after second dose of mRNA-1273. The rechallenge is not applicable. The benefit-risk relationship of Spikevax is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 28-Sep-2021: Translated document received on 30-Sep-2021 and added dose information.<br>On 18-Oct-2021: Follow up received contains no new information. |
| 4.1(b) | 4.1(b) | This case was initially received via European Medicines Agency (Reference number: 4.1(b) ) on 28-Sep-2021. The most |

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| | | recent information was received on 21-Oct-2021 and was forwarded to Moderna on 21-Oct-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (4.1(b) in a 17-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 3004493 and 3005697) for COVID-19 vaccination.<br><br>The patient's past medical history included ADHD.<br><br>On 14-Aug-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form.<br>On 11-Sep-2021, received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. On 11-Sep-2021, the patient experienced MYOCARDITIS (4.1(b) (seriousness criteria hospitalization prolonged and medically significant).<br>At the time of the report, MYOCARDITIS (4.1(b) had not resolved.<br><br>For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.<br><br>No concomitant and treatment medications were provided.<br><br>Lab data contain SARS-CoV-2 test with inconclusive result.<br><br>Company comment: This case concerns a 17-year-old, male patient with no relevant medical history, who experienced the expected serious (hospitalization) event of Myocarditis. The event Myocarditis was also upgraded to serious (Medically Significant) as per important medical event terms list (MedDRA version 24.0). The event occurred on the same day after the second dose of Spikevax. The rechallenge was assessed as not applicable as the event occurred after the second dose. Lab data contains SARS-CoV-2 test with inconclusive result. Very limited information regarding clinical course of the event has been provided at this time. The event is consistent with the current understanding of the mechanism of action of the vaccine. The benefit-risk relationship of Spikevax is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 28-Sep-2021: Translation received on 30-Sep-2021, contains no new information.<br>On 21-Oct-2021: Significant follow-up received, Suspect information, medical history, event start date and lab data updated. |
| 4.1(b) | 4.1(b) | This case was received via 4.1(b) (Reference number: 4.1(b) on 28-Sep-2021 and was forwarded to Moderna on 28-Sep-2021.<br>This regulatory authority case was reported by an other health care professional and describes the occurrence of PERICARDIAL EFFUSION (Pericardial effusion), PERICARDIAL FIBROSIS (Pericardial fibrosis), ABDOMINAL DISTENSION (Bloating/Abdominal distension), CHEST DISCOMFORT (Cracking chest pressure), CHEST PAIN (Chest pain), COUGH (Cough), DISCOMFORT (Uncomfortable lying flat/Discomfort), DIZZINESS (Lightheadedness/Dizziness), DYSPNOEA (Shortness of breath (SOB)/Dyspnoea), HYPERHIDROSIS (Diaphoresis), PAIN (Pain), |

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| | | PYREXIA (Fevers), MYALGIA (Severe Body aches), DEEP VEIN THROMBOSIS (Gastrocnemius thrombus extending into the popliteal vein), PAIN IN EXTREMITY (Pain of lower extremities), PERIPHERAL SWELLING (Swelling in his left lower extremity), MYOCARDITIS (Myocarditis) and PERICARDITIS (Pericarditis) in a 30-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 046C21A and 036C21A) for COVID-19 vaccination.<br><br>Concurrent medical conditions included Sulfonamide allergy (Sulfa antibiotics) and Dyslipidemia.<br><br>On 13-Aug-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form.<br>On 10-Sep-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 21-Aug-2021, the patient experienced PAIN IN EXTREMITY (Pain of lower extremities) (seriousness criterion hospitalization) and PERIPHERAL SWELLING (Swelling in his left lower extremity) (seriousness criterion hospitalization). On 25-Aug-2021, the patient experienced DEEP VEIN THROMBOSIS (Gastrocnemius thrombus extending into the popliteal vein) (seriousness criteria hospitalization and medically significant). On 10-Sep-2021, the patient experienced MYALGIA (Severe Body aches) (seriousness criterion hospitalization). On 11-Sep-2021, the patient experienced PERICARDIAL EFFUSION (Pericardial effusion) (seriousness criteria hospitalization and medically significant), PERICARDIAL FIBROSIS (Pericardial fibrosis) (seriousness criteria hospitalization and medically significant), ABDOMINAL DISTENSION (Bloating/Abdominal distension) (seriousness criterion hospitalization), CHEST DISCOMFORT (Cracking chest pressure) (seriousness criterion hospitalization), CHEST PAIN (Chest pain) (seriousness criterion hospitalization), COUGH (Cough) (seriousness criterion hospitalization), DISCOMFORT (Uncomfortable lying flat/Discomfort) (seriousness criterion hospitalization), DIZZINESS (Lightheadedness/Dizziness) (seriousness criterion hospitalization), DYSPNOEA (Shortness of breath (SOB)/Dyspnoea) (seriousness criterion hospitalization), HYPERHIDROSIS (Diaphoresis) (seriousness criterion hospitalization), PAIN (Pain) (seriousness criterion hospitalization), PYREXIA (Fevers) (seriousness criterion hospitalization), MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant) and PERICARDITIS (Pericarditis) (seriousness criteria hospitalization and medically significant). The patient was treated with RIVAROXABAN (XARELTO) on 25-Aug-2021 for DVT, at an unspecified dose and frequency; IBUPROFEN (oral) for Adverse event, at a dose of 600 milligram three times a day and COLCHICINE (oral) for Adverse event, at a dose of .6 milligram three times a day. At the time of the report, PERICARDIAL EFFUSION (Pericardial effusion), PERICARDIAL FIBROSIS (Pericardial fibrosis), ABDOMINAL DISTENSION (Bloating/Abdominal distension), CHEST DISCOMFORT (Cracking chest pressure), CHEST PAIN (Chest pain), COUGH (Cough), DISCOMFORT (Uncomfortable lying flat/Discomfort), DIZZINESS (Lightheadedness/Dizziness), DYSPNOEA (Shortness of breath (SOB)/Dyspnoea), HYPERHIDROSIS (Diaphoresis), PAIN (Pain), PYREXIA (Fevers), MYOCARDITIS (Myocarditis) and PERICARDITIS (Pericarditis) had not resolved and MYALGIA (Severe Body aches), DEEP VEIN THROMBOSIS (Gastrocnemius thrombus extending into the |

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| | | popliteal vein), PAIN IN EXTREMITY (Pain of lower extremities) and PERIPHERAL SWELLING (Swelling in his left lower extremity) outcome was unknown.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 25-Aug-2021, Ultrasound scan: abnormal (abnormal) An US was then obtained which showed a gastrocnemius thrombus extending into the popliteal vein.<br>On 13-Sep-2021, C-reactive protein: 12.5 (High) Increased.<br>On 13-Sep-2021, Electrocardiogram: abnormal (abnormal) Electrocardiogram PR segment depression.<br>On 13-Sep-2021, Electrocardiogram ST segment: abnormal (abnormal) EKG was obtained which shows diffuse ST segment elevation and PR depression, along with PR elevation and ST segment depression in AVR.<br>On 13-Sep-2021, Liver function test: normal (normal) Normal.<br>On 13-Sep-2021, Red blood cell sedimentation rate: 32 (High) Increased.<br>On 13-Sep-2021, SARS-CoV-2 test: negative (Negative) Patient was negative for COVID.<br>On 13-Sep-2021, Troponin: 5.20 (High) Initial troponin 5.20, and trended down to 1.94.<br>On 14-Sep-2021, Ejection fraction: 64 (Low) Normal LV size, wall thickness and systolic function - LVEF 64%..<br>On 14-Sep-2021, Magnetic resonance imaging heart: abnormal (abnormal) CMRI obtained consistent with pericarditis with some myocardial involvement consistent with myopericarditis..<br>On an unknown date, Fibrin D dimer: negative (Negative) D-dimer was completed which was negative.<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments.<br><br>The patient had normal left ventricle (LV) size, wall thickness and systolic function – left ventricular ejection fraction (LVEF) was 64%. No late gadolinium enhancement. Normal right ventricle (RV) size and function, normal atria and no significant valvular pathology. The pericardium was mildly thickened along the lateral cardiac border, with some tethering seen. There was a trivial pericardial effusion primarily along the lateral cardiac border. Pericardial late gadolinium enhancement along the lateral border noted. On 25-Aug-2021, patient was encouraged to present to the emergency department and was started on Xarelto. On 10-Sep-2021, patient received second dose of Moderna vaccination, he developed severe body aches, fevers, chest pain and shortness of breath (SOB). Patient presented to the ED on 13-Sep-2021, pain worsened with lying flat. Also leaning forward did not alleviate the pain. Patient noted that he initially thought he had bad reflux, then it felt like a cracking chest pressure. He has felt very uncomfortable lying flat with coughing and SOB. He also noted some bloating, diaphoresis, and lightheadedness. Patient was provided with ibuprofen 600mg PO TID along with colchicine 0.6mg 1 tab PO BID. On 14-Sep-2021, he continued to have symptoms only with increased movement, otherwise his symptoms were improving. He continued to have diaphoresis. |

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| | | This case concerns a 30-year-old, male patient with relevant medical history of dyslipidemia, who experienced the unexpected events of pericardial effusion, pericardial fibrosis, dyspnoea and deep vein thrombosis and the expected events of myocarditis and pericarditis. The events occurred 8 days after the first dose of mRNA-1273. The rechallenge was not applicable since the events have not resolved prior to dose 2 and additional AEs started after dose 2. The benefit-risk relationship of mRNA-1273 in not affected by this report. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 28-Sep-2021 and was forwarded to Moderna on 28-Sep-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (4.1(b) in a 23-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3002917) for Primary immunization.<br><br>The patient's past medical history included Allergic asthma.<br><br>On 17-Jul-2021, the patient received first dose of mRNA-1273 (Spikevax) (Subcutaneous) 1 dosage form.<br>On 22-Jul-2021, received second dose of mRNA-1273 (Spikevax) (Subcutaneous) dosage was changed to 1 dosage form. On 28-Aug-2021, after starting mRNA-1273 (Spikevax), the patient experienced MYOCARDITIS (4.1(b) (seriousness criterion medically significant). At the time of the report, MYOCARDITIS (4.1(b) was resolving.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 28-Aug-2021, C-reactive protein: not provided (Inconclusive) Not provided.<br>On 28-Aug-2021, Troponin T: inconclusive (Inconclusive) Inconclusive.<br><br>For mRNA-1273 (Spikevax) (Subcutaneous), the reporter did not provide any causality assessments.<br><br>On 28-Aug-2021, C-reactive protein and Troponin T test was performed.<br><br>No relevant concomitant medications were reported.<br>Treatment information was unknown.<br><br>This case concerns a 23-year-old male patient with relevant medical history of Allergic asthma, who experienced the expected serious AESI event of Myocarditis. The event occurred approximately 1 month 7 days after the second dose of Moderna COVID-19 Vaccine administration. The rechallenge was unknown since the vaccination 1 and 2 dates reported 5 days apart and require clarification. Additional event of inappropriate vaccination scheduled has been considered. The benefit-risk relationship is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 28-Sep-2021: Translation document received on 01 Oct 2021 contains translated event terms. |

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| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 28-Sep-2021 and was forwarded to Moderna on 28-Sep-2021.<br>This regulatory authority case was reported by a consumer and describes the occurrence of CHEST PAIN (During the night between Thursday, 2-Sep and Friday, I had a probable vaccine-related myocarditis:chest pain and tightness that lasted all night. Before this, I had pain in my limbs), PAIN IN EXTREMITY (During the night between Thursday, 2-Sep and Friday, I had a probable vaccine-related myocarditis:chest pain and tightness that lasted all night. Before this, I had pain in my limbs) and MYOCARDITIS (During the night between Thursday, 2-Sep and Friday, I had a probable vaccine-related myocarditis:chest pain and tightness that lasted all night. Before this, I had pain in my limbs.) in a 23-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 3005294) for COVID-19 immunisation.<br><br>No Medical History information was reported.<br><br>On 01-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to .5 milliliter in total. On an unknown date, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 03-Sep-2021, the patient experienced CHEST PAIN (During the night between Thursday, 2-Sep and Friday, I had a probable vaccine-related myocarditis:chest pain and tightness that lasted all night. Before this, I had pain in my limbs) (seriousness criterion life threatening), PAIN IN EXTREMITY (During the night between Thursday, 2-Sep and Friday, I had a probable vaccine-related myocarditis:chest pain and tightness that lasted all night. Before this, I had pain in my limbs) (seriousness criterion life threatening) and MYOCARDITIS (During the night between Thursday, 2-Sep and Friday, I had a probable vaccine-related myocarditis:chest pain and tightness that lasted all night. Before this, I had pain in my limbs.) (seriousness criteria medically significant and life threatening). At the time of the report, CHEST PAIN (During the night between Thursday, 2-Sep and Friday, I had a probable vaccine-related myocarditis:chest pain and tightness that lasted all night. Before this, I had pain in my limbs), PAIN IN EXTREMITY (During the night between Thursday, 2-Sep and Friday, I had a probable vaccine-related myocarditis:chest pain and tightness that lasted all night. Before this, I had pain in my limbs) and MYOCARDITIS (During the night between Thursday, 2-Sep and Friday, I had a probable vaccine-related myocarditis:chest pain and tightness that lasted all night. Before this, I had pain in my limbs.) outcome was unknown.<br><br>The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was not applicable.<br><br>No concomitant medications were provided.<br>Treatment medications was not provided.<br><br>The patient received 2nd dose administered at 05:36 p.m.<br><br>Company Comment: |

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| | | This case concerns a 23 year-old female with no medical history provided, who experienced the unexpected events of Myocarditis, Pain in extremity, and Chest pain. These events occurred 2 days after the second dose of Spikevax. The event for Myocarditis was considered probable. The benefit-risk relationship of Spikevax is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 28-Sep-2021: Translation received on 30-09-2021 and does not contain any new information. Added "Probable" for event myocarditis in Causality. Updated Sender's Comment in I-Narrative.<br>On 29-Oct-2021: Follow up received on 29-Oct-2021, NNI |
| 4.1(b) | 4.1(b) | This case was received via 4.1(b) (Reference number: 4.1(b) on 28-Sep-2021 and was forwarded to Moderna on 28-Sep-2021.<br>This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCARDITIS (Myocarditis) and PERICARDITIS (Pericarditis) in a 35-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below.<br><br>Concurrent medical conditions included Food allergy (Allergy to ginger).<br><br>On 17-Mar-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 06-Jul-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criterion medically significant), PERICARDITIS (Pericarditis) (seriousness criterion medically significant) and CHEST PAIN (Chest pain). On 25-Jul-2021, the patient experienced PALPITATIONS (Palpitations). At the time of the report, MYOCARDITIS (Myocarditis), PERICARDITIS (Pericarditis), CHEST PAIN (Chest pain) and PALPITATIONS (Palpitations) had not resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 06-Jul-2021, Fibrin D dimer: high (High) Increased.<br>On 06-Jul-2021, Troponin: high (High) Increased.<br>On 25-Jul-2021, Heart rate: high (High) Increased.<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments.<br><br>No concomitant medications were reported.<br>No treatment medications were provided.<br>On 06 Jul 2021, the patient experienced chest pains and elevated troponins.On 25 Jul 2021, patient had chest pains,palpitations and had elevated heart rates.<br>Laboratory test performed on 06 Jul 2021, included cardiac stress test, chest X-ray, echocardiogram, electrocardiogram , laboratory test and the results were unknown.<br><br>Company Comment: This case concerns a 35 year old female with no relevant medical history who experienced serious expected events of |

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| | | myocarditis and pericarditis 3 months 20 days after the second dose of the Moderna Covid 19 vaccine. Rechallenge was not applicable. The benefit-risk relationship is not affected by this report. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 28-Sep-2021 and was forwarded to Moderna on 28-Sep-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (4.1(b) ) in a 28-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3005689) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 09-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 13-Sep-2021, after starting mRNA-1273 (Spikevax), the patient experienced MYOCARDITIS 4.1(b) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS 4.1(b) had not resolved.<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.<br><br>Concomitant medication use was not provided.<br>Treatment information was not provided.<br><br>Company comment: This case concerns a 28 year-old, male patient with no relevant medical history, who experienced the serious expected adverse event of special interest due to hospitalization of Myocarditis. The event occurred approximately 5 days after the second dose of Spikevax. The rechallenge was not applicable, as the event was reported exclusively after the second dose. The benefit-risk relationship of Spikevax is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 28-Sep-2021: Translation received on 30-Sep-21 added dose related information from translated event verbatim.<br>On 29-Sep-2021: Follow up received as no new information. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 29-Sep-2021 and was forwarded to Moderna on 29-Sep-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (4.1(b) and COVID-19 IMMUNISATION (4.1(b) in a 17-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 3002616) for Vaccination.<br><br>Previously administered products included for Vaccination: Comirnaty. Past adverse reactions to the above products included No adverse event with Comirnaty. |

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| | | On 15-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. In 2021, the patient experienced COVID-19 IMMUNISATION (4.1(b)) (seriousness criterion hospitalization). On 15-Sep-2021, the patient experienced MYOCARDITIS (4.1(b)) (seriousness criteria hospitalization and medically significant). In 2021, COVID-19 IMMUNISATION (4.1(b)) was resolving. On 21-Sep-2021, MYOCARDITIS (4.1(b)) was resolving.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>In September 2021, Electrocardiogram: st-elevation (High) ST-elevation.<br>In September 2021, Troponin: high (High) High.<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered MYOCARDITIS (4.1(b)) to be possibly related. No further causality assessment was provided for COVID-19 IMMUNISATION (4.1(b))<br><br>No concomitant medications reported<br>No treatment medications provided<br><br>Company Comment:<br>This is a case of revaccination with different Covid-19 vaccine for this 17-year-old, female patient with no relevant medical history, who experienced the unexpected event of chest pain and expected event of myocarditis. The events chest pain and myocarditis occurred 1 day after the administration of labeled dose number two of mRNA-1273 vaccine. The rechallenge was not applicable because the patient previously received other brand of Covid-19 vaccine (Comirnaty). The patient's age and vaccine history of receiving of other brand of Covid-19 vaccine (Comirnaty) remains confounders. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 29-Sep-2021: Translated document Received on 30-sep-2021 contains information from verbatim added to the narrative |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b)) on 29-Sep-2021 and was forwarded to Moderna on 29-Sep-2021.<br>This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (Perimyocarditis) in a 32-year-old male patient who received mRNA-1273 (Spikevax) for Prophylactic vaccination.<br><br>No Medical History information was reported.<br><br>On 16-Aug-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form.<br>On an unknown date, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 11-Sep-2021, the patient experienced MYOCARDITIS (Perimyocarditis) (seriousness criteria |

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| | | hospitalization and medically significant). At the time of the report, MYOCARDITIS (Perimyocarditis) was resolving.<br><br>No concomitant product was reported.<br>No treatment information was reported.<br><br>Company Comment: This case concerns a 32-year-old, male patient with no relevant medical history, who experienced the serios expected event of Myocarditis. The event occurred around 27 days after the second dose of Spikevax. The rechallenge was not applicable since the event occurred after the second dose and no events were reported after the first dose. The benefit-risk relationship of Spikevax is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 29-Sep-2021: Translation received on 02-sep-2021 has no new information |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 29-Sep-2021 and was forwarded to Moderna on 29-Sep-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (PERIMYOCARDITIS) in a 25-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3004498) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below.<br><br>Co-suspect product included non-company product TOZINAMERAN (COMIRNATY) for an unknown indication.<br><br>The patient's past medical history included Migraine.<br>Previously administered products included for Vaccination: COMIRNATY.<br>Concomitant products included VERAPAMIL (ISOPTIN [VERAPAMIL]) for Migraine.<br><br>On 06-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form.<br>On an unknown date, the patient started TOZINAMERAN (COMIRNATY) (unknown route) at an unspecified dose. On 07-Sep-2021, the patient experienced MALAISE (MALAISE) and PYREXIA (FEVER). On 08-Sep-2021, the patient experienced CHEST PAIN (CHEST PAIN). On 09-Sep-2021, the patient experienced MYOCARDITIS (PERIMYOCARDITIS) (seriousness criteria hospitalization and medically significant). On an unknown date, the patient experienced COVID-19 IMMUNISATION (Revaccination with different covid-19 vaccine). At the time of the report, MYOCARDITIS (PERIMYOCARDITIS) was resolving and COVID-19 IMMUNISATION (Revaccination with different covid-19 vaccine), MALAISE (MALAISE), CHEST PAIN (CHEST PAIN) and PYREXIA (FEVER) outcome was unknown.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 09-Sep-2021, Echocardiogram: normal (normal) No pathology.. |

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| | | On 09-Sep-2021, Electrocardiogram: abnormal (abnormal) Typical changes as seen in pericarditis..<br>On 09-Sep-2021, Magnetic resonance imaging heart: abnormal (abnormal) Typical changes as seen in myocarditis, oedema and T1/T2 mapping, preserved ventricular function..<br>On 09-Sep-2021, Troponin T: 3962 ng/L (Inconclusive) Inconclusive.<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered MYOCARDITIS (PERIMYOCARDITIS), COVID-19 IMMUNISATION (Revaccination with different covid-19 vaccine), MALAISE (MALAISE), CHEST PAIN (CHEST PAIN) and PYREXIA (FEVER) to be possibly related.<br><br>Treatment information was not provided.<br><br>Company Comment: This is a case of Revaccination with different COVID- 19 VACCINE for this 25-year-old, male patient with no reported relevant medical history, who experienced the serious expected event of Myocarditis. The event of Myocarditis occurred 3 days after the second dose of Spikevax after initially receiving the first dose of Comirnaty. The rechallenge was unknown for the event, as there is only information available about one dose. The benefit-risk relationship of Spikevax is not affected by this report<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 29-Sep-2021: Translation received on 01-Oct-2021 contains no new information. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 29-Sep-2021 and was forwarded to Moderna on 29-Sep-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Acute myocarditis) in a 32-year-old female patient who received mRNA-1273 (Spikevax) (batch nos. 3003610 and 3002184) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 10-Jun-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form.<br>On 12-Jul-2021, received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to 1 dosage form. On 20-Aug-2021, the patient experienced MYOCARDITIS (Acute myocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Acute myocarditis) had not resolved.<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.<br><br>Concomitant medications were not reported.<br><br>Treatment medications were not reported. |

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| | | Company Comment : This case concerns a 32-year-old, female patient with no relevant medical history, who experienced the unexpected event of Myocarditis. The event occurred approximately 2 months after the second dose of Spikevax. The rechallenge was not applicable, as the event happened after the second dose. The event was considered related to the product per the reporter's assessment. The benefit-risk relationship of Spikevax is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 29-Sep-2021: Translation received on 01-Oct-2021, dose 1 details added. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 29-Sep-2021 and was forwarded to Moderna on 29-Sep-2021.<br>This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (4.1(b) in a 22-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3004235) for Prophylactic vaccination.<br><br>No Medical History information was reported.<br><br>On 09-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form.<br>On an unknown date, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 13-Sep-2021, the patient experienced MYOCARDITIS (4.1(b) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (4.1(b) was resolving.<br><br>No concomitant and treatment information were reported by the reporter.<br><br>Patient reported that he was experiencing Myocarditis with chest pain, cardiac, arrhythmias.<br><br>Company Comment : This case concerns a 45-year-old, male patient with no relevant medical history, who experienced the expected event of Myocarditis. The event occurred approximately 5 days after the second dose of Spikevax. The rechallenge was not applicable, as the event happened after the second dose. The event was considered related to the product per the reporter's assessment. The benefit-risk relationship of Spikevax is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 29-Sep-2021: Translation received on 02-OCT-2021 is significant. Event verbatim is translated and sender's comment translated. |
| 4.1(b) | 4.1(b) | This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (4.1(b) in a 33-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination.<br><br>No Medical History information was reported. |

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| | | In May 2021, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form.<br>On 02-Jun-2021, received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) dosage was changed to 1 dosage form. On 03-Jun-2021, the patient experienced MYOCARDITIS [redacted] (seriousness criteria hospitalization and medically significant). The patient was hospitalized from 05-Jun-2021 to 09-Jun-2021 due to MYOCARDITIS. The patient was treated with IBUPROFEN for Adverse event, at an unspecified dose and frequency. At the time of the report, MYOCARDITIS [redacted] was resolving.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 03-Jun-2021, Pyrexia: 39 (High) 39 Celsius.<br>On 05-Jun-2021, Electrocardiogram: high (High) Diffuse ST elevations V3-V6, I, II, aVF.<br>On 08-Jun-2021, Magnetic resonance imaging: abnormal (abnormal) Discreet late gadolinium enhancement (LGE)in the inferoseptal (basal) region and at the inferior septal insertion point consistent with myocarditis..<br>On 09-Jun-2021, Computerised tomogram: abnormal (abnormal) Coronary arteries -Unremarkable.<br>On an unknown date, Computerised tomogram: a coronary vascular occlusion was ruled out A coronary vascular occlusion was ruled out.<br>On an unknown date, Myocardial necrosis marker: increased increased.<br><br>For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered MYOCARDITIS [redacted] to be possibly related.<br><br>Patient experienced pressure on the chest without radiation, was in a stable hemodynamic and pulmonary condition and was afebrile. patient was treated with Ibuprofen ( exact product name not known) and shown a good response to the treatment with decreasing symptoms and a regression in the cardiac enzymes and inflammatory parameters.<br><br>No concomitant medication information was provided.<br><br>Company comment:<br>This case concerns a 33 year-old, male patient with no relevant medical history, who experienced the serious expected adverse event of special interest of Myocarditis. The event occurred approximately 1 day after the second dose of Moderna COVID-19 vaccine. The rechallenge was not applicable, as the event was reported exclusively after the second dose. The benefit-risk relationship of Moderna COVID-19 vaccine is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 29-Sep-2021: Translation received Added Lab Data, Concomitant Products,Events |
| [redacted] | [redacted] | This case was received via European Medicines Agency (Reference number: [redacted]) on 29-Sep-2021 and was forwarded to Moderna on 29-Sep-2021. |

| Case ID | WW Identifier | Narrative |
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| | | This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myopericarditis) in a 28-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 214021 and 3004234) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 14-Aug-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form.<br>On 04-Sep-2021, received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to 1 dosage form. On 06-Sep-2021, the patient experienced MYOCARDITIS (Myopericarditis) (seriousness criterion medically significant). At the time of the report, MYOCARDITIS (Myopericarditis) had resolved.<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.<br><br>Concomitant product use was not provided by the reporter.<br>Treatment information was not provided.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 29-Sep-2021: Translation document received on 04 Oct 2021 included suspect vaccine details. |
| 4.1(b) | 4.1(b) | This case was received via 4.1(b) (Reference number: 4.1(b) on 29-Sep-2021 and was forwarded to Moderna on 29-Sep-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of PERICARDITIS (Pericarditis) in a 31-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below.<br><br>Concurrent medical conditions included Asthma and Ehlers-Danlos syndrome.<br><br>On 13-Aug-2021, the patient received second dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 14-Aug-2021, the patient experienced PERICARDITIS (Pericarditis) (seriousness criterion medically significant). On an unknown date, the patient experienced CHEST PAIN (chest pain). On 17-Aug-2021, PERICARDITIS (Pericarditis) was resolving. At the time of the report, CHEST PAIN (chest pain) was resolving.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 14-Aug-2021, SARS-CoV-2 test: negative (Negative) Negative.<br><br>The action taken with mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown) was unknown. |

| Case ID | WW Identifier | Narrative |
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| | | For mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown), the reporter did not provide any causality assessments.<br><br>No concomitant medication details was provided.<br>No treatment medication details was provided.<br><br>Reporter stated he had fluish symptoms within few hours, then pericarditis chest pain by 12 hours and attended A&E by 24 hours.<br>Lab test included Trop neg CRP 34. Lymphocytes 0.9 L WCC 10.9H Neutrophils 9.3H.<br>Patient started on ibuprofen and colchicine 500mcg po bd for 3/12.<br>Possible inferior hypokinesis on ECHO. Planning Cardiac MRI.<br><br>Patient has not tested positive for COVID-19 since having the vaccine<br><br>Patient was not enrolled in clinical trial.<br><br>Company comment: This case concerns a 31 year old male with a history of asthma who experienced the serious listed event of Pericarditis one day after the second dose of mRNA-1273. Re-challenge is unknown for the first dose as no information is reported and not applicable for dose 2. The history of asthma remains a confounder as it could cause chest pain. Benefit-risk relationship of mRNA-1273 is not affected by this event. |
| 4.1(b) | 4.1(b) | This case was initially received via 4.1(b) (Reference number: 4.1(b) ) on 29-Sep-2021. The most recent information was received on 26-Oct-2021 and was forwarded to Moderna on 26-Oct-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myopericarditis), CHEST PAIN (Chest pain) and MYALGIA (Myalgia) in a 20-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 17-Sep-2021, the patient received second dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 17-Sep-2021, the patient experienced MYOCARDITIS (Myopericarditis) (seriousness criteria hospitalization and medically significant) and CHEST PAIN (Chest pain) (seriousness criterion hospitalization). 17-Sep-2021, the patient experienced MYALGIA (Myalgia) (seriousness criterion hospitalization). On 22-Sep-2021, MYOCARDITIS (Myopericarditis) was resolving. At the time of the report, CHEST PAIN (Chest pain) and MYALGIA (Myalgia) outcome was unknown.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 18-Sep-2021, C-reactive protein: 16.7 (abnormal) 16.7.<br>On 18-Sep-2021, Electrocardiogram: pericarditic st elevation (normal) Pericarditic ST elevation.<br>On 18-Sep-2021, Lymphocyte count: 1.1 (abnormal) 1.1.<br>On 18-Sep-2021, Neutrophil count: 8.8 (abnormal) 8.8.<br>On 18-Sep-2021, SARS-CoV-2 test: negative (Negative) Negative.<br>On 18-Sep-2021, Troponin T: 5.9 (abnormal) 5.9.<br>On 18-Sep-2021, White blood cell count: 11.2 (abnormal) 11.2. |

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| | | On 19-Sep-2021, C-reactive protein: 60 (abnormal) 60.<br>On 19-Sep-2021, Troponin T: 442 (abnormal) 442.<br>On 20-Sep-2021, Echocardiogram: normal (normal) normal.<br>On 20-Sep-2021, Troponin T: 1053 (abnormal) 1053.<br>On 21-Sep-2021, C-reactive protein: 14 (abnormal) 14.<br>On 21-Sep-2021, Troponin T: 1167 (abnormal) 1167.<br>On 22-Sep-2021, Echocardiogram: normal (normal) normal.<br>On 22-Sep-2021, Troponin T: 494 (abnormal) 494.<br><br>For mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown), the reporter did not provide any causality assessments.<br><br>Concomitant medication was not provided.<br><br>It was reported that within 6 hours of Moderna second dose mylagia and chest pains and attended hospital on 18 Sep 2021. Pericarditic ST elevation on ECG. trop T initially 5.9 on 18 Sep 2021, to 442 on 19 Sep 2021, to 1053 on 20 Sep 2021, to 1167 on 21 Sep 2021, to 494 on 22 Sep 2021. CRP 16.7 on 18 Sep 2021 , 60 on 19 Sep 2021, to 14 on 21 Sep 2021. On 18 Sep 2021, WCC 11.2H, Neutrophils 8.8H,& lymphocytes 1.1 N.ECHO normal on 20 Sep 2021 & 22 Sep 2021. Patient started on ibuprofen and colchicine on 20 Sep 2021, 500mcg po bd for 3/12. For OP cardiac MRI. Pain controlled by discharge, no other symptoms reported.<br><br>Patient was not tested positive for COVID-19 since vaccination.<br>Patient was not enrolled in clinical trial.<br><br>Company comment: This case concerns a 20-year-old, male patient with no relevant medical history, who experienced the serious expected event of myocarditis and serious unexpected event of myalgia. Event myalgia seriousness assessed as unexpected as the event retained as serious per regulatory authority reporting. The event chest pain is a possible manifestation of myocarditis. The events occurred the same day after the second dose of Moderna CoviD-19 Vaccine. Electrocardiogram showed ST elevation and Troponin-T was elevated. Patient was treated with ibuprofen and colchicine with pain relief. The rechallenge was unknown since no information about the first dose was disclosed. The benefit-risk relationship of Moderna CoviD-19 Vaccine is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 26-Oct-2021: significant follow up received on 26-Oct-2021, lab data, action taken with suspect drug and new AEs were added |
| 4.1(b) | 4.1(b) | This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) ) on 24-Sep-2021 and was forwarded to Moderna on 30-Sep-2021.<br>This case, initially reported to the 4.1(b) by a (physician), was received via the 4.1(b) (Ref, 4.1(b)<br><br>On an unknown date, the patient received the 1st dose of this vaccine.<br><br>On 12-Sep-2021, the patient received the 2nd dose of this vaccine. |

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| | | On 13-Sep-2021, pyrexia developed.<br><br>On 14-Sep-2021, pyrexia persisted.<br><br>On 15-Sep-2021, the patient was aware of pain in the chest and queasy in the morning and took pain relief.<br><br>On 16-Sep-2021, at 10:00, pain in the chest developed again, and the patient visited the reporting hospital. AST 83, LDH 295, CK 537, CK-MB 57.8, and troponin T 9,330.7. Marked elevation of cardiac enzymes was noted, and the patient was diagnosed with acute myocarditis. The patient was hospitalized on the purpose of follow-up.<br><br>On 17-Sep-2021, symptom recovery was confirmed. The patient was discharged from the hospital.<br><br>The outcome of acute myocarditis was reported as recovered.<br>Follow-up investigation will be made.<br>Reporter comments continuation:<br><br>The reaction occurred within several days after the vaccination, and the causality with the vaccination cannot clearly be ruled out. The patient had acute myocarditis, but on the 2nd day of hospitalization, the elevation of enzymes was also normalized, and the symptoms rapidly improved, and the patient was thus discharged home. The progress around this time was also rapid, and it is considered to be different from the general course of myocarditis, and a causal relationship with the vaccination is suspected.<br><br>Company Comment:<br><br>The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. |
| 4.1(b) | 4.1(b) | This case was initially received via Takeda Pharmaceuticals (Reference number: 4.1(b) ) on 25-Sep-2021. The most recent information was received on 04-Nov-2021 and was forwarded to Moderna on 10-Nov-2021.<br>This case, reported by a physician, was received by Takeda via Moderna's adverse reaction reporting site (4.1(b) and reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref, 4.1(b)<br><br>On 04-Nov-2021, follow up information, reported by a physician, was received by Takeda Pharmaceutical Company Limited via Moderna's adverse reaction reporting site (4.1(b)<br><br>On 05-Nov-2021, follow up information, initially reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref, 4.1(b)<br><br>On an unknown date, the patient received the 1st dose of the vaccine.<br><br>On 20-Sep-2021, the patient received the 2nd dose of the vaccine. |

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| | | On an unknown date, the patient had pyrexia and took an over-the-counter antipyretic.<br><br>On 23-Sep-2021, at 07:30, the patient became aware of chest pain. The patient urgently visited the reporting hospital and was hospitalized because the result of a blood test showed positive for TnI. A catheterization was performed and showed no significant abnormalities in the coronary artery, and the patient was diagnosed with myocarditis and pericarditis.<br><br>On 26-Sep-2021, as chest pain improved, the patient was discharged from the hospital with relief of the symptom.<br><br>The outcome of myocarditis and pericarditis was reported as resolving.<br><br>No follow-up investigation will be made.<br><br>Follow-up received on 04-NOV-2021<br><br>Updated: Lab Data, Event Information, Narrative, Reporter Comments<br><br>Company Comment:<br><br>The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. |
| 4.1(b) | 4.1(b) | This case was initially received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 27-Sep-2021. The most recent information was received on 04-Nov-2021 and was forwarded to Moderna on 16-Nov-2021.<br>This case, reported by a physician, was received by Takeda via Moderna's adverse reaction reporting site (4.1(b) and reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref, 4.1(b)<br><br>On 04-Nov-2021, follow-up information, reported by a physician, was received by Takeda Pharmaceutical Company Limited via Moderna's adverse reaction reporting site (4.1(b)<br><br>On 05-Nov-2021, follow-up information, reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref, 4.1(b)<br><br>On 26-Aug-2021, the patient received the 1st dose of the vaccine.<br><br>On 20-Sep-2021, the patient received the 2nd dose of the vaccine.<br><br>On 23-Sep-2021, in the morning, the patient experienced chest pain and visited a medical institution. The patient was diagnosed with myocarditis because the result of a blood test showed TnI positive and 12-leads electrocardiogram showed negative T wave with the precordial lead.<br><br>On 01-Oct-2021, resolution of the symptom was confirmed.<br><br>The outcome of myocarditis was reported as resolved. |

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| | | No follow-up investigation will be made.<br><br>Follow-up received on 04-NOV-2021<br><br>Updated: Lab Data, Product Information, Event Information, Narrative<br><br>Company Comment:<br><br>The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.<br><br>Company Comment: This case concerns a 20-year-old male patient with no relevant medical history provided who experienced serious expected event of special interest Myocarditis. The event occurred three days after the second dose of mRNA-1273. The rechallenge was not applicable as the event occurred following the second dose of the vaccine. It was reported that the result of a blood test showed Troponin I positive and 12-leads electrocardiogram showed negative T wave with the precordial lead. At the time of the report the event resolved. The reporter assessed the event as related to the product. The benefit risk relationship of mRNA-1273 is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes: On 04-Nov-2021: Follow-up received on 04-Nov-2021 with Lab Data, Product Information, Event Information and Narrative updated. |
| 4.1(b) | 4.1(b) | This case was initially received via European Medicines Agency (Reference number: 4.1(b) ) on 29-Sep-2021. The most recent information was received on 14-Oct-2021 and was forwarded to Moderna on 16-Oct-2021.<br>This regulatory authority case was reported by a consumer and describes the occurrence of CHEST PAIN (The patient had the second dose of the Moderna vaccine on Sep 08, 2021, and, 6 days later, had chest pain and left arm pain. Vaccine-induced myocarditis. Urgent hospitalization.), PAIN IN EXTREMITY (The patient had the second dose of the Moderna vaccine on Sep 08, 2021, and, 6 days later, had chest pain and left arm pain. Vaccine-induced myocarditis. Urgent hospitalization.) and MYOCARDITIS (The patient had the second dose of the Moderna vaccine on Sep 08, 2021, and, 6 days later, had chest pain and left arm pain. Vaccine-induced myocarditis. Urgent hospitalization.) in a 17-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3004669) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 08-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) .5 milliliter. On 14-Sep-2021, the patient experienced CHEST PAIN (The patient had the second dose of the Moderna vaccine on Sep 08, 2021, and, 6 days later, had chest pain and left arm pain. Vaccine-induced myocarditis. Urgent hospitalization.) (seriousness criterion hospitalization), PAIN IN EXTREMITY (The patient had the second dose of the Moderna vaccine on Sep 08, 2021, and, 6 days later, had chest pain and left arm pain. Vaccine-induced myocarditis. Urgent hospitalization.) (seriousness criterion hospitalization) and MYOCARDITIS (The patient had the second dose of the Moderna |

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| | | vaccine on Sep 08, 2021, and, 6 days later, had chest pain and left arm pain. Vaccine-induced myocarditis. Urgent hospitalization.) (seriousness criteria hospitalization and medically significant). At the time of the report, CHEST PAIN (The patient had the second dose of the Moderna vaccine on Sep 08, 2021, and, 6 days later, had chest pain and left arm pain. Vaccine-induced myocarditis. Urgent hospitalization.), PAIN IN EXTREMITY (The patient had the second dose of the Moderna vaccine on Sep 08, 2021, and, 6 days later, had chest pain and left arm pain. Vaccine-induced myocarditis. Urgent hospitalization.) and MYOCARDITIS (The patient had the second dose of the Moderna vaccine on Sep 08, 2021, and, 6 days later, had chest pain and left arm pain. Vaccine-induced myocarditis. Urgent hospitalization.) had not resolved.<br><br>Concomitant product was not provided by the reporter.<br>Treatment product was not provided by the reporter.<br>Patient had taken second dose on 08-Sep-2021 after 6 days patient developed chest pain, left arm pain and vaccine induced myocarditis.<br><br>Company comment: This case concerns a 17-year-old, female patient with no relevant medical history, who experienced the serious, unexpected events of myocarditis, chest pain and pain in extremity which required hospitalization. Myocarditis is expected event for adult patients. The events occurred approximately 6 days after the second dose of Moderna COVID-19 Vaccine. The rechallenge was not applicable as events occurred after second dose and no further dosing was reported or planned, based on information provided. The reporter assessed the events as related to the product. The benefit-risk relationship of Moderna COVID-19 Vaccine is not affected by this report. Event seriousness assessed as per Regulatory Authority reporting. Chest pain is likely the consequence of myocarditis.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 14-Oct-2021: Translation document received on 16-Oct-2021, updated dose number, action taken, and event verbatim updated to English.<br>On 02-Nov-2021: Follow up contains no new information. |
| 4.1(b) | 4.1(b) | This case was initially received via European Medicines Agency (Reference number: 4.1(b) ) on 30-Sep-2021. The most recent information was received on 06-Oct-2021 and was forwarded to Moderna on 06-Oct-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myocarditis) and CHEST PAIN (The patient was hospitalized with chest pain. Approximately 12 hours after onset, the patient no longer experiences chest pain) in a 27-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 3004493 and 3004730) for COVID-19 immunisation.<br><br>The patient's past medical history included Subarachnoid haemorrhage (After car accident).<br>Concurrent medical conditions included Substance abuse and Anxiety. |

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| | | Concomitant products included LAMOTRIGINE (LAMOTRIGIN 1A FARMA) from 21-Aug-2020 to an unknown date for Mood swings, MELATONIN from 24-Apr-2020 to an unknown date for Sleeplessness.<br><br>On 28-Jul-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form.<br>On 25-Aug-2021, received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. On 15-Sep-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization, medically significant and life threatening) and CHEST PAIN (The patient was hospitalized with chest pain. Approximately 12 hours after onset, the patient no longer experiences chest pain) (seriousness criteria hospitalization and life threatening). On 16-Sep-2021, CHEST PAIN (The patient was hospitalized with chest pain. Approximately 12 hours after onset, the patient no longer experiences chest pain) had resolved. At the time of the report, MYOCARDITIS (Myocarditis) had not resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>In September 2021, Angiocardiogram: acute (unknown result) (abnormal) Acute (unknown result).<br>In September 2021, Blood creatine phosphokinase MB: 67.9 unit (abnormal) Maximum: 67.9 Unit not specified.<br>In September 2021, Cardiac telemetry: 2 ves at run, no arrhythmia (abnormal) 2 VES at run, no arrhythmia and 2 (High) 2 VES at run, no arrhythmia.<br>In September 2021, Ejection fraction: 45%, mild/moderately reduced (abnormal) 45%, mild/moderately reduced.<br>In September 2021, Electrocardiogram: abnormal (abnormal) SR, AV signal conduction normal,, abnormal (abnormal) slender QRS intervals, abnormal (abnormal) suspected hyperactive T wave V3-V4 and suspicion of stemi (abnormal) Suspicion of STEMI.<br>In September 2021, Magnetic resonance imaging heart: compatible with widespread myocarditis (abnormal) Compatible with widespread myocarditis.<br>In September 2021, Percutaneous coronary intervention: acute pci: disproves stemi. shows clean vessels (normal) Acute PCI: disproves STEMI. Shows clean vessels.<br>In September 2021, Troponin I: 23800 unit (abnormal) First measurement: 23800 Unit not specified.<br>In September 2021, Troponin T: 2740 unit (abnormal) Maximum: 2740 Unit not specified.<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.<br><br>No treatment medications provided by the reporter.<br>On SEP-2021, Patient had done laboratory investigation of echocardiography and result was unknown.<br>The patient was hospitalized with chest pain. Approximately 12 hours after onset, the patient no longer experiences chest pain. |

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| | | Company Comment: This case concerns a 27 year-old male patient with Concurrent medical conditions including Substance abuse, who experienced the unexpected event of Chest pain. This event occurred approximately 20 days after the second dose of Spikevax.Approximately 12 hours after onset, the patient no longer experiences chest pain. The concurrent medical condition of substance abuse may be a cofounder. The benefit-risk relationship of Spikevax is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 30-Sep-2021: Translation document received on 04-Oct-2021 included no new information.<br>On 06-Oct-2021: Follow-up Information received included historical condition and lab data. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 30-Sep-2021 and was forwarded to Moderna on 30-Sep-2021.<br>This regulatory authority case was reported by a consumer and describes the occurrence of INFARCTION (4.1(b) and PERICARDITIS (4.1(b) in a 38-year-old male patient who received mRNA-1273 (Spikevax) for Vaccination. The occurrence of additional non-serious events is detailed below.<br><br>No Medical History information was reported.<br><br>On 02-Sep-2021 at 7:35 AM, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 13-Sep-2021, the patient experienced PERICARDITIS (4.1(b) (seriousness criteria hospitalization and medically significant). On an unknown date, the patient experienced INFARCTION (4.1(b) (seriousness criteria hospitalization and medically significant), FEELING COLD (4.1(b) ), CHEST PAIN (4.1(b) ), VISUAL IMPAIRMENT (4.1(b) and DYSPNOEA (4.1(b) . At the time of the report, INFARCTION (4.1(b) FEELING COLD (4.1(b) ), CHEST PAIN (4.1(b) ), VISUAL IMPAIRMENT (4.1(b) and DYSPNOEA (4.1(b) outcome was unknown and PERICARDITIS (4.1(b) was resolving.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On an unknown date, Blood test: abnormal (abnormal) Showed heart infarctionl.<br>On an unknown date, Computerised tomogram: abnormal (abnormal) Showed calcifications / plaque in one vein and pericarditis.<br>On an unknown date, Electrocardiogram: abnormal (abnormal) Showed abnormal results.<br><br>Concomitant medication use information was not provided by reporter.<br>Treatment medication use information was not provided by reporter.<br><br>The patient reported sick leave due to the ADRs. The patient went to the doctor's office. Took ECG that showed |

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| | | abnormal findings, was sent to hospital. Took 3 ECGs that were normal.<br><br>Company comment: This case concerns a 38-year-old male patient with no reported relevant medical history, who experienced the expected serious AESI event of Pericarditis and unexpected serious AESI event of Infarction. The event Pericarditis occurred approximately 11 days after the second dose of Spikevax administration and the event of Infarction occurred on unknown date. The rechallenge was not applicable since information on the first dose was not provided and no additional dosing will be given. The benefit-risk relationship is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 30-Sep-2021: Additional information received on 4-OCT-2021 that contains updated Narrative. |
| 4.1(b) | 4.1(b) | This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) ) on 28-Sep-2021 and was forwarded to Moderna on 01-Oct-2021.<br><br>This case, initially reported to the 4.1(b) by a pharmacist, was received via the 4.1(b) (Ref 4.1(b)<br><br>The patient had a history of pollinosis and allergy to house dust.<br><br>On an unknown date, the patient received the 1st dose of the vaccine.<br><br>On 17-Sep-2021, at 15:30, the patient received the 2nd dose of the vaccine. At 22:00, the patient noticed malaise.<br><br>On 18-Sep-2021, in the morning, the patient noticed pyrexia, palpitations, and tingling pain.<br><br>On 19-Sep-2021, as the symptoms persisted, the patient visited an emergency department. Physical examinations, blood sampling, cardiac ultrasonography, and a simple thoracoabdominal CT were performed, and a diagnosis of suspected myocarditis was made. The patient was hospitalized to be followed up conservatively.<br><br>On an unspecified date, after the hospitalization, there was an improvement of subjective symptoms. Therefore, the attending physician considered that the patient was able to be discharged from the hospital with a follow-up by blood sampling.<br><br>On 23-Sep-2021, it was confirmed that symptoms were resolving. In the morning, the patient was discharged home from the hospital.<br><br>The outcome of myocarditis was reported as resolving.<br><br>Follow-up investigation will be made.<br><br>Company Comment:<br><br>The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. |

| Case ID | WW Identifier | Narrative |
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| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 30-Sep-2021 and was forwarded to Moderna on 30-Sep-2021.<br>This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (4.1(b) in a 22-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 3004671) for Prophylactic vaccination.<br><br>No Medical History information was reported.<br><br>On 21-Aug-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form.<br>On an unknown date, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 24-Aug-2021, the patient experienced MYOCARDITIS (4.1(b) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (4.1(b) was resolving.<br><br>No concomitant medication were reported. No treatment information was provided by the reporter.<br>Patient experienced Malaise, She stayed in hospital with confirmation of myocarditis.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 30-Sep-2021: Translation document received on 05-OCT-2021.<br>Sender's comment updated in narrative supplement. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 30-Sep-2021 and was forwarded to Moderna on 30-Sep-2021.<br>This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (4.1(b) in a 23-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3003183) for Prophylactic vaccination.<br><br>No Medical History information was reported.<br><br>On 05-Jul-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form.<br>On an unknown date, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 03-Sep-2021, the patient experienced MYOCARDITIS (4.1(b) (seriousness criteria hospitalization and medically significant). The patient was hospitalized on sometime in September 2021 due to MYOCARDITIS. At the time of the report, MYOCARDITIS (4.1(b) was resolving.<br><br>Concomitant medication was not provided.<br>Treatment information was not provided.<br><br>Patient reported that he was on 6 days of inpatient treatment. |

| Case ID | WW Identifier | Narrative |
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| | | Company comment:<br>This case concerns a 23-year-old, male patient with no relevant medical history, who experienced the serious expected event of Myocarditis. The event occurred 60 days after the second dose of mRNA-1273. The rechallenge was not applicable as no information about the first dose was provided. The benefit-risk relationship of mRNA-1273 is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 30-Sep-2021: Translation received on 05-Oct-2021 include significant information. Sender's comments. |
| 4.1(b) | 4.1(b) | This case was initially received via European Medicines Agency (Reference number: 4.1(b) on 30-Sep-2021. The most recent information was received on 12-Oct-2021 and was forwarded to Moderna on 12-Oct-2021.<br>This regulatory authority case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of HAEMATEMESIS (Vomiting blood), CARDIAC DISORDER (Heart defect), LOSS OF CONSCIOUSNESS (Loss of consciousness), DYSPNOEA (Breathing difficulties), PULMONARY HAEMORRHAGE (the lungs were filled with blood coming from a heart disorder), ACUTE PULMONARY OEDEMA (ACUTE PULMONARY EDEMA), HOSPITALISATION (Hospitalisation) and MYOCARDITIS (Myocarditis (the patient called it a Heart Disorder)) in a 37-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3003604) for Vaccination. The occurrence of additional non-serious events is detailed below.<br><br>Previously administered products included for Vaccination: Comirnaty (5'capped mRNA encoding full length SARS-CoV-2 spike protein).<br>Past adverse reactions to the above products included No adverse event with Comirnaty.<br><br>On 08-Sep-2021 at 1:20 PM, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 11-Sep-2021, the patient experienced HAEMATEMESIS (Vomiting blood) (seriousness criteria hospitalization, medically significant and life threatening), CARDIAC DISORDER (Heart defect) (seriousness criteria hospitalization and life threatening), LOSS OF CONSCIOUSNESS (Loss of consciousness) (seriousness criteria hospitalization, medically significant and life threatening), DYSPNOEA (Breathing difficulties) (seriousness criteria hospitalization and life threatening), PULMONARY HAEMORRHAGE (the lungs were filled with blood coming from a heart disorder) (seriousness criteria hospitalization and medically significant), ACUTE PULMONARY OEDEMA (ACUTE PULMONARY EDEMA) (seriousness criteria hospitalization and medically significant), HOSPITALISATION (Hospitalisation) (seriousness criterion hospitalization) and MYOCARDITIS (Myocarditis (the patient called it a Heart Disorder)) (seriousness criteria hospitalization, medically significant and life threatening). In September 2021, the patient experienced INFLUENZA LIKE ILLNESS (Had mild influenza-like adverse reactions on the night -9-sep-21.). On an unknown date, the patient experienced COVID-19 IMMUNISATION (REVACCINATION WITH DIFFERENT COVID-19 VACCINE). The patient was hospitalized from 11-Sep-2021 to |

| Case ID | WW Identifier | Narrative |
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| | | 13-Sep-2021 due to ACUTE PULMONARY OEDEMA, CARDIAC DISORDER, DYSPNOEA, HAEMATEMESIS, HOSPITALISATION, LOSS OF CONSCIOUSNESS, MYOCARDITIS and PULMONARY HAEMORRHAGE. On 13-Sep-2021, HAEMATEMESIS (Vomiting blood), CARDIAC DISORDER (Heart defect), DYSPNOEA (Breathing difficulties) and MYOCARDITIS (Myocarditis (the patient called it a Heart Disorder)) was resolving, LOSS OF CONSCIOUSNESS (Loss of consciousness) had resolved with sequelae, PULMONARY HAEMORRHAGE (the lungs were filled with blood coming from a heart disorder) outcome was unknown, ACUTE PULMONARY OEDEMA (ACUTE PULMONARY EDEMA) and HOSPITALISATION (Hospitalisation) had resolved. At the time of the report, INFLUENZA LIKE ILLNESS (Had mild influenza-like adverse reactions on the night -9-sep-21.) and COVID-19 IMMUNISATION (REVACCINATION WITH DIFFERENT COVID-19 VACCINE) outcome was unknown.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 11-Sep-2021, Computerised tomogram thorax: abnormal (abnormal) Changes mostly suspect for interstitial alveolar edema, alt. infection less probable..<br>On 11-Sep-2021, Ejection fraction: 40 (Low) Left ventricle ejection fraction just below 40 % on admission to the hospital.<br>On 11-Sep-2021, Oxygen saturation: 50 (Low) The patient's oxygen saturation was 50% when the ambulance personnel arrived..<br>On 12-Sep-2021, Ejection fraction: 40 (Low) Left ventricle ejection fraction just below 40 % on admission to the hospital.<br>On 13-Sep-2021, Ejection fraction: normal (normal) Completely normalized.<br>In September 2021, C-reactive protein: high (High) 4-126.<br>In September 2021, Echocardiogram: abnormal (abnormal) Reduced cardiac function..<br>In September 2021, Troponin T: slightly elevated (Inconclusive) Slightly elevated.<br><br>Concomitant medication was not provided. The night to 09/Sep/2021, the patient developed light flu-like symptoms. The patient reported that if the ambulance had not arrived quickly, he probably would not have survived due to the lungs being filled with blood (pulmonary haemorrhage). Heart disorder which was replaced with myocarditis reported by the physician. It was difficult to know if the patient meant acute pulmonary edema (as reported by the physician) when reporting pulmonary haemorrhage. The physician considers the patient most likely experienced acute pulmonary edema due to myocarditis which was secondary to dose no. 2. Vomiting up blood, the lungs were filled with blood as a result of heart failure. Heart defect, Breathing difficulties. He was admitted to the hospital from 11-Sep-2021 to 13-Sep-2021.The physician reported that the patient was treated with Ceftriaxon for 2 days,No respiratory symptoms beside dyspnea on 11/Sep/2021.<br>Company comment: This case of REVACCINATION WITH DIFFERENT COVID-19 VACCINE concerns a 37 year-old male patient with no relevant medical history reported, who experienced the expected serious |

| Case ID | WW Identifier | Narrative |
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| | | event and AESI of Myocarditis, and the unexpected serious events of HAEMATEMESIS, CARDIAC DISORDER, LOSS OF CONSCIOUSNESS, DYSPNOEA, PULMONARY HAEMORRHAGE, ACUTE PULMONARY OEDEMA and HOSPITALISATION. Diagnostic results reported decreased ejection fraction, increased troponin, and increased C-reactive protein. The patient received Cormirnaty as the first dose of the vaccination schedule on an unknown date and then Spikevax on September 8th. The events occurred 3 days after the dose of Spikevax vaccine. The rechallenge was not applicable, as the event occurred after the third dose and no additional dose is expected to be given. The use of Cormirnaty remains a confounder. The benefit-risk relationship of Spikevax is not affected by this report.<br><br>Contact with healthcare professionals: Other healthcare professional, physician, public health nurse, nurse. The patient reported that if the ambulance had not arrived quickly, he would probably die [sic have died] as a result of the lungs being filled with blood that came from a HEART DISORDER. O2 saturation in his blood was 50% at thearrival of the ambulance personnel.<br>The suspected product was changed from Covid-19 Vaccine Janssen Inj væske to Spikevax due to available information in 4.1(b) [redacted].<br><br>Loss of consciousness, Haematemesis and Pulmonary haemorrhage and Myocarditis are IME.<br>The serious criteria "Disability Or Permanent Damage" was removed because the report does not fulfill the criteria "Disability or Permanent damage" at reporting time.<br><br>The patient reported onset date as 11/Sep/2021 and End date as 13/Sep/2021 for CARDIAC DISORDER, DYSPNEA, VOMITIONG BLOOD and LOSS OF CONSCIOUSNESS. The patient also answered "No" to the reactions being still ongoing.<br>In contrast, the patient reported the outcome for CARDIAC DISORDER, DYSPNEA and VOMITIONG BLOOD as "Recovering/Resolving", and "Recovered/resolved with sequelae" for LOSS OF CONSCIOUSNESS.<br><br>Feedback given to HCP (reporter of duplicate case)<br><br>4.1(b) [redacted] |

| Case ID | WW Identifier | Narrative |
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| | | Most recent FOLLOW-UP info |
| 4.1(b) | 4.1(b) | This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) ) on 29-Sep-2021 and was forwarded to Moderna on 02-Oct-2021.<br>This case, initially reported to the 4.1(b) by a (physician), was received via the 4.1(b) (Ref, 4.1(b)<br><br>On an unknown date, the patient received the 1st dose of this vaccine.<br><br>On an unknown date, body temperature before the vaccination: 36.8 degrees Celsius.<br><br>On 21-Sep-2021, at 10:30, the patient received the 2nd dose of this vaccine.<br><br>On 22-Sep-2021, acute myocarditis developed around noon. The patient was aware of chest pain.<br><br>On 23-Sep-2021, the symptoms did not improve, and chest pain worsened. Blood tests showed CRP positive, CK 1284 U/L, CK-MB 93 U/L, troponin positive, and increased AST and LDH. Electrocardiogram showed no change. Echocardiography showed no myocardial edema. The patient was hospitalized.<br><br>On an unknown date, since the patient's symptoms improved with treatment, and the blood test showed normal, the patient was planned to be discharged from the hospital.<br><br>On 27-Sep-2021, the symptoms were resolving.<br><br>The outcome of acute myocarditis was reported as resolving.<br><br>Follow-up investigation will be made.<br><br>Company Comment:<br>The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. |
| 4.1(b) | 4.1(b) | This case was received via 4.1(b) (Reference number: 4.1(b) ) on 01-Oct-2021 and was forwarded to Moderna on 01-Oct-2021.<br>This regulatory authority case was reported by a pharmacist and describes the occurrence of PALPITATIONS (palpitations), MALAISE (Generally unwell), ELECTROCARDIOGRAM QT PROLONGED (qtc prolonged) and MYOCARDITIS (Myocarditis) in a 37-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for Vaccination.<br><br>The patient's past medical history included Anxiety.<br>Family history included Hypertension (Both parents have hypertension.) since an unknown date.<br><br>On 01-Aug-2021, the patient received first dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. |

| Case ID | WW Identifier | Narrative |
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| | | On 26-Sep-2021, received second dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 27-Sep-2021, after starting mRNA-1273 (Moderna CoviD-19 Vaccine), the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). On an unknown date, the patient experienced PALPITATIONS (palpitations) (seriousness criteria hospitalization and medically significant), MALAISE (Generally unwell) (seriousness criteria hospitalization and medically significant) and ELECTROCARDIOGRAM QT PROLONGED (qtc prolonged) (seriousness criteria hospitalization and medically significant). At the time of the report, PALPITATIONS (palpitations), MALAISE (Generally unwell) and ELECTROCARDIOGRAM QT PROLONGED (qtc prolonged) had resolved and MYOCARDITIS (Myocarditis) had not resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 28-Sep-2021, SARS-CoV-2 test: negative (Negative) No - Negative COVID-19 test.<br><br>The action taken with mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown) was unknown.<br><br>For mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown), the reporter did not provide any causality assessments.<br><br>Patient previously had heavy alcohol during COVID lockdown but none recently and denied any drugs specifically cocaine.<br><br>The patient received 1st dose 8 weeks ago and developed palpitations after and settled after a couple of weeks and had 2nd dose on Sunday developed palpitations and felt generally unwell after. The patient found to have BP greater than 200. The patient was advised to go to Emergency Department. On an unknown date, in morning patient took BP and was still greater than 200, went to Emergency Department. It was Shortness of Breath with palpitation but no acute SOB. The patient had muscle aches.<br><br>Patient stated that he had an abnormal ECHO as a child but that resolved. Patient took paracetamol and ephedrine OTC. Looked well. Pain was then settled. HS normal, Chest clear, JVP not raised, legs not swollen.<br><br>Various Investigations included CRP 22.1, WCC 13.41, neutrophil 11.27, Creatinine 122, Troponin T 19, D-dimer 3.11, LFTs and bone NAD, CK, Mg and TFTs normal, Lact 1.1, ECGs - Variable Ant T inv. Sinus tachycardia. QTc prolonged. The patient diagnosis as had Myocarditis which was possibly secondary to COVID vaccine viral. Patient was given Bisoprolol 2.5mg and Malodipine 5mg then. Cardiology review was done and telemetry EDD 2-3 days.<br><br>Upon internal on 09-Nov-2021, the age and gender of the patient was updated in the company comment.<br><br>Company Comment: |

| Case ID | WW Identifier | Narrative |
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| | | This case concerns a 37-year-old male patient, with medical history of anxiety and family medical history of hypertension, who experienced the unexpected serious events of Palpitations, Malaise, Electrocardiogram QT prolonged and expected serious event myocarditis. Myocarditis occurred 1 day after the 2nd dose of RNAm Moderna vaccine, the rest of The events occurred on an unknown date after the second dose.<br>Relevant lab data: (As per SD) CRP 22.1, WCC 13.41, Creat 122, TropT 19, D-dimer 3.11, CK, Mg and TFTs normal, Lact 1.1. ECGs - Variable Ant T inv. Sinus tachy. QTc prolonged.<br>The rechallenge was N/A (information about other dose was not provided). The medical history medical history of anxiety and family medical history of hypertension remains a confounder. The benefit-risk relationship of Spikevax is not affected by this report.<br>Please note that interval between doses was >35 days (1st dose 1 Aug, 2nd 29 Sept) |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) on 04-Oct-2021 and was forwarded to Moderna on 04-Oct-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myocarditis) and CHEST PAIN (Chest pain as with acute coronary syndrome) in a 34-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 3004959 and 3004218) for COVID-19 immunisation.<br><br>No Medical History information was reported.<br><br>On 12-Jul-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form.<br>On 15-Aug-2021, received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to 1 dosage form. On 16-Aug-2021, after starting mRNA-1273 (Spikevax), the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). On 19-Aug-2021, the patient experienced CHEST PAIN (Chest pain as with acute coronary syndrome) (seriousness criterion hospitalization). At the time of the report, MYOCARDITIS (Myocarditis) had not resolved and CHEST PAIN (Chest pain as with acute coronary syndrome) outcome was unknown.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>In August 2021, Angiogram: normal (normal) No coronary disorders.<br>In August 2021, Blood creatine phosphokinase MB: 25 (abnormal) 25 (elevated) unit not specified.<br>In August 2021, C-reactive protein: 22 (abnormal) 22 unit not specified.<br>In August 2021, Cardiac telemetry: normal (normal) Without arrythmias.<br>In August 2021, Electrocardiogram: normal (normal) Nothing abnormal.<br>In August 2021, Imaging procedure: abnormal (abnormal) Radiological adenopathy.<br>In August 2021, Myoglobin blood: 37 (normal) 37 (Normal) Unit not specified.<br>On 19-Aug-2021, Troponin T: 300 (abnormal) Elevated to >300 unit not specified.<br>On 20-Aug-2021, Troponin T: 494 (abnormal) still increasing to 494 unit not specified. |

| Case ID | WW Identifier | Narrative |
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| | | For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.<br><br>It was reported On ??-AUG-2021, lab test MRI was planned on 23Aug2021.<br>It was reported patient is not known with any diseases.<br>No concomitant medication was reported.<br>Treatment information was not provided by reporter.<br><br>Company Comment:<br>This case concerns a 34-year-old male patient with no relevant medical history, who experienced the expected serious AESI event of Myocarditis and unexpected serious event of Chest pain. The event Myocarditis occurred approximately 2 days after the second dose of Spikevax administration and the event of Chest pain occurred approximately 5 days after the second dose. The rechallenge was not applicable since no events were reported after the first dose and no additional dosing will be given. The benefit-risk relationship is not affected by this report. |
| 4.1(b) | 4.1(b) | This case was initially received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 29-Sep-2021. The most recent information was received on 09-Nov-2021 and was forwarded to Moderna on 17-Nov-2021.<br>This case, initially reported to the 4.1(b) by a (physician), was received via the 4.1(b) (Ref, 4.1(b)<br><br>On 09-Nov-2021, additional information was received by a physician.<br><br>On 30-Aug-2021, the patient received the 1st dose of this vaccine.<br><br>On 15-Sep-2021, the patient received the 2nd dose of this vaccine.<br><br>On 16-Sep-2021, pyrexia was noted.<br><br>On 17-Sep-2021, at 11:00, acute myocarditis developed. Chest pain developed. The patient visited a nearby hospital. Electrocardiogram showed ST elevation, and coronary angiography was performed immediately on the same day. There was no significant coronary artery stenosis, and left ventriculography showed decreased overall wall motion of the left ventricle. Laboratory tests, chest X-ray, and electrocardiography were performed. No new coronavirus was detected. SARS-CoV-2 antigen was less than the detection sensitivity. Chest X-ray showed no abnormalities. Electrocardiography showed ST elevation in 1, 2, aVL, and V5 -6, and negative T in V1 to 2. The patient was diagnosed with acute myocarditis.<br><br>On 18-Sep-2021, the patient was hospitalized with a diagnosis of acute myocarditis.<br><br>The patient was in bed rest with a dehydration.<br><br>On 19-Sep-2021, chest pain improved over time, and it disappeared. CK/CK-MB peak out. |

| Case ID | WW Identifier | Narrative |
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| | | On 24-Sep-2021, there were no abnormalities in echocardiography test. In the echocardiography, EF was 58%, and septum was slightly decreased.<br><br>On 25-Sep-2021, the symptoms were resolving, and the patient was discharged from the hospital.<br><br>On 29-Oct-2021, echocardiography test was performed. EF was 61% and no asynergy was observed.<br><br>The outcome of acute myocarditis was reported as resolving.<br><br>No follow-up investigation will be made.<br><br>Follow-up received on 09-NOV-2021<br><br>Updated: Patient Information, Other Relevant History, Lab Data, Product Information, Narrative, Reporter Comments<br><br>Company Comment:<br><br>The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 04-Oct-2021 and was forwarded to Moderna on 04-Oct-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of PERICARDITIS (4.1(b) in a 21-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 3004959 and 3002616) for Vaccination.<br><br>No Medical History information was reported.<br><br>On 09-Aug-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form.<br>On 08-Sep-2021, received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to 1 dosage form. On 09-Sep-2021, the patient experienced PERICARDITIS (4.1(b) (seriousness criteria hospitalization and medically significant). At the time of the report, PERICARDITIS (4.1(b) was resolving.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 10-Sep-2021, Echocardiogram: normal (normal) No pathological findings..<br>On 10-Sep-2021, Troponin I: 2236 (abnormal) 2236 ng/L (nanogram per litre).<br><br>For mRNA-1273 (Spikevax) (Unknown), the reporter considered PERICARDITIS (4.1(b) to be possibly related.<br><br>Concomitant product use was not provided by the reporter.<br><br>No treatment information was provided. |

| Case ID | WW Identifier | Narrative |
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| | | Company Comment: This case concerns a 21-year-old male patient, with no reported medical history, who experienced the expected event of Pericarditis. The event occurred 1 day after the second dose of mRNA-1273 (Moderna COVID-19 Vaccine). The rechallenge was not applicable as event developed after the second. The event was assessed as related to mRNA-1273 (Moderna COVID-19 Vaccine) by the reporter. The benefit-risk relationship of mRNA-1273 (Moderna COVID-19 Vaccine) was not affected by this report. Event seriousness assessed serious per Regulatory authority as event resulted in hospitalization and is a medical important event. Pericarditis is an adverse event of special interest.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 04-Oct-2021: Translation received on 06-Oct-2021, contains no new information. |
| 4.1(b) | 4.1(b) | This case was initially received via European Medicines Agency (Reference number: 4.1(b) ) on 04-Oct-2021. The most recent information was received on 22-Oct-2021 and was forwarded to Moderna on 22-Oct-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myocarditis) in a 20-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3005835) for COVID-19 vaccination.<br><br>The patient's past medical history included Patent ductus arteriosus repair (operated on at 4 years of age).<br><br>On 07-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 12-Sep-2021, after starting mRNA-1273 (Spikevax), the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Myocarditis) was resolving.<br><br>For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.<br><br>No concomitant medications were provided by the reporter.<br><br>No treatment information was provided by the reporter.<br><br>Company comment: This case concerns a 20-year-old male patient with relevant medical history of Patent ductus arteriosus repair, who experienced the expected serious AESI event of Myocarditis. The event occurred approximately 5 days after the second dose of Spikevax administration. The rechallenge was not applicable since no events reported after the first dose and no additional dosing was expected. The medical history of Patent ductus arteriosus repair considered as confounder. The benefit-risk relationship is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 22-Oct-2021: Follow up report contains added height and weight of the patient, added batch number. |

| Case ID | WW Identifier | Narrative |
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| | | On 22-Oct-2021: Translation received on 26-Oct-2021; medical history comment updated. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 04-Oct-2021 and was forwarded to Moderna on 04-Oct-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myopericarditis) in a 17-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 20-Aug-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form.<br>On 18-Sep-2021, received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. On 21-Sep-2021, the patient experienced MYOCARDITIS (Myopericarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Myopericarditis) was resolving.<br><br>For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.<br><br>No concomitant medication reported.<br><br>No treatment was provided.<br><br>Company comment: This case concerns a 17-year-old, male patient with no relevant medical history, who experienced the expected event of myocarditis. The event myocarditis occurred 3 days after the second dose of mRNA-1273 vaccine administration. The rechallenge was unknown as there's no information available about the first dose. The patient age and gender remains confounders. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. The RA SD contained the same dose number for 2 different dates of vaccine administration. The onset latency was captured as 33 days instead of 3 days and the onset from the last dose was captured as 4 days instead of 3 days. RA SD coding was captured and maintained. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 04-Oct-2021 and was forwarded to Moderna on 04-Oct-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (4.1(b) ) in an 18-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3005835) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 14-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 17-Sep-2021, the patient experienced MYOCARDITIS 4.1(b) ) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (4.1(b) ) had not resolved. |

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| | | For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.<br><br>No relevant concomitant medication information provided. No relevant treatment medication information provided. Action taken with mRNA-1273 (Spikevax) was Not Applicable.<br><br>Company comment:<br>This case concerns a 18 year-old male patient with no reported medical history, who experienced the unexpected serious event of acute myocarditis. The event occurred 4 days after the second dose of mRNA-1273 vaccine. Details of clinical presentation, diagnostic criteria, and clinical course were not provided. Additional information is not expected for this RA case. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 04-Oct-2021: Translation received on 06-Oct-2021 and included suspect vaccine dose number was added as second.<br>On 14-Oct-2021: Follow-up information included no new information. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 04-Oct-2021 and was forwarded to Moderna on 04-Oct-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of CHEST PAIN 4.1(b) .), HEART RATE INCREASED (4.1(b) .), COVID-19 IMMUNISATION 4.1(b) and PERICARDITIS (4.1(b) in a 37-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 3005697) for Vaccination.<br><br>Previously administered products included for Vaccination: Comirnaty. Past adverse reactions to the above products included Adverse event with Comirnaty.<br><br>On 25-Aug-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. In 2021, the patient experienced COVID-19 IMMUNISATION 4.1(b) (seriousness criterion hospitalization). On 28-Aug-2021, the patient experienced CHEST PAIN 4.1(b) .) (seriousness criterion hospitalization) and PERICARDITIS (4.1(b) (seriousness criteria hospitalization and medically significant). On 18-Sep-2021, the patient experienced HEART RATE INCREASED 4.1(b) (seriousness criterion hospitalization). At the time of the report, CHEST PAIN 4.1(b) .), HEART RATE INCREASED (4.1(b) .), |

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| | | COVID-19 IMMUNISATION 4.1(b) and PERICARDITIS (Perikarditt) was resolving.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 31-Aug-2021, Cardiovascular examination: abnormal (abnormal) A 1 cm fluid brake was detected behind the left ventricle. Interpreted as possible pericarditis..<br>On 18-Sep-2021, C-reactive protein: 5 (Inconclusive) 5.<br>On 18-Sep-2021, Cardiovascular examination: abnormal (abnormal) Approx. 1 cm pericardial fluid brake was detected at the right atrium and approx. 0.5 cm at right ventricle..<br>On 18-Sep-2021, Red blood cell sedimentation rate: 26 (slightly elevated) (High) 26 (slightly elevated).<br>On 21-Sep-2021, Echocardiogram: abnormal (abnormal) Unchanged amount of pericardial fluid.<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered CHEST PAIN 4.1(b) ), HEART RATE INCREASED 4.1(b) ) and PERICARDITIS 4.1(b) to be possibly related. No further causality assessment was provided for COVID-19 IMMUNISATION 4.1(b) .).<br><br>No relevant concomitant medications were reported.<br><br>The Patient was examined on 31 AUG 2021 because she had felt episodic pressure on the chest since July, with worsening on 28 AUG 2021.<br><br>No treatment information was provided.<br><br>Company comment: This case concerns a 37-year-old, female patient with no relevant medical history, who experienced, serious unlisted AESI of pericarditis, among other serious events. The event occurred 4 days after the dose of Moderna COVID-19 Vaccine. However, only the second dose was Moderna COVID-19 Vaccine and details of the first dose was not provided. The administration of two different vaccines remains a confounder. The rechallenge was unknown as the event occurred after second vaccine dose. The benefit-risk relationship of Moderna COVID-19 Vaccine is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 04-Oct-2021: Translation received on 06-Oct-2021 included updated event related information and updated narrative |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 04-Oct-2021 and was forwarded to Moderna on 04-Oct-2021. |

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| | | This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (4.1(b) and COVID-19 IMMUNISATION (REVACCINATION WITH DIFFERENT COVID-19 VACCINE) in a 31-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3004224) for Vaccination.<br><br>Previously administered products included for Vaccination: Comirnaty.<br><br>On 25-Aug-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 17-Sep-2021, the patient experienced MYOCARDITIS (4.1(b) (seriousness criteria hospitalization and medically significant) and COVID-19 IMMUNISATION (REVACCINATION WITH DIFFERENT COVID-19 VACCINE) (seriousness criterion hospitalization). At the time of the report, MYOCARDITIS (4.1(b) and COVID-19 IMMUNISATION (REVACCINATION WITH DIFFERENT COVID-19 VACCINE) was resolving.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>In August 2021, Echocardiogram: findings compatible with perimyocarditis findings compatible with perimyocarditis.<br>In August 2021, Magnetic resonance imaging heart: findings compatible with perimyocarditis findings compatible with perimyocarditis.<br>In August 2021, Troponin: maximum at 1582 Maximum at 1582.<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.<br><br>Concomitant product use was not provided by reporter.<br><br>Treatment information was not provided.<br><br>Company comment: This case concerns revaccination with different COVID-19 vaccine in a 31 year-old male patient with no reported medical history, who experienced the expected serious event of perimyocarditis. The event occurred 24 days after the dose of mRNA-1273 vaccine, which followed a previous dose of Comirnaty vaccine. Findings on echocardiogram and cardiac MRI were reported to be consistent with perimyocarditis and maximum troponin value was reported to be 1582. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 04-Oct-2021: Translation document received on 06-Oct-2021 as live follow up included NNI. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 04-Oct-2021 and was forwarded to Moderna on 04-Oct-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of ACUTE PULMONARY OEDEMA (Acute pulmonary edema) and MYOCARDITIS (Myocarditis) in a 37-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3003604) for Vaccination. The occurrence of additional non-serious events is detailed below. |

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| | | Previously administered products included for Vaccination: COMIRNATY. Past adverse reactions to the above products included No adverse reaction with COMIRNATY.<br><br>On 08-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 11-Sep-2021, the patient experienced ACUTE PULMONARY OEDEMA (Acute pulmonary edema) (seriousness criteria hospitalization and medically significant) and MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). On an unknown date, the patient experienced COVID-19 IMMUNISATION (Revaccination with different COVID-19). On 13-Sep-2021, ACUTE PULMONARY OEDEMA (Acute pulmonary edema) and MYOCARDITIS (Myocarditis) had resolved. At the time of the report, COVID-19 IMMUNISATION (Revaccination with different COVID-19) outcome was unknown.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 11-Sep-2021, Computerised tomogram thorax: abnormal (abnormal) Changes mostly suspect for interstitial alveolar edema, alt. infection less probable..<br>On 11-Sep-2021, Ejection fraction: abnormal (abnormal) Left ventricle ejection fraction just below 40 % on admission to hospital and also on 12/Sep/2021.<br>On 13-Sep-2021, Ejection fraction: abnormal (abnormal) Completely normalized.<br>In September 2021, C-reactive protein: 4-126 (abnormal) 4-126.<br>In September 2021, Echocardiogram: abnormal (abnormal) Reduced cardiac function.<br>In September 2021, Troponin T: high (High) Slightly elevated. 118-135-82..<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered ACUTE PULMONARY OEDEMA (Acute pulmonary edema) and MYOCARDITIS (Myocarditis) to be possibly related. No further causality assessment was provided for COVID-19 IMMUNISATION (Revaccination with different COVID-19).<br><br>The reporter considered the patient most likely experienced acute pulmonary edema due to myocarditis which was secondary to the second dose with mRNA Covid-19 vaccine. However, Troponin T was not very high and clinical and echocardiographic recovering was very quick, so the causal relation is uncertain.<br><br>Concomitant product usage were not provided.<br><br>The patient was hospitalized on 12 Sep 2021.<br><br>Treatment details were not provided.<br><br>Company comment |

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| | | This case concerns a 37-year-old, male patient with no relevant medical history, who experienced the unexpected event of Acute pulmonary oedema, Myocarditis and Covid-19 immunisation. The events of Acute pulmonary oedema, Myocarditis occurred 3 days after the second dose of Moderna Covid-19 vaccine. The rechallenge was not applicable, as the event happened only after the second dose. The events were considered related to the product per the reporter's assessment. The benefit-risk relationship of Moderna Covid-19 vaccine is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 04-Oct-2021: Translation received on 06-Oct-2021 included hospitalization details updated in narrative.<br>On 08-Oct-2021: Follow-up contains non-significant information. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 04-Oct-2021 and was forwarded to Moderna on 04-Oct-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (4.1(b) in a 37-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 immunisation.<br><br>No Medical History information was reported.<br><br>On 08-Aug-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 milliliter. On 11-Aug-2021, after starting mRNA-1273 (Spikevax), the patient experienced MYOCARDITIS (4.1(b) (seriousness criteria hospitalization and medically significant). On 14-Aug-2021, MYOCARDITIS (4.1(b) had resolved.<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered MYOCARDITIS (4.1(b) to be probably related.<br><br>No concomitant medications reported by reporter.<br><br>No treatment medications provided by the reporter.<br><br>Company Comment: This case concerns a 37 year-old male patient with no reported medical history, who experienced the expected serious event of Myocarditis. The event occurred 3 days after the second dose of mRNA-1273 vaccine. Details of clinical presentation, diagnostic criteria, and clinical course were not provided. Additional information is not expected for this RA case. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 04-Oct-2021: Translation document received on 06-Oct-2021 and reporter causality was updated. |
| 4.1(b) | 4.1(b) | This case was initially received via European Medicines Agency (Reference number: 4.1(b) ) on 04-Oct-2021. The most recent information was received on 20-Oct-2021 and was forwarded to Moderna on 20-Oct-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Perimyocarditis) in a 23-year-old male |

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| | | patient who received mRNA-1273 (Spikevax) (batch no. 3006273) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 16-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 19-Sep-2021, the patient experienced MYOCARDITIS (Perimyocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Perimyocarditis) was resolving.<br><br>For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.<br><br>No concomitant medications reported by reporter.<br>No treatment medications provided by the reporter.<br><br>Company comment: This case concerns a 23-year-old, male patient with no relevant medical history, who experienced the serious expected event of Myocarditis. The event occurred 3 days after the second dose of Spikevax. The rechallenge was not applicable, as the event happened after the second dose. No lab information was provided to support the diagnosis. The benefit-risk relationship of Spikevax is not affected by this report.<br><br>Follow-up received on 27-OCT-21 included no new information<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 20-Oct-2021: Follow-up document received and product batch number was updated.<br>On 27-Oct-2021: Follow up document received and contains no new information. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 04-Oct-2021 and was forwarded to Moderna on 04-Oct-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of PERICARDITIS (PERICARDITIS) in a 24-year-old male patient who received mRNA-1273 (Spikevax) for Vaccination.<br><br>Previously administered products included for Vaccination: Comirnaty. Past adverse reactions to the above products included Adverse drug reaction with Comirnaty.<br><br>On 20-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 23-Sep-2021, the patient experienced PERICARDITIS (PERICARDITIS) (seriousness criteria hospitalization prolonged and medically significant). At the time of the report, PERICARDITIS (PERICARDITIS) had not resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 23-Sep-2021, C-reactive protein: 22 (High) 22 milligram per litre. |

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| | | On 23-Sep-2021, Electrocardiogram: abnormal (abnormal) Abnormal ECG..<br>On 23-Sep-2021, Troponin T: negative (Negative) Cardiac troponin T negative..<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered PERICARDITIS (PERICARDITIS) to be possibly related.<br><br>No concomitant medications reported.<br>No treatment information was provided.<br><br>Company Comment: This case concerns a 24-year-old, male patient with no relevant medical history, who experienced the expected event of Pericarditis. The event occurred approximately 3 days after the second dose of Moderna vaccine. The rechallenge was unknown as the events occurred only after the second dose. The event was considered related to the product per the reporter's assessment. The event of Pericarditis is consistent with the current understanding of the mechanism of action of the vaccine. The benefit-risk relationship of Moderna Covid-19 vaccine is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 04-Oct-2021: Translation received 07 OCT 2021 contains no new information |
| 4.1(b) | 4.1(b) | This case was received via 4.1(b) (Reference number: 4.1(b) on 05-Oct-2021 and was forwarded to Moderna on 05-Oct-2021.<br>This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCARDITIS (Myocarditis) and PERICARDITIS (Pericarditis) in a 29-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 048F21A) for COVID-19 vaccination.<br><br>Concurrent medical conditions included Penicillin allergy.<br>Concomitant products included BUPROPION HYDROCHLORIDE (WELLBUTRIN) for an unknown indication.<br><br>On 13-Sep-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 15-Sep-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant) and PERICARDITIS (Pericarditis) (seriousness criteria hospitalization and medically significant). The patient was hospitalized on sometime in September 2021 due to MYOCARDITIS and PERICARDITIS. At the time of the report, MYOCARDITIS (Myocarditis) and PERICARDITIS (Pericarditis) had not resolved.<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments.<br><br>Patient's treatment was still ongoing.<br>Patient was on frequent ingestion of anti-inflammation medication. |

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| | | Lab test included Blood work on 16-SEP-2021 and Echocardiogram, Cardiac catheter on 17-SEP-2021, however results were not provided.<br><br>Company comment:<br>This case concerns a 29-year-old, female patient with penicillin allergy, who experienced the unexpected events of myocarditis and pericarditis. The event occurred approximately 3 days after the second dose of Moderna Covid-19 vaccine and resolved after hospitalization. The rechallenge was not applicable, as the event happened after the first dose. The benefit-risk relationship of the vaccine is not affected by this report. |
| 4.1(b) | 4.1(b) | This case was initially received via 4.1(b) (Reference number: 4.1(b) ) on 05-Oct-2021. The most recent information was received on 21-Oct-2021 and was forwarded to Moderna on an unknown date.<br>This regulatory authority case was reported by a physician and describes the occurrence of CHEST PAIN (Chest pain), PAIN IN JAW (Pain in jaw), HEART RATE INCREASED (Heart rate high) and MYOCARDITIS (Acute myocarditis) in a 19-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) (batch no. 3004668) for COVID-19 vaccination and Ill-defined disorder.<br><br>Concurrent medical conditions included Myocarditis.<br><br>On 30-Sep-2021, the patient received second dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) .5 ml. On 03-Oct-2021, after starting mRNA-1273 (Moderna CoviD-19 Vaccine), the patient experienced MYOCARDITIS (Acute myocarditis) (seriousness criteria hospitalization and medically significant). On an unknown date, the patient experienced CHEST PAIN (Chest pain) (seriousness criteria hospitalization and medically significant), PAIN IN JAW (Pain in jaw) (seriousness criteria hospitalization and medically significant) and HEART RATE INCREASED (Heart rate high) (seriousness criteria hospitalization and medically significant). At the time of the report, CHEST PAIN (Chest pain), PAIN IN JAW (Pain in jaw) and HEART RATE INCREASED (Heart rate high) outcome was unknown and MYOCARDITIS (Acute myocarditis) was resolving.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 03-Oct-2021, Troponin: high (High) Trop 1318 rise to 2370, 3 days after second vaccine.<br>On 04-Oct-2021, Magnetic resonance imaging: abnormal (abnormal) Consultant confirmed myocarditis.<br>On 04-Oct-2021, Troponin: 1700 (Low) Slightly decreased to 1700.<br>On an unknown date, Blood pressure measurement: normal (normal) normal.<br>On an unknown date, Echocardiogram: normal (normal) normal.<br>On an unknown date, Electrocardiogram: normal (normal) normal.<br>On an unknown date, Heart rate: inconclusive (Inconclusive) 90s.<br><br>For mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. |

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| | | Concomitant medications was not reported. The patient experienced chest pains and pain in jaw on left side of the body. He went to hospital accident and emergency (a and e) as they suspected a heart attack. The hospital admitted him to the CCU (Coronary care unit) on 03-Oct-2021, placed on unspecified beta blockers 2.5 milligram (mg) to slow heart rate from high 90s, so no more strain was placed on the heart muscle. He had not tested positive for COVID-19 since having the vaccine, and not enrolled in clinical trial.<br><br>Company comment: This case concerns a 19-year-old, male patient with no medical history reported, who experienced the unexpected serious event of chest pain, pain in jaw and heart rate increased with the expected serious adverse event of special interest of myocarditis. The event of myocarditis occurred 3 days after the second dose of Moderna COVID-19 vaccine; start date of the rest of the events, related to myocarditis, is not reported. The rechallenge was not applicable since the events occurred after the second dose. The benefit-risk relationship of Moderna COVID-19 vaccine is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 21-Oct-2021: Upon internal review on 10-NOV-2021, dosage regimen section, case level outcome and narrative updated. |
| 4.1(b) | 4.1(b) | This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (4.1(b) in a 21-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 26-Aug-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 29-Aug-2021, the patient experienced MYOCARDITIS (4.1(b) (seriousness criteria hospitalization prolonged and medically significant). At the time of the report, MYOCARDITIS (4.1(b) outcome was unknown.<br><br>For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.<br><br>No concomitant product use was reporter.<br>No treatment medication was reporter.<br><br>Company comment: This case concerns a 21-year-old, male patient with no relevant medical history, who experienced the expected event of Myocarditis. The event occurred approximately 3 days after the second dose of Moderna vaccine. The rechallenge was not applicable as the event occurred only after the second dose. The event was considered related to the product per the reporter's assessment. The event of Myocarditis is consistent with the current understanding of the mechanism of action of the vaccine. The benefit-risk relationship of Moderna Covid-19 vaccine is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes: |

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| | | On 05-Oct-2021: Translation document received On 07-OCT-2021 and contains updated dosage text. |
| 4.1(b) | 4.1(b) | This case was initially received via European Medicines Agency (Reference number: 4.1(b) ) on 05-Oct-2021. The most recent information was received on 06-Jan-2022 and was forwarded to Moderna on 06-Jan-2022.<br>This regulatory authority case was reported by a physician and describes the occurrence of CHEST DISCOMFORT (Chest pressure), CHEST PAIN (Chest pain), MALAISE (General malaise), VOMITING (Vomiting), ASTHENIA (Weakness) and MYOCARDITIS INFECTIOUS (Myocarditis infectious) in a 15-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 3004954 and 3004954) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 13-Aug-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form.<br>On 13-Sep-2021, received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to 1 dosage form. On 14-Sep-2021, the patient experienced CHEST DISCOMFORT (Chest pressure) (seriousness criteria hospitalization and life threatening), CHEST PAIN (Chest pain) (seriousness criteria hospitalization and life threatening), MALAISE (General malaise) (seriousness criteria hospitalization and life threatening), VOMITING (Vomiting) (seriousness criteria hospitalization and life threatening), ASTHENIA (Weakness) (seriousness criteria hospitalization and life threatening) and MYOCARDITIS INFECTIOUS (Myocarditis infectious) (seriousness criteria hospitalization, medically significant and life threatening). At the time of the report, CHEST DISCOMFORT (Chest pressure), CHEST PAIN (Chest pain), MALAISE (General malaise), VOMITING (Vomiting), ASTHENIA (Weakness) and MYOCARDITIS INFECTIOUS (Myocarditis infectious) was resolving.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>In September 2021, C-reactive protein: 68 (increased) mg/ml (High) 68 (increased) mg/mL.<br>In September 2021, Echocardiogram: abnormal (abnormal) OBS slightly decreased left ventricle function.<br>In September 2021, Ejection fraction: 45 (abnormal) 45 (%percent).<br>In September 2021, Electrocardiogram: abnormal (abnormal) Monstrous ST-elevations.<br>In September 2021, Troponin T: 2289.3 (High) 2289.3 (increased) ng/L.<br>In September 2021, Ultrasound scan: abnormal (abnormal) Myocarditis infectious.<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.<br><br>Concomitant medications was not reported.<br>Treatment information was not reported.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 06-Jan-2022: Follow up received as event and lab data updated. |

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| 4.1(b) | 4.1(b) | This case was received via 4.1(b) (Reference number: 4.1(b) on 05-Oct-2021 and was forwarded to Moderna on 05-Oct-2021.<br>This regulatory authority case was reported by an other health care professional and describes the occurrence of PAIN (Pain) and MYOCARDITIS (Myocarditis) in a 24-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 020f21A and 059e21A) for COVID-19 vaccination.<br><br>The patient's past medical history included Anxiety and Depression. Concomitant products included ESCITALOPRAM OXALATE (LEXAPRO) for an unknown indication.<br><br>On 15-Sep-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form.<br>On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 18-Sep-2021, the patient experienced PAIN (Pain) (seriousness criteria hospitalization and life threatening) and MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization, medically significant and life threatening). The patient was treated with ASA at an unspecified dose and frequency and KETOROLAC TROMETHAMINE (TORADOL) for Pain, at an unspecified dose and frequency. At the time of the report, PAIN (Pain) and MYOCARDITIS (Myocarditis) had resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 18-Sep-2021, Electrocardiogram: abnormal (abnormal) abnormal.<br>On 18-Sep-2021, Troponin: increased (High) increased.<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments.<br><br>On 18 Sep 2021 Laboratory Test Blood creatine phosphokinase MB, C-reactive protein, Echocardiogram , Laboratory test, Red blood cell sedimentation rate were performed and results were not reported.<br><br>Company Comment:<br>This case concerns a 24-year old, male subject with no relevant medical history, who experienced the serious expected event of Myocarditis(AESI) and serious unexpected event of Pain. The events occurred approximately 3 days after the second dose of MODERNA COVID-19 VACCINE. Rechallenge is not applicable as the start date coded for both dose 1 and dose 2 are the same. The benefit-risk relationship of MODERNA COVID-19 VACCINE is not affected by this report. The Regulatory Authority report captured both doses as occurring on same date; this information is retained although there's no mention of this in the case narrative and it is unlikely that this occurred. Date recorded by RA is taken as being of the second dose. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 05-Oct-2021 and was forwarded to Moderna on 05-Oct-2021. |

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| | | This regulatory authority case was reported by a consumer and describes the occurrence of PERICARDITIS (4.1(b) in a 37-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 16-Jul-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 21-Jul-2021, after starting mRNA-1273 (Spikevax), the patient experienced PERICARDITIS (4.1(b) (seriousness criteria hospitalization, disability, medically significant and life threatening). At the time of the report, PERICARDITIS (perikardit) was resolving.<br><br>No concomitant medication was reported by the reporter.<br>No treatment was reported by the reporter.<br><br>Company comment:<br>This case concerns a 37-year-old, female patient with no relevant medical history, who experienced the serious expected event of Pericarditis(AESI). The event occurred 5 days after the second dose of Spikevax. Rechallenge is not applicable as no information about the first dose is available and no additional dose is expected to be given. The benefit-risk relationship of Spikevax is not affected by this report. Event seriousness assessed as per Regulatory Authority reporting; however, there was no information in the source document supporting that the event resulted in a persistent or permanent disability/incapacity.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 05-Oct-2021: Translation received 07-OCT-2021 is significant follow up dosage text updated |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 04-Oct-2021 and was forwarded to Moderna on 04-Oct-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myocarditis) in a 17-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3004669) for Vaccination.<br><br>No Medical History information was reported.<br><br>On 08-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 14-Sep-2021, after starting mRNA-1273 (Spikevax), the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Myocarditis) was resolving.<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. |

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| | | Concomitant product use was not provided by the reporter.<br>Lab data included Magnetic resonance imaging heart on 22-SEP-2021,Troponin I on 15-SEP-2021.<br>It stated that myocarditis was confirmed by cardiac MRI and symptoms occurred about 6 days after administration of second dose of the Covid vaccine.<br>Treatment information was not provided.<br><br>Company Comment: This case concerns a 17-year-old, male patient with no relevant medical history, who experienced the expected event of myocarditis. The event myocarditis occurred 6 days after the second dose of mRNA-1273 administration. The rechallenge was unknown as there's no information available about the first dose. The patient's age and gender remains confounders. The benefit-risk relationship of mRNA-1273 is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 04-Oct-2021: Followup received on 04-oct-2021,contain no new information<br>On 04-Oct-2021: Translation received on 07 Oct 2021 included: Event as reported by primary source has changed, added reporter's comments in inarrative supplement and updated narrative.<br>On 05-Oct-2021: Follow up received contain no new information. |
| 4.1(b) | 4.1(b) | This case was received via 4.1(b) (Reference number: 4.1(b) on 05-Oct-2021 and was forwarded to Moderna on 05-Oct-2021.<br><br>This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCARDITIS (Myocarditis) in a 36-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 027C21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below.<br><br>Concurrent medical conditions included Asthma and Allergy.<br>Concomitant products included BUDESONIDE, FORMOTEROL FUMARATE (SYMBICORT) for an unknown indication.<br><br>On 27-Aug-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 18-Sep-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criterion medically significant) and DYSPNOEA (Dyspnoea/ Shortness of breath). At the time of the report, MYOCARDITIS (Myocarditis) and DYSPNOEA (Dyspnoea/ Shortness of breath) outcome was unknown.<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments.<br><br>No treatment medication use was reported.<br><br>On 31-Aug-2021 (four days after dose two) and on 18-Sep-2021, X-ray and electrocardiogram was performed but results were not available.<br><br>The patient experienced myocarditis and shortness of breath. |

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| | | Company Comment - This case concerns a 36-year-old, male subject with no relevant medical history reported, who experienced the expected event of MYOCARDITIS. The event occurred twenty-two days after the second dose of Spikevax. The rechallenge was not applicable as no additional dose is expected to be given. The event is consistent with the current understanding of the mechanism of action of the study medication. The benefit-risk relationship of Spikevax is not affected by this report. Very limited information regarding the events have been provided at this time. |
| 4.1(b) | 4.1(b) | This case was received via 4.1(b) (Reference number: 4.1(b) on 05-Oct-2021 and was forwarded to Moderna on 05-Oct-2021.<br>This regulatory authority case was reported by an other health care professional and describes the occurrence of CHEST PAIN (Chest pain), DYSPNOEA (Dyspnoea), EXTRASYSTOLES (Extrasystoles), PALPITATIONS (Palpitations), INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (Inappropriate schedule of product administration) and PERICARDITIS (Pericarditis) in a 28-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 24-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form.<br>On 17-Sep-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 17-Sep-2021, the patient experienced INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (Inappropriate schedule of product administration) (seriousness criterion hospitalization). On 21-Sep-2021, the patient experienced CHEST PAIN (Chest pain) (seriousness criterion hospitalization), DYSPNOEA (Dyspnoea) (seriousness criterion hospitalization), EXTRASYSTOLES (Extrasystoles) (seriousness criterion hospitalization), PALPITATIONS (Palpitations) (seriousness criterion hospitalization) and PERICARDITIS (Pericarditis) (seriousness criteria hospitalization and medically significant). On 17-Sep-2021, INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (Inappropriate schedule of product administration) had resolved. At the time of the report, CHEST PAIN (Chest pain), DYSPNOEA (Dyspnoea), EXTRASYSTOLES (Extrasystoles), PALPITATIONS (Palpitations) and PERICARDITIS (Pericarditis) had not resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 21-Sep-2021, C-reactive protein: increased (High) Increased.<br>On 21-Sep-2021, Cardiac monitoring: abnormal (abnormal) abnormal.<br>On 21-Sep-2021, Red blood cell sedimentation rate: increased (High) Increased.<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments.<br><br>No concomitant medications were provided. |

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| | | Treatment medications included NSAIDs for pain.<br><br>The patient experienced significant chest pain and shortness of breath that started 4 days after the vaccine. Additionally, sensation of heart skipping beats and then beating "hard." Pain was better with sitting forward. Determination of acute pericarditis was made by an infectious disease consultant in the hospital. Pain marginally improved with NSAIDs but is still persisting.<br><br>Company comment:<br>This case concerns a 28-year-old, male patient with no relevant medical history, who experienced the unexpected events of Chest pain, Dyspnea, Extrasystoles, Palpitations, and listed event of Pericarditis. The events occurred approximately 4 days after the second dose of Spikevax. It is noted that the C-reactive protein showed increase and cardiac monitoring was abnormal after the 2nd dose was received. The rechallenge was unknown since no event about the first dose was disclosed. The benefit-risk relationship of Spikevax is not affected by this report. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 04-Oct-2021 and was forwarded to Moderna on 04-Oct-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myopericarditis) in a 20-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 3005285 and 3003187) for SARS-CoV-2 vaccination.<br><br>No Medical History information was reported.<br><br>On 27-Jul-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form.<br>On 26-Aug-2021, received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to 1 dosage form. On 28-Aug-2021, after starting mRNA-1273 (Spikevax), the patient experienced MYOCARDITIS (Myopericarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Myopericarditis) was resolving.<br><br>mRNA-1273 (Spikevax) (Intramuscular) was withdrawn on an unknown date.<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.<br><br>Concomitant medications was not provided by the reporter<br>Treatment information was not provided.<br><br>Company Comment:<br>This case concerns a 20-year-old male patient with no reported medical history who experienced the expected event myocarditis. The event occurred 2 days after the second dose of mRNA-1273 mRNA-1273 (Spikevax) The rechallenge was not applicable as the event occurred after the second dose. Causality assessment for the reported events were not provided by the reporter. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Event is confounded by the patient's |

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| | | underlying thyroid disease as they are known to cause changes in heart function. Event seriousness assessed as serious per Regulatory Authority reporting as event require hospitalization and is an important medical event. Event is an adverse event of special interest<br><br>Most recent FOLLOW-UP information incorporated above includes: On 04-Oct-2021: Translation received on 07-OCT-2021, first dose information of suspect product updated. |
| 4.1(b) | 4.1(b) | This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 01-Oct-2021 and was forwarded to Moderna on 06-Oct-2021.<br>This case, initially reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref, 4.1(b)<br><br>On an unknown date, the patient received the 1st dose of this vaccine.<br><br>On an unknown date, body temperature before vaccination: 36.6 degrees Celsius.<br><br>On 23-Aug-2021, at 14:17, the patient received the 2nd dose of this vaccine.<br><br>On 24-Aug-2021, at 01:00, the patient experienced pyrexia and difficulty of breathing and was urgently transported to a hospital. The patient was diagnosed with suspected myocarditis at the hospital where the patient was transported. Afterwards, the patient was spontaneously resolving with follow-up.<br><br>On 26-Aug-2021, recovery of the symptoms was confirmed.<br><br>The outcome of pyrexia, difficulty of breathing, and suspected myocarditis was reported as recovered.<br><br>Follow-up investigation will be made.<br><br>Company Comment:<br><br>The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. |
| 4.1(b) | 4.1(b) | This case was received via 4.1(b) (Reference number: 4.1(b) on 05-Oct-2021 and was forwarded to Moderna on 05-Oct-2021.<br>This regulatory authority case was reported by an other health care professional and describes the occurrence of PERICARDITIS (Pericarditis) in a 33-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 052C2114) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below.<br><br>Previously administered products included for Product used for unknown indication: FLU.<br>Concurrent medical conditions included Systemic lupus erythematosus (lupus), Postural orthostatic tachycardia syndrome (Hyperadrenergic |

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| | | POTS), Hashimoto's disease, Mast cell activation syndrome, Celiac disease, Drug allergy (prednisone) and Penicillin allergy.<br>Concomitant products included HYDROXYCHLOROQUINE SULFATE (PLAQUENIL [HYDROXYCHLOROQUINE SULFATE]), LORATADINE, LEVOTHYROXINE SODIUM (SYNTHROID), CARVEDILOL and 4.1(b) [CROMOGLICIC ACID] for an unknown indication.<br><br>On 03-Sep-2021, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 06-Sep-2021, the patient experienced PERICARDITIS (Pericarditis) (seriousness criterion medically significant), CHEST PAIN (Chest pain/ Crushing chest pain), DECREASED APPETITE (Decreased appetite), DYSPNOEA (Dyspnoea/ SOB), MUSCULOSKELETAL PAIN (Musculoskeletal pain/ Pain started radiating to left shoulder and scapula), PAIN (Pain), SINUS TACHYCARDIA (Sinus tachycardia/ tachycardia/ low voltage sinus tachycardia), STRESS (Stress), NAUSEA (Nausea), FATIGUE (Fatigue), ARTHRALGIA (Arthralgia) and VOMITING (Vomiting/ emesis x 9). At the time of the report, PERICARDITIS (Pericarditis), CHEST PAIN (Chest pain/ Crushing chest pain), DECREASED APPETITE (Decreased appetite), DYSPNOEA (Dyspnoea/ SOB), MUSCULOSKELETAL PAIN (Musculoskeletal pain/ Pain started radiating to left shoulder and scapula), PAIN (Pain), SINUS TACHYCARDIA (Sinus tachycardia/ tachycardia/ low voltage sinus tachycardia), STRESS (Stress), NAUSEA (Nausea), FATIGUE (Fatigue), ARTHRALGIA (Arthralgia) and VOMITING (Vomiting/ emesis x 9) had not resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 06-Sep-2021, C-reactive protein: increased (High) C-reactive protein increased, CRP elevated at 2.3.<br>On 06-Sep-2021, Chest X-ray: normal (normal) Chest X-ray normal.<br>On 06-Sep-2021, Echocardiogram: normal (normal) Echocardiogram normal.<br>On 06-Sep-2021, Electrocardiogram: abnormal (abnormal) Electrocardiogram abnormal.<br>On 06-Sep-2021, Red blood cell sedimentation rate: 12 (High) Red blood cell sedimentation rate increased, ESR 12.<br>On 06-Sep-2021, Troponin: normal (normal) Troponin normal.<br>On 06-Sep-2021, White blood cell count: normal (normal) White blood cell count normal.<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments.<br><br>No treatment medications were provided.<br><br>Day 1: Crushing chest pain and SOB, worse when recumbent and lying on left side. Pain started radiating to left shoulder and scapula. Day 2: pain stayed the same and also had tachycardia. Went to ER. EKG had low voltage sinus tachycardia. CXR, WBC nl. CRP elev at 2.3, ESR 12 - high for the patient. Troponin normal. Told by ER doc, symptoms due to stress. Day 3: chest pain etc continued, but developed severe nausea and emesis x 9. Day 4: wife (MD) called CDC medical consultation team |

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| | | to discuss presumptive diagnosis of myopericarditis. Days5-6: symptoms started to improve slightly but felt very fatigued and appetite was decreased. Day 7: appt with cardiologist did echo which was normal but he concurred with ex of pericarditis.<br><br>Company comment -This case concerns a 33-year-old female patient, with reported medical history of systemic lupus erythematosus (lupus), postural orthostatic tachycardia syndrome (Hyperadrenergic POTS), Hashimoto's disease, mast cell activation syndrome, Celiac disease, drug allergy (prednisone and penicillin) who experienced the expected event of pericarditis. The event occurred 3 days after the third dose of mRNA-1273 (Moderna COVID-19 Vaccine). The rechallenge was unknown as no details about the first or second dose was disclosed. Causality for the reported events were not provided. The event is consistent with the current understanding of the mechanism of action of the vaccine. The benefit-risk relationship of Moderna COVID-19 Vaccine is not affected by this report. Event seriousness assessed as serious per Regulatory authority as event is a medical important event. Pericarditis is an adverse event of special interest. |
| 4.1(b) | 4.1(b) | This case was received via 4.1(b) (Reference number: 4.1(b) on 05-Oct-2021 and was forwarded to Moderna on 05-Oct-2021.<br>This regulatory authority case was reported by an other health care professional and describes the occurrence of DYSPNOEA (Dyspnoea/Feeling short of breath), CHEST PAIN (Chest pain) and MYOCARDITIS (Myocarditis) in a 33-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 002F21A and 053E21A) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 20-Sep-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form.<br>On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 20-Sep-2021, the patient experienced DYSPNOEA (Dyspnoea/Feeling short of breath) (seriousness criteria hospitalization and life threatening), CHEST PAIN (Chest pain) (seriousness criteria hospitalization and life threatening) and MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization, medically significant and life threatening). The patient was treated with ASPIRIN [ACETYLSALICYLIC ACID] for Chest pain, at an unspecified dose and frequency. On 20-Sep-2021, CHEST PAIN (Chest pain) had resolved. At the time of the report, DYSPNOEA (Dyspnoea/Feeling short of breath) and MYOCARDITIS (Myocarditis) outcome was unknown.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 20-Sep-2021, Troponin: increased (High) Troponin on arrival was 1.4 and peaked at 2.4..<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. |

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| | | No concomitant medication was given.<br><br>Laboratory data was mentioned as on 20-Sep-2021 patient took the tests for blood magnesium, blood phosphorus, C-reactive protein, full blood count, lipase, metabolic function test, red blood cell sedimentation rate and SARS-CoV-2 test but the results was not given.<br><br>On 20-Sep-2021 Chest X-ray, Echocardiogram and Electrocardiogram were performed and results were normal.<br><br>Patient had short of breath a few hours later, and chest pain at evening and he was admitted to hospital overnight for myocarditis monitoring.<br><br>Company comment: This case concerns a 33-year-old male patient, with no reported medical history who experienced the unexpected event of dyspnoea, chest pain, and expected event of myocarditis. The events occurred on the same day after the second dose of mRNA-1273 (Moderna COVID-19 Vaccine). The rechallenge was unknown as no details about the first dose was disclosed. Causality for the reported events were not provided. The event pf myocarditis is consistent with the current understanding of the mechanism of action of the vaccine. The benefit-risk relationship of Moderna COVID-19 Vaccine is not affected by this report. Event assessed as serious per Regulatory authority as event required hospitalization. Myocarditis is an adverse event of special interest. |
| 4.1(b) | 4.1(b) | This case was received via 4.1(b) (Reference number: 4.1(b) on 05-Oct-2021 and was forwarded to Moderna on 05-Oct-2021.<br>This regulatory authority case was reported by an other health care professional and describes the occurrence of PERICARDITIS (Pericarditis) in a 31-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 052E21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below.<br><br>No Medical History information was reported.<br><br>On 04-Sep-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 05-Sep-2021, the patient experienced PYREXIA (100 degree fever 24 hours after injection). On 20-Sep-2021, the patient experienced PERICARDITIS (Pericarditis) (seriousness criterion medically significant) and INJECTION SITE PAIN (Injection site pain/ injection site soreness). At the time of the report, PERICARDITIS (Pericarditis), INJECTION SITE PAIN (Injection site pain/ injection site soreness) and PYREXIA (100 degree fever 24 hours after injection) outcome was unknown.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 20-Sep-2021, Body temperature: 100 (Inconclusive) 100 degree fever.<br>On 20-Sep-2021, Electrocardiogram: pericarditis (abnormal) ST greater than.10mV, ant/ lat.<br>On 20-Sep-2021, Heart rate: abnormal (abnormal) abnormal. |

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| | | For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments.<br><br>No relevant concomitant medications were reported.<br>Treatment information was unknown. |
| 4.1(b) | 4.1(b) | This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) ) on 02-Oct-2021 and was forwarded to Moderna on 06-Oct-2021.<br>This case, initially reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref, 4.1(b)<br><br>On an unknown date, the patient received the 1st dose of this vaccine.<br><br>On an unknown date, body temperature before the vaccination: 36.4 degrees Celsius.<br><br>On 28-Sep-2021, at 13:30, the patient received the 2nd dose of this vaccine.<br><br>On 29-Sep-2021, pyrexia of 40 degrees Celsius developed.<br><br>On 01-Oct-2021, at 07:00, the patient was raced to a hospital for chest discomfort. Since an abnormally high level of troponin I of 1,700 was confirmed, the patient was hospitalized on the same day for suspected myocarditis.<br><br>The outcome of pyrexia and suspected myocarditis was unknown.<br><br>Follow-up investigation will be made.<br><br>Company Comment:<br><br>The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. |
| 4.1(b) | 4.1(b) | This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) ) on 02-Oct-2021 and was forwarded to Moderna on 06-Oct-2021.<br>This case, initially reported to the 4.1(b) by a (physician), was received via the 4.1(b) (Ref, 4.1(b)<br>On an unknown date, the patient received the 1st dose of this vaccine.<br><br>On an unknown date, body temperature before vaccination: 36.6 degrees Celsius.<br><br>On 24-Sep-2021, at 17:00, the patient received the 2nd dose of this vaccine.<br><br>On 25-Sep-2021, pyrexia of 38.0-38.9 degrees Celsius developed. |

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| | | On 26-Sep-2021, fever went down to 37 degrees Celsius. At 17:00, myocarditis developed. Chest pain and respiratory discomfort were noted.<br><br>On 27-Sep-2021, the patient's symptoms did not improve, and the patient visited a nearby physician. ECG showed ST-segment elevation in 1, aVL, and V2. The patient was referred to another hospital, and emergency catheterization was performed. The coronary artery was normal. The patient was hospitalized on the same day. There were no abnormalities in blood pressure and SPO2. Blood test showed increased CK and troponin I.<br><br>Around 29-Sep-2021, ST tended to improve on ECG.<br>Around 30-Sep-2021, subjective symptoms improved.<br>On 01-Oct-2021, recovery of symptoms was confirmed. The patient was discharged from the hospital.<br>The outcome of pyrexia and myocarditis was reported as recovered.<br><br>Follow-up investigation will be made.<br>A data correction was performed on 30-NOV-2021. The need for a correction was identified on 25-NOV-2021. As Determined Listedness was updated.<br><br>Company Comment:<br>The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. |
| 4.1(b) | 4.1(b) | This case was received via 4.1(b) (Reference number: 4.1(b) on 05-Oct-2021 and was forwarded to Moderna on 05-Oct-2021.<br>This regulatory authority case was reported by an other health care professional and describes the occurrence of PERICARDITIS (Pericarditis) in a 40-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 053E21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below.<br><br>The patient's past medical history included Eczema.<br>Concurrent medical conditions included Drug hypersensitivity (Sulfa).<br>Concomitant products included DUPILUMAB (DUPIXENT) and LEVONORGESTREL (MIRENA) for an unknown indication.<br><br>On 10-Sep-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 13-Sep-2021, the patient experienced PERICARDITIS (Pericarditis) (seriousness criterion medically significant), DYSPNOEA EXERTIONAL (Dyspnoea exertional) and CHEST PAIN (Chest pain). The patient was treated with IBUPROFEN at an unspecified dose and frequency and COLCHICINE for Pericarditis, at an unspecified dose and frequency. At the time of the report, PERICARDITIS (Pericarditis), DYSPNOEA EXERTIONAL (Dyspnoea exertional) and CHEST PAIN (Chest pain) had resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): |

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| | | On 15-Sep-2021, Blood test: normal (normal) Blood work within normal limits.<br>On 15-Sep-2021, Chest X-ray: normal (normal) Chest X-ray clear.<br>On 15-Sep-2021, Electrocardiogram: abnormal (abnormal) abnormal.<br>On 16-Sep-2021, Fibrin D dimer: normal (normal) Within normal limits.<br>On 16-Sep-2021, Oxygen saturation: decreased (Low) Drop in O2 saturation level.<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments.<br><br>Company comment: This case concerns a 40-year-old, female patient with no relevant medical history, who experienced the serious expected event (AESI) of Pericarditis. The event occurred three days after the second dose of mRNA-1273. The rechallenge was not applicable as no information about the first dose was provided. The benefit-risk relationship of mRNA-1273 is not affected by this report. |
| 4.1(b) | 4.1(b) | This case, initially reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref, 4.1(b)<br><br>On 09-Nov-2021, follow-up information was received from the physician.<br><br>A patient who participated in sports or other intense physical activities. On an unknown date, the patient received the 1st dose of this vaccine.<br><br>On an unknown date, body temperature before the vaccination: 36.3 degrees Celsius.<br><br>On 26-Sep-2021, during the medical interview, the patient complained of a sort of chest discomfort. The patient received the 2nd dose of this vaccine.<br><br>On 27-Sep-201, pyrexia of 39.0-39.9 degrees Celsius developed.<br><br>On 28-Sep-2021, around 10:00, the patient was aware of mild chest pain. Around 18:00, as the chest pain was exacerbated to the level that the patient had never experienced, the patient visited a medical institution with a chief compliant of chest pain. There were findings of acute myocarditis, and the patient was raced to the reporting hospital. BT: 37.5 degrees Celsius, BP: 115/86, and HR: 100 (100-112) with a sinus rhythm.<br><br>Coronary CT: no significant stenosis was shown in the left and right coronary arteries. DE was found in the epicardium of the anterior wall in the middle of the heart.<br><br>Chest X-ray: no findings.<br><br>Electrocardiography: sinus rhythm, 74 bpm, no abnormalities in PQ/QRS/QT intervals, and ST elevation in a wide range of leads. ST elevation in I, aVL and V3-6 and ST depression in III and aVF. |

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| | | Echocardiography: regarding left ventricular wall motion, mid-level hypokinesis limited in the region from the anterior wall to anterior wall septum was found. There was no VHD.<br><br>Coronary CT showed no significant stenosis, and abnormally enhanced image was shown in the epicardium of the anterior wall in the middle of the heart, which were findings consistent with myocarditis.<br><br>On 29-Sep-2021, the patient was hospitalized and received no medications. CT showed delayed image on the side of epicardium of the anterior wall. Pericardial and endomyocardial biopsy was performed, and inflammatory cell infiltrate was detected on the endocardium.<br><br>On 30-Sep-2021, cardiac enzymes returned to normal levels, and chest pain also disappeared.<br><br>On 01-Oct-2021, the patient was discharged from the hospital.<br><br>On 12-Oct-2021, MRI was performed and showed delayed image on the side of epicardium of the anterior wall.<br><br>On 02-Nov-2021, myocarditis disappeared without treatments. The patient was recovering from the events.<br><br>The outcome of acute myocarditis was reported as resolving.<br><br>No follow-up investigation will be made.<br><br>Follow-up received on 09-NOV-2021<br><br>Updated: Patient Information, Other Relevant History, Lab Data, Event Information, Narrative<br><br>Company Comment:<br>The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. |
| 4.1(b) | 4.1(b) | This case was received via 4.1(b) (Reference number: 4.1(b) on 05-Oct-2021 and was forwarded to Moderna on 05-Oct-2021.<br>This regulatory authority case was reported by an other health care professional and describes the occurrence of ACUTE MYOCARDIAL INFARCTION (Acute myocardial infarction), MYOCARDIAL INFARCTION (Myocardial infarction), CHEST PAIN (Chest pain), DYSPNOEA (Dyspnoea), TROPONIN INCREASED (Troponin increased) and MYOCARDITIS (Myocarditis) in a 25-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination.<br><br>Concurrent medical conditions included Allergy to vaccine (Pertussis Toxoid).<br><br>On 17-Sep-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 17-Sep-2021, the patient experienced ACUTE MYOCARDIAL INFARCTION (Acute myocardial infarction) (seriousness criteria hospitalization and |

| Case ID | WW Identifier | Narrative |
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| | | medically significant) and MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). 17-Sep-2021, the patient experienced MYOCARDIAL INFARCTION (Myocardial infarction) (seriousness criteria hospitalization and medically significant), CHEST PAIN (Chest pain) (seriousness criterion hospitalization), DYSPNOEA (Dyspnoea) (seriousness criterion hospitalization) and TROPONIN INCREASED (Troponin increased) (seriousness criterion hospitalization). The patient was hospitalized on 19-Jul-2021 due to TROPONIN INCREASED, then on 19-Sep-2021 due to ACUTE MYOCARDIAL INFARCTION, CHEST PAIN, DYSPNOEA, MYOCARDIAL INFARCTION and MYOCARDITIS. At the time of the report, ACUTE MYOCARDIAL INFARCTION (Acute myocardial infarction), MYOCARDIAL INFARCTION (Myocardial infarction), CHEST PAIN (Chest pain), DYSPNOEA (Dyspnoea), TROPONIN INCREASED (Troponin increased) and MYOCARDITIS (Myocarditis) had not resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 19-Sep-2021, Electrocardiogram: st elevation (abnormal) ST elevation consider inferolateral injury or acute infarct.<br>On 19-Sep-2021, Troponin: 869 (High) 869.<br>On 20-Sep-2021, Catheterisation cardiac: acute st-elevation mi (abnormal) Acute ST-elevation myocardial infarction (MI). This appears to be related to myocarditis..<br>On 20-Sep-2021, Troponin: 1799 (High) 1799.<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments.<br><br>Concomitant product use was not provided by the reporter.<br><br>No treatment information was provided.<br><br>Patient reported worsening chest pain (8 out of 10) and shortness of breath.<br><br>On 17 Sep 2021, echocardiogram and magnetic resonance imaging heart was performed (results were pending).<br><br>Company comment: This case concerns a 25-year-old, male patient with no previous relevant medical history reported, who experienced the unexpected events of acute myocardial infarction, myocardial infarction, chest pain, dyspnoea, myocarditis and troponin increased. The events occurred the same day after the second dose of mRNA-1273. The rechallenge was not applicable since the events happened after the second dose. The benefit-risk relationship of mRNA-1273 is not affected by this report. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) on 05-Oct-2021 and was forwarded to Moderna on 05-Oct-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of PERICARDITIS (Pericarditis) and COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine) in a 21- |

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| | | year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3003604) for Vaccination.<br><br>Previously administered products included for Product used for unknown indication: Comirnaty.<br>Past adverse reactions to the above products included No adverse event with Comirnaty.<br><br>On 02-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 02-Sep-2021, the patient experienced PERICARDITIS (Pericarditis) (seriousness criteria hospitalization and medically significant) and COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine) (seriousness criterion hospitalization). At the time of the report, PERICARDITIS (Pericarditis) and COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine) outcome was unknown.<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered PERICARDITIS (Pericarditis) and COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine) to be possibly related.<br><br>No concomitant medications were reported<br>No treatment medications were reported.<br><br>Company Comment : This case concerns a 21-year-old, male patient with no relevant medical history, who experienced, listed AESI/ serious event of pericarditis and other serious unlisted event of revaccination with different Covid-19 vaccine. The event occurred same day after the second dose of Moderna COVID-19 Vaccine. The Serious criteria for the event "revaccination with different Covid-19" was assessed as per Regulatory Authority reporting, however there was no information in the source document supporting that the events were serious/IME. However, only the second dose was Moderna COVID-19 Vaccine and details of the first dose was not provided. The administration of two different vaccines remains a confounder. The rechallenge was unknown as the event occurred after second vaccine dose. The benefit-risk relationship of Moderna COVID-19 Vaccine is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 05-Oct-2021: Translation document received on 08-Oct-2021 include translated sender's Comment and pharmaceutical form (Dosage form) |
| 4.1(b) | 4.1(b) | This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 23-Sep-2021 and was forwarded to Moderna on 07-Oct-2021.<br><br>This case, initially reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref, 4.1(b)<br><br>On 14-Aug-2021, the patient received the 1st dose of this vaccine. There was no remarkable change at the vaccination. |

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| | | On 11-Sep-2021, at 19:40, the patient received the 2nd dose of this vaccine. Pyrexia of 38 to 39 degrees Celsius developed.<br><br>On 14-Sep-2021, at 00:00, chest pain developed. The patient visited an emergency outpatient department of another hospital and was instructed to take acetaminophen orally. The symptoms did not improve thereafter. In the morning, the patient visited the reporting hospital. The extensive ST elevation was found in the electrocardiogram. Blood test showed increased values of CRP 5.35 mg/dL, CPK 1,491 U/L, CKMB 60.2 ng/mL, and high-sensitivity troponin I 23,102 pg/mL. Echocardiography showed no abnormal findings. The patient was admitted on the same day with a diagnosis of acute perimyocarditis. The patient received anti-inflammatory and analgesic medications and was monitored.<br><br>On an unknown date, chest pain and laboratory findings improved smoothly.<br><br>On 22-Sep-2021, the remission of the symptoms was confirmed. The patient was discharged from the hospital.<br><br>The outcome of acute perimyocarditis was reported as resolving.<br><br>Follow-up investigation will be made.<br><br>Company Comment:<br>The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) on 06-Oct-2021 and was forwarded to Moderna on 06-Oct-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of HYPERHIDROSIS (Sweating attack), DIZZINESS (Light headedness), PALPITATIONS (Heart racing), CHEST DISCOMFORT (Pressure chest) and MYOCARDITIS (Myocarditis) in a 27-year-old male patient who received mRNA-1273 (Spikevax) for Prophylactic vaccination.<br><br>Previously administered products included for COVID-19 vaccination: COVID-19 Vaccine Moderna (COVID-19 Vaccine Moderna dispersion for injectionCOVID-19 mRNA Vaccine (nucleoside modified)SpykeVax) in June 2021.<br>Past adverse reactions to the above products included No adverse reaction with COVID-19 Vaccine Moderna.<br><br>In June 2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form.<br>On 01-Jul-2021, received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. On 05-Jul-2021, the patient experienced HYPERHIDROSIS (Sweating attack) (seriousness criterion medically significant), DIZZINESS (Light headedness) (seriousness criterion medically significant), PALPITATIONS (Heart racing) (seriousness criterion medically significant), CHEST DISCOMFORT (Pressure chest) (seriousness criterion medically significant) and MYOCARDITIS (Myocarditis) (seriousness criterion medically significant). At the time of the report, |

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| | | HYPERHIDROSIS (Sweating attack), DIZZINESS (Light headedness), PALPITATIONS (Heart racing), CHEST DISCOMFORT (Pressure chest) and MYOCARDITIS (Myocarditis) had resolved.<br><br>For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.<br><br>Concomitant medications details were not reported by the reporter. Treatment details was not reported by the reporter.<br><br>Company Comment: This case concerns a 27-year-old male patient with no relevant medical history, who experienced the unexpected, serious (medically significant) events of myocarditis, hyperhidrosis, dizziness, palpitations and chest discomfort. The events occurred approximately 1 month after the first dose of mRNA-1273 and 4 days after the second dose of mRNA-1273. At the time of the event onset, myocarditis was considered an unexpected event. The rechallenge was not applicable. The benefit-risk relationship of mRNA-1273 is not affected by this report. |
| 4.1(b) | 4.1(b) | This case was received via 4.1(b) (Reference number: 4.1(b) on 06-Oct-2021 and was forwarded to Moderna on 06-Oct-2021.<br>This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDIAL INFARCTION (heart attack), ELECTROCARDIOGRAM NORMAL (ECG normal) and MYOCARDITIS (Myocarditis) in a 19-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) (batch no. 3004668) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 30-Sep-2021, the patient received second dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 03-Oct-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). On an unknown date, the patient experienced MYOCARDIAL INFARCTION (heart attack) (seriousness criteria hospitalization and medically significant) and ELECTROCARDIOGRAM NORMAL (ECG normal) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDIAL INFARCTION (heart attack) and ELECTROCARDIOGRAM NORMAL (ECG normal) had resolved and MYOCARDITIS (Myocarditis) was resolving.<br><br>The action taken with mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown) was unknown.<br><br>No concomitant medication was provided by reporter.<br><br>Patient experienced chest pain and pain in jaw on left side of the body. Doctor advised to go to hospital as doctor suspected a heart attack. Patient was admitted to coronary care unit on 03-Oct-2021. The ECG, |

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| | | echocardiogram and blood pressure was normal; Troponin was 1318 which then increased to more than 2000. Patient was placed on beta blockers 2.5mg to slow heart rate from high 90 so no more strain was placed on the heart muscle. Troponin level on 04-Oct-2021 was 1700. The MRI on 04-Oct-2021, the myocarditis was confirmed.<br><br>No treatment drug was provided by reporter.<br><br>Company Comment: This case concerns a 19-year-old, male patient with no relevant medical history, who experienced the unexpected events of Myocardial infarction, Electrocardiogram normal and the expected event of Myocarditis. The event of Myocarditis occurred approximately 3 days after the second dose of Moderna vaccine. The rechallenge was unknown as no information was provided about the first dose. The events were considered related to the product per the reporter's assessment. The event of Myocarditis is consistent with the current understanding of the mechanism of action of the vaccine. The benefit-risk relationship of Moderna Covid-19 vaccine is not affected by this report. |
| 4.1(b) | 4.1(b) | This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 04-Oct-2021 and was forwarded to Moderna on 07-Oct-2021.<br><br>This case, initially reported to the 4.1(b) by a (physician), was received via the 4.1(b) (Ref, 4.1(b)<br><br>On 25-Aug-2021, the patient received the 1st dose of this vaccine. After the vaccination, there was no problem.<br><br>On 22-Sep-2021, in the morning, the patient received the 2nd dose of this vaccine.<br><br>On 25-Sep-2021, at 03:15, chest pain developed on admission, and troponin, CKMB, and CRP were increased. The patient was diagnosed with myocarditis based on the clinical course.<br><br>On 26-Sep-2021, electrocardiogram showed negative T wave. Cardiac function was normal by echocardiography.<br><br>On 01-Oct-2021, after oral administration of loxoprofen sodium hydrate and colchicine, inflammation and cardiac enzymes decreased to within the normal range. The patient was discharged from the hospital.<br><br>On 02-Oct-2021, the symptoms were resolving.<br><br>The outcome of myocarditis was reported as resolving.<br><br>Follow-up investigation will be made.<br><br>Company Comment:<br>The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. |
| 4.1(b) | 4.1(b) | This case was initially received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 01-Oct-2021. The most recent information |

| Case ID | WW Identifier | Narrative |
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| | | was received on 06-Oct-2021 and was forwarded to Moderna on 19-Oct-2021.<br>This case, reported by a pharmacist, was received by Takeda via Moderna's adverse reaction reporting site (4.1(b) and reported to the 4.1(b) by a pharmacist, was received via the 4.1(b) (Ref, 4.1(b)<br><br>On 06-Oct-2021, follow-up information, initially reported by a pharmacist, was received by Takeda via Moderna's adverse reaction reporting site 4.1(b)<br><br>On 07-Oct-2021, follow-up information, initially reported to the 4.1(b) by a pharmacist, was received via the 4.1(b) (Ref, 4.1(b)<br><br>On 31-Aug-2021, the patient received the 1st dose of this vaccine.<br><br>On 28-Sep-2021, the patient received the 2nd dose of this vaccine.<br><br>On 30-Sep-2021, severe chest pain developed. It was considered that acute myocarditis developed.<br><br>On 01-Oct-2021, the patient visited a medical institution. Electrocardiogram showed extensive ST elevation, and echocardiography showed decreased wall hypokinesia. CK: 698, CK-MB: 52, TnT: 0.818, NT-proBNP: 148, which increased.<br><br>Myocarditis after the vaccination with this vaccine was suspected. The patient was hospitalized in the reporting hospital.<br><br>On an unknown date, after the hospitalization, follow-up was performed, and CK and NT-proBNP levels returned to normal.<br><br>On 04-Oct-2021, the recovery was confirmed, and the patient was discharged from the hospital.<br><br>The outcome of acute myocarditis was reported as recovered.<br><br>No follow-up investigation will be made.<br><br>Follow-up received on 06-OCT-2021<br><br>Updated: Lab Data, Product Information, Event Information, Narrative<br><br>Company Comment:<br><br>The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 06-Oct-2021 and was forwarded to Moderna on 06-Oct-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of PERICARDITIS (SUSPICION OF DRY PERICARDITIS) in a 30-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. |

| Case ID | WW Identifier | Narrative |
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| | | No Medical History information was reported.<br><br>On 19-Aug-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 01-Sep-2021, the patient experienced PERICARDITIS (SUSPICION OF DRY PERICARDITIS) (seriousness criterion medically significant). At the time of the report, PERICARDITIS (SUSPICION OF DRY PERICARDITIS) outcome was unknown.<br><br>For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.<br><br>As per source document event as reported by primary source was SUSPICION OF DRY PERICARDITIS.<br>No concomitant medication was reported.<br>No treatment medication was reported.<br><br>Company Comment:<br>This case concerns a 30-year-old, female patient with no medical history reported, who experienced the expected event of pericarditis. The event occurred approximately 13 days after the second dose of Moderna COVID-19 Vaccine. As reported per source document there was a suspicion of dry pericarditis. The rechallenge was not applicable as events occurred after second dose and no further dosing was reported or planned, based on information provided. The benefit-risk relationship of Moderna COVID-19 Vaccine is not affected by this report. Event seriousness assessed as per Regulatory Authority reporting.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 06-Oct-2021: Translation document received on 08-OCT-2021, contains updated event term reported by primary source. |
| 4.1(b) | 4.1(b) | This case was received via 4.1(b) (Reference number: 4.1(b) on 05-Oct-2021 and was forwarded to Moderna on 05-Oct-2021.<br>This regulatory authority case was reported by an other health care professional and describes the occurrence of PERICARDITIS (Pericarditis) in a 35-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below.<br><br>No Medical history was provided.<br>Concomitant products included MULTIVITAMINS [VITAMINS NOS] for an unknown indication.<br><br>On 17-Mar-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 06-Jul-2021, the patient experienced PERICARDITIS (Pericarditis) (seriousness criterion medically significant), ANXIETY (Anxiety), CHEST PAIN (Chest pain), IMPAIRED WORK ABILITY (Impaired work ability) and LOSS OF PERSONAL INDEPENDENCE IN DAILY ACTIVITIES (Loss of personal independence in daily activities). 06-Jul-2021, the patient experienced |

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| | | FRUSTRATION TOLERANCE DECREASED (Frustration tolerance decreased). At the time of the report, PERICARDITIS (Pericarditis), ANXIETY (Anxiety), CHEST PAIN (Chest pain), IMPAIRED WORK ABILITY (Impaired work ability), LOSS OF PERSONAL INDEPENDENCE IN DAILY ACTIVITIES (Loss of personal independence in daily activities) and FRUSTRATION TOLERANCE DECREASED (Frustration tolerance decreased) had not resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 06-Jul-2021, Heart rate: high (High) Heart rate increased.<br>On 06-Jul-2021, Troponin: high (High) Troponin increased.<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments.<br><br>Patient have been went to the ER visits in the dates of 7-8-2021, and 8-13-2021,7-22-2021, 7-25-2021, and 8-22-2021,9-14-2021.<br>The other lab data includes Echocardiogram, holter monitor, event monitor and stress test on 06-JULY- 2021 in which results were not provided.<br>Patient know that she has to take betablocker for her heart rate and undergone GI evaluation and result was negative.<br><br>Company Comment : This case concerns a 35 year-old, female patient with no relevant medical history, who experienced the serious expected adverse event of special interest of Pericarditis. The event occurred approximately 3 months and 20 days after the second dose of Moderna COVID-19 vaccine. The rechallenge was not applicable, as the event was reported exclusively after the second dose. The benefit-risk relationship of Moderna COVID-19 vaccine is not affected by this report. |
| 4.1(b) | 4.1(b) | This case was initially received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 04-Oct-2021. The most recent information was received on 09-Nov-2021 and was forwarded to Moderna on 17-Nov-2021.<br>This case, initially reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref 4.1(b)<br><br>On 09-Nov-2021, follow-up information was received from a physician.<br><br>On an unknown date, the patient received the 1st dose of this vaccine.<br><br>On 20-Sep-2021, around 19:00, the patient received the 2nd dose of this vaccine.<br><br>On 21-Sep-2021, pyrexia of 38.0 degrees Celsius developed and persisted for two days.<br><br>On 22-Sep-2021, at 19:00, as chest pain developed and did not disappear with oral administration of loxoprofen sodium hydrate with slightly improvement, the patient visited the reporting hospital. ST elevation on ECG and increase of in TnT, CK, and CKMB were observed |

| Case ID | WW Identifier | Narrative |
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| | | on blood test. The patient was hospitalized with a diagnosis of acute epicarditis and myocarditis. CK/CKMB was 367/35 at the peak.<br><br>On 23-Sep-2021, oral administration of aspirin 3 g/day at 3 × 1 was started. Chest pain disappeared, and ST tended to decrease.<br><br>On 25-Sep-2021, T wave was negative, and electrocardiogram normalized. Acute pericarditis and myocarditis disappeared.<br><br>On 27-Sep-2021, echocardiography was performed. The results were normal.<br><br>On 28-Sep-2021, MRI scan was performed. Mottled late gadolinium enhancement in the mid-left ventricular wall, suggestive of myocarditis.<br><br>On 29-Sep-2021, the patient recovered from the symptoms and was discharged from the hospital.<br><br>On 30-Sep-2021, administration of aspirin 3 g/day 3 × 1 was completed.<br><br>The outcome of acute epicarditis, and myocarditis was reported as recovered.<br><br>No follow-up investigation will be made.<br><br>Reporter comments continuation:<br><br>Since myocardial enzyme elevation, ST elevation on ECG, and findings of myocarditis on MRI are present, and definitive diagnoses of pericarditis and myocarditis are made. Since the events developed on the 2nd day after vaccination, the occurrence of adverse events is temporally related to the timing of administration of this vaccine.<br><br>Follow-up received on 09-NOV-2021<br><br>Updated: Patient Information, Other Relevant History, Lab Data, Event Information, Narrative, Reporter Comments<br><br>Company Comment:<br><br>The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 07-Oct-2021 and was forwarded to Moderna on 07-Oct-2021.<br>This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (Retrosternal pain / chest pain) in a 27-year-old male patient who received mRNA-1273 (Spikevax) for Prophylactic vaccination.<br><br>The patient's past medical history included Cholecystectomy.<br>Concurrent medical conditions included Drug allergy (Mivacurium allergy).<br><br>On 16-Jun-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. |

| Case ID | WW Identifier | Narrative |
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| | | On 30-Jul-2021, received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. On 20-Aug-2021, after starting mRNA-1273 (Spikevax), the patient experienced MYOCARDITIS (Retrosternal pain / chest pain) (seriousness criteria hospitalization and medically significant). The patient was hospitalized from 20-Aug-2021 to 24-Aug-2021 due to MYOCARDITIS. At the time of the report, MYOCARDITIS (Retrosternal pain / chest pain) was resolving.<br><br>No relevant concomitant medications were reported.<br><br>Patient was discharged with pain medication. Patient had consulted with the primary care physician due to chest pain/ heart palpitations. Physician determined patient had positive troponin levels in evening. In hospital patient had MRI which diagnosed Myocarditis. Patient was hospitalized on 20-AUG-2021. Patient was discharged on 24-AUG-2021 with subjective well-being.<br><br>Company comment: This case concerns a 27 year old male with no relevant history who experienced the serious, expected event of Myocarditis 24 days after the second dose of Spikevax. Re-challenge is unknown for dose 1 as no information is reported and not applicable for dose 2 as no further dosing is expected. Benefit-risk relationship of Spikevax is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 07-Oct-2021: Translation received on 12-OCT-2021 contains: Event Verbatim Updated and Sender's comment which contains information about allergy, pre-existing condition, treatment medication and event information updated in narrative. |
| 4.1(b) [redacted] | 4.1(b) [redacted] | This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 07-Oct-2021 and was forwarded to Moderna on 07-Oct-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of PERICARDITIS (Acute pericarditis) in a 29-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3004498) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below.<br><br>Previously administered products included for Vaccination: Comirnaty. Past adverse reactions to the above products included No adverse event with Comirnaty.<br><br>On 25-Aug-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 23-Sep-2021, the patient experienced PERICARDITIS (Acute pericarditis) (seriousness criteria hospitalization and medically significant). On an unknown date, the patient experienced COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine). At the time of the report, PERICARDITIS (Acute pericarditis) was resolving and COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine) had resolved. |

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| | | DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>In September 2021, Echocardiogram: abnormal (abnormal) showed pericardial effusion.<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.<br><br>Concomitant product use was not provided by the reporter.<br>Treatment medication was not provided by the reporter.<br><br>Company comment<br>This case concerns a 29-year-old male patient with no relevant medical history, who experienced the expected serious AESI event of Pericarditis. The event occurred approximately 30 days after the second dose of Spikevax administration. The rechallenge was not applicable since no information available on the first dose and no additional dosing was expected. The benefit-risk relationship is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 07-Oct-2021: Translation received 08-OCT-2021 contains no new information. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) on 07-Oct-2021 and was forwarded to Moderna on 07-Oct-2021.<br>This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (Myocarditis) in a 22-year-old male patient who received mRNA-1273 (Spikevax) for Prophylactic vaccination.<br><br>No Medical History information was reported.<br><br>On 12-Aug-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form.<br>On an unknown date, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 15-Aug-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization prolonged and medically significant). At the time of the report, MYOCARDITIS (Myocarditis) was resolving.<br><br>Concomitant product use was not provided by the reporter.<br><br>Had inpatient treatment in hospital for myocarditis.<br><br>No treatment information was provided.<br><br>Company comment-<br>This case concerns a 22-year-old male patient with no relevant medical history, who experienced the expected serious event of Myocarditis. The event occurred approximately 04 days after the second dose of Spikevax. The patient had inpatient treatment in hospital for myocarditis. The rechallenge was unknown as there's no information available about the |

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| | | first dose. The event is consistent with the current understanding of the mechanism of action of the vaccine. The benefit-risk relationship of Spikevax is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 07-Oct-2021: Translation document received on 11-Oct-2021 and narrative was updated. |
| 4.1(b) | 4.1(b) | This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 01-Oct-2021 and was forwarded to Moderna on 08-Oct-2021.<br>This case was reported by a physician via a medical representative.<br><br>Myocarditis was assessed as serious by the MAH.<br><br>On an unknown date, the patient received the 1st dose of the vaccine.<br><br>On 28-Sep-2021, the patient received the 2nd dose of the vaccine.<br><br>On 30-Sep-2021, myocarditis developed. In the morning, chest pain was noted when the patient was examined at the reporting hospital, and examinations were performed. Elevations in CPK and ST were observed.<br><br>The outcome of myocarditis was unknown.<br><br>Follow-up investigation will be made.<br><br>Company Comment:<br><br>The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. |
| 4.1(b) | 4.1(b) | This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) ) on 04-Oct-2021 and was forwarded to Moderna on 08-Oct-2021.<br>This case, reported by a pharmacist, was received by Takeda via Moderna's adverse reaction reporting site (4.1(b) and reported to the 4.1(b) ) by a pharmacist, was received via the 4.1(b) (Ref, 4.1(b)<br><br>On 02-Sep-2021, the patient received the 1st dose of this vaccine.<br><br>On 30-Sep-2021, at 10:00, the patient received the 2nd dose of this vaccine.<br><br>On 01-Oct-2021, the patient was aware of chest pain and breathlessness.<br><br>On 03-Oct-2021, at 11:09, the patient visited a nearby physician. Electrocardiogram showed ST elevation. The patient was referred to the reporting hospital. Blood test showed increased troponin, and echocardiography showed decreased lower wall motion. The patient was admitted to the hospital with a diagnosis of acute myocarditis.<br><br>On 04-Oct-2021, the symptoms were ongoing.<br><br>The outcome of acute myocarditis was reported as ongoing and unchanged. |

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| | | Follow-up investigation will be made.<br><br>Company Comment:<br><br>The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 07-Oct-2021 and was forwarded to Moderna on 07-Oct-2021.<br>This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (Myocarditis) in a 19-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 3004233 and 214007) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below.<br><br>No Medical History information was reported.<br><br>On 23-Jul-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form.<br>On 20-Aug-2021, received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. On 22-Aug-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criterion medically significant), TACHYCARDIA (Tachycardia) and CHEST DISCOMFORT (Complaints of retrosternal pressure). On 26-Aug-2021, MYOCARDITIS (Myocarditis), TACHYCARDIA (Tachycardia) and CHEST DISCOMFORT (Complaints of retrosternal pressure) had resolved.<br><br>Treatment information was not provided.<br><br>3 days after the second vaccination, Patient developed complaints of retrosternal pressure, tachycardia (206/min).<br><br>The laboratory data's were reported as creatine kinase, Creatine kinase-MB, C-reactive protein, with unknown results and troponin TR showed elevation and result of D-dimer was reported as neg. After three days the c-reactive protein level showed elevation. . Fast progression, inconspicuous heart echo were also reported.<br><br>Company Comment:<br>This case concerns a 19 year old male with no medical history who experienced the serious listed event of Myocarditis 2 days after the second dose of Spikevax. Re-challenge is unknown for dose 1 as no information is reported and not applicable for dose 2 as no further dosing is expected. Benefit-risk relationship of Spikevax is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 07-Oct-2021: Translation received on 11-OCT-2021 contain significant information that include event verbatim updated and I narrative updated. |

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| 4.1(b) | 4.1(b) | This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) ) on 05-Oct-2021 and was forwarded to Moderna on 09-Oct-2021.<br>This case, reported by a physician, was received by Takeda via Moderna's adverse reaction reporting site 4.1(b) and reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref, 4.1(b)<br><br>On 08-Sep-2021, the patient received the 1st dose of this vaccine.<br><br>On 29-Sep-2021, at 18:00, the patient received the 2nd dose of this vaccine. Vomiting developed 3 times.<br><br>On 30-Sep-2021, at 00:00, pyrexia of 38.0-38.9 degrees Celsius and chest discomfort developed. The patient experienced increased malaise and difficulty in moving, and an emergency call was made. At the time of transport, the patient had pyrexia of 37.9 degrees Celsius and slightly increased CRP of 2.82. There was no increase in troponin I, but there was ST elevation in V4-6 of electrocardiogram. PCR for coronavirus was negative.<br><br>On 01-Oct-2021, pericarditis and myocarditis developed. The patient was hospitalized for pericarditis after the vaccination.<br><br>On 05-Oct-2021, recovery was confirmed.<br><br>The outcome of vomiting, pyrexia, malaise, pericarditis, and myocarditis was reported as resolved.<br><br>Follow-up investigation will be made.<br><br>Company Comment:<br><br>The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 08-Oct-2021 and was forwarded to Moderna on 08-Oct-2021.<br>This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (Myocarditis) in a 32-year-old male patient who received mRNA-1273 (Spikevax) for Prophylactic vaccination.<br><br>Previously administered products included for Prophylactic vaccination: COVID-19 Vaccine Moderna dispersion for injection COVID-19 mRNA Vaccine (nucleoside modified)SpykeVax.<br><br>On 21-Aug-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form.<br>On an unknown date, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 24-Aug-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Myocarditis) had not resolved. |

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| | | No concomitant medications were reported. Treatment information included use of beta blockers and antihypertensive for cardiac relief.<br><br>The patient had no allergies, and none risk factor or preexisting conditions.<br><br>The patient experienced heart problem or chest pain on 23 Aug 2021 and was admitted to hospital via emergency doctor. He was hospitalized for about 5 days and MRI of heart was taken from a separate hospital. Appointment for cardiologist were also taken.<br><br>Company Comment:<br>This case concerns a 32-year-old male patient with no reported medical history, who experienced the expected event of myocarditis. The event occurred 3 days after the second dose of mRNA-1273 (Spikevax). The rechallenge was not applicable as the event occurred after the second dose. Causality for the reported event was not provided by the reporter. The event is consistent with the current understanding of the mechanism of action of the vaccine. The benefit-risk relationship of Moderna COVID-19 Vaccine is not affected by this report. Event assessed as serious (medically significant(per Regulatory authority. Myocarditis is an adverse event of special interest<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 08-Oct-2021: Translation document was received on 12 Oct 21 and narrative was updated.<br>On 15-Oct-2021: Follow up received contain no new information.<br>On 08-Dec-2021: Follow up received on 08 Dec 2021 contains non-Significant information. |
| 4.1(b) | 4.1(b) | This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) ) on 06-Oct-2021 and was forwarded to Moderna on 11-Oct-2021.<br>This case, reported by a physician, was received by Takeda via Moderna's adverse reaction reporting site (4.1(b) and reported to the 4.1(b) ) by a physician, was received via the 4.1(b) (Ref, 4.1(b)<br><br>Myocarditis was assessed as serious by the MAH.<br><br>On an unknown date, the patient received the 1st dose of this vaccine.<br><br>On 21-Sep-2021, the patient received the 2nd dose of this vaccine.<br><br>On 22-Sep-2021, at 20:00, chest pain developed. There were ECG changes and elevated troponin I, and the patient was diagnosed with myocarditis.<br><br>On 04-Oct-2021, recovery of symptoms was confirmed.<br><br>The outcome of myocarditis was reported as recovered.<br><br>Follow-up investigation will be made.<br><br>Company Comment: |

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| | | The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 08-Oct-2021 and was forwarded to Moderna on 08-Oct-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of VENTRICULAR DYSFUNCTION (Myocarditis occuring two days after the second dose of vaccine,with associated left ventricular dysfunction.) and MYOCARDITIS (Myocarditis occuring two days after the second dose of vaccine,with associated left ventricular dysfunction.) in a 21-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 immunisation.<br><br>The patient's past medical history included Smoker.<br><br>On 23-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to .5 milliliter in total. On an unknown date, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) .5 ml. On 25-Sep-2021, the patient experienced VENTRICULAR DYSFUNCTION (Myocarditis occuring two days after the second dose of vaccine,with associated left ventricular dysfunction.) (seriousness criterion hospitalization) and MYOCARDITIS (Myocarditis occuring two days after the second dose of vaccine,with associated left ventricular dysfunction.) (seriousness criterion hospitalization). At the time of the report, VENTRICULAR DYSFUNCTION (Myocarditis occuring two days after the second dose of vaccine,with associated left ventricular dysfunction.) and MYOCARDITIS (Myocarditis occuring two days after the second dose of vaccine,with associated left ventricular dysfunction.) was resolving.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 26-Sep-2021, Troponin I: 21704 (High) 21704 ng.<br>On 26-Sep-2021, White blood cell count: 16840 (High) 16840 INTERNATIONAL UNIT(S)-(UNDER 100).<br>On 27-Sep-2021, C-reactive protein: 6 (normal) 6 mg.<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.<br><br>Concomitant medications was not reported. Treatment history was not reported.<br><br>This case concerns a 21-year-old male patient with no reported relevant medical history, who experienced the expected serious AESI event of Myocarditis and the unexpected serious event of Ventricular dysfunction. The events occurred approximately 3 days after the second dose of Spikevax administration. The rechallenge was not applicable since no events were reported after the first dose and no additional dosing was expected. The benefit-risk relationship is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 08-Oct-2021: Follow up received contains No new information |

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| | | On 08-Oct-2021: Translated document received on 12-OCT-2021 contains updated event verbatim and relevant past drug name as reported and updated Narrative.<br>On 08-Nov-2021: Follow up received contains no new information. |
| 4.1(b) | 4.1(b) | This case was initially received via European Medicines Agency (Reference number: 4.1(b) ) on 08-Oct-2021. The most recent information was received on 14-Oct-2021 and was forwarded to Moderna on 14-Oct-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myopericarditis in a patient who recently had the MODERNA Covid vaccine. Blood tests carried out : - CRP 61 - troponin 4700 - serodiagnosis in progress) in a 17-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 214027 and 214019) for SARS-CoV-2 vaccination.<br><br>No Medical History information was reported.<br><br>On 13-Aug-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form.<br>On 24-Sep-2021, received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to 1 dosage form. On 27-Sep-2021, the patient experienced MYOCARDITIS (Myopericarditis in a patient who recently had the MODERNA Covid vaccine. Blood tests carried out : - CRP 61 - troponin 4700 - serodiagnosis in progress) (seriousness criterion medically significant). At the time of the report, MYOCARDITIS (Myopericarditis in a patient who recently had the MODERNA Covid vaccine. Blood tests carried out : -CRP 61 - troponin 4700 - serodiagnosis in progress) was resolving.<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.<br><br>Concomitant product information was not provided.<br>Treatment information was not provided.<br><br>Laboratory data was mentioned as on an unknown date patient took blood test and it shows CRP value as 61 and Troponin value as 4700.<br><br>Company comment: This case concerns a 17 year old male patient with no relevant medical history, who experienced the expected AESI event of myocarditis. The event occurred approximately 44 days after the fist dose and 3 days after the second dose of the Moderna COVID-19 vaccine. The rechallenge was not applicable. The benefit-risk relationship of the Moderna COVID-19 vaccine is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 14-Oct-2021: Follow-up received contains added Route of administration and Indication for use.<br>On 14-Oct-2021: Translation received on 20-Oct-2021 contains no new information |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 08-Oct-2021 and was forwarded to Moderna on 08-Oct-2021. |

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| | | This regulatory authority case was reported by a physician and describes the occurrence of DYSPNOEA (DYSPNEA) and MYOCARDITIS (MYOCARDITIS) in a 25-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3004224) for Vaccination.<br><br>No Medical History information was reported.<br><br>On 21-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 26-Sep-2021, the patient experienced DYSPNOEA (DYSPNEA) (seriousness criterion hospitalization) and MYOCARDITIS (MYOCARDITIS) (seriousness criteria hospitalization and medically significant). At the time of the report, DYSPNOEA (DYSPNEA) and MYOCARDITIS (MYOCARDITIS) was resolving.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 26-Sep-2021, Echocardiogram: no signs of pericardial fluid, normal ventricular (normal) No signs of pericardial fluid, normal ventricular function.<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered DYSPNOEA (DYSPNEA) and MYOCARDITIS (MYOCARDITIS) to be possibly related.<br><br>Concomitant product use was not provided by the reporter.<br><br>Treatment information was not provided.<br><br>On 26-Sep-2021, Troponin T: 401 (normal) Maximum measured value: 401 ng/L.<br><br>Company comment: This case concerns a 25-year-old male patient with no reported medical history who experienced the unexpected events of dyspnea and expected event of myocarditis. The events occurred 5 days after the second dose of mRNA-1273 (Spikevax). The rechallenge was unknown no details about the first dose was provided. The reported assessed the reported evens as related to the product use. Myocarditis is consistent with the current understanding of the mechanism of action of the vaccine. The benefit-risk relationship of Spikevax is not affected by this report. Event assessed as serious per Regulatory authority as the events were noted as medically significant. Myocarditis is an adverse event of special interest<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 08-Oct-2021: Translation received on 12-Oct-2021, contains no new information. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 08-Oct-2021 and was forwarded to Moderna on 08-Oct-2021.<br>This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (Myocarditis) in a 24-year-old male |

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| | | patient who received mRNA-1273 (Spikevax) (batch no. 3004671) for Prophylactic vaccination.<br><br>No Medical History information was reported.<br><br>On 18-Aug-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 25-Aug-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). The patient was hospitalized for 7 days due to MYOCARDITIS. At the time of the report, MYOCARDITIS (Myocarditis) had not resolved.<br><br>Concomitant product use was not provided by the reporter.<br><br>Patient was allergic to amoxicillin. Patient was hospitalized for 1 week, signed off sick since hospitalization, no final examination yet.<br><br>No treatment information was provided.<br><br>Company Comment: This case concerns a 24-year-old male subject, with no relevant medical history, who experienced the serious, expected, AESI event of Myocarditis. The event occurred approximately 8 days after the second dose of Spikevax. The rechallenge is not applicable, as no additional dose will be given. The benefit-risk relationship of Spikevax is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 08-Oct-2021: Translation received on 12-OCT-2021 in which sender's comment and event verbatim were updated.<br>On 25-Oct-2021: Follow-up received contains no new information. |
| 4.1(b) | 4.1(b) | This case was received via 4.1(b) (Reference number: 4.1(b) ) on 08-Oct-2021 and was forwarded to Moderna on 08-Oct-2021.<br>This regulatory authority case was reported by a consumer and describes the occurrence of COSTOCHONDRITIS (Costochondritis) and PERICARDITIS (Pericarditis) in a 23-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for COVID-19 vaccination.<br><br>Concomitant products included IBUPROFEN for an unknown indication.<br><br>On 10-Sep-2021, the patient received second dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 13-Sep-2021, the patient experienced PERICARDITIS (Pericarditis) (seriousness criterion medically significant). On 02-Oct-2021, the patient experienced COSTOCHONDRITIS (Costochondritis) (seriousness criterion medically significant). At the time of the report, COSTOCHONDRITIS (Costochondritis) had not resolved and PERICARDITIS (Pericarditis) was resolving. |

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| | | DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On an unknown date, SARS-CoV-2 test: no - negative covid-19 test (Negative) Negative COVID-19 test.<br><br>The action taken with mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown) was unknown.<br><br>Treatment product was not provided by the reporter<br><br>Patient was in Ibuprofen and Paracetamol.<br><br>Patient had not tested positive for COVID-19 since having the vaccine.<br><br>Patient was not enrolled in clinical trial.<br><br>Lab test included ecg blood and xray (xray on second hospital visit).<br><br>Company Comment: This case concerns a 23 year-old, male subject with no clinical history who experienced the unexpected event of COSTOCHONDRITIS and the expected event of PERICARDITIS (AESI). The events occurred between the third and the 28th. day after the second dose of [Spikevax]<br>The rechallenge is “not applicable” as the events occurred after the second dose and no details were provided about the first dose<br>The benefit-risk relationship of the vaccine is not affected by this report |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number 4.1(b) ) on 08-Oct-2021 and was forwarded to Moderna on 08-Oct-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of PERICARDITIS (Acute pericarditis) and MYOCARDITIS (Acute myocarditis) in a 13-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 23-Aug-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form.<br>On 18-Sep-2021, received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. On 22-Sep-2021, the patient experienced PERICARDITIS (Acute pericarditis) (seriousness criteria hospitalization and medically significant) and MYOCARDITIS (Acute myocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, PERICARDITIS (Acute pericarditis) and MYOCARDITIS (Acute myocarditis) was resolving.<br><br>For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.<br><br>Concomitant medication was not provided |

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| | | Treatment medication was not provided<br><br>Company Comment: This case concerns a 13-year-old male patient with no reported medical history who experienced the expected events of acute myocarditis and pericarditis. The event occurred 4 days after the second dose of mRNA-1273 (Spikevax). The rechallenge was unknown details about the first dose was not disclosed. Causality for the reported event was not provided by the reporter. Myocarditis and pericarditis are consistent with the current understanding of the mechanism of action of the vaccine. The benefit-risk relationship of Spikevax is not affected by this report. Event assessed as serious per Regulatory authority as the events were noted as medically significant. The events are adverse event of special interest<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 08-Oct-2021: Translation document received on 12OCT2021.<br>Contains non significant information. Dosage text translated to English. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 08-Oct-2021 and was forwarded to Moderna on 08-Oct-2021.<br>This regulatory authority case was reported by a consumer and describes the occurrence of PERICARDITIS (Pericardial irritation) in an 18-year-old female patient who received mRNA-1273 (Spikevax) (batch nos. 3004217 and 3003609) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 18-Jul-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form.<br>On 15-Aug-2021, received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. On 18-Aug-2021, after starting mRNA-1273 (Spikevax), the patient experienced PERICARDITIS (Pericardial irritation) (seriousness criteria hospitalization and medically significant). On 01-Sep-2021, PERICARDITIS (Pericardial irritation) had not resolved.<br><br>No concomitant medications were mentioned.<br>No treatment details were reported.<br>It was reported that patient investigation included increased hs-TNT 3 times.<br>fluoride,myocarditis, ischemia, infection investigations were excluded.<br><br>Company comment:<br>This case concerns a 18-year-old, female patient with no relevant medical history, who experienced the expected event of pericarditis. The event pericarditis occurred 3 days after the second dose of mRNA-1273 vaccine administration. The rechallenge was unknown as there's no information available about the first dose. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. The RA SD contain conflicting information, the RA SD captured the end date of the event pericarditis as 1 September 2021 but the outcome of event pericarditis at the time of last |

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| | | observation is not recovered/not resolved/ongoing. RA SD coding was captured and maintained.<br><br>Most recent FOLLOW-UP information incorporated above includes: On 08-Oct-2021: Translation received on 13 OCT 2021 contains significant information, Event verbatim was updated, Sender's comment was updated. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 08-Oct-2021 and was forwarded to Moderna on 08-Oct-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Acute myocarditis) in a 20-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 prophylaxis.<br><br>No Medical History information was reported.<br><br>On 20-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form.<br>On an unknown date, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 23-Sep-2021, the patient experienced MYOCARDITIS (Acute myocarditis) (seriousness criterion medically significant). On 27-Sep-2021, MYOCARDITIS (Acute myocarditis) had resolved.<br><br>For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.<br><br>No concomitant product use was provided by the reporter.<br>No treatment medication was provided.<br><br>Company comment: This case concerns a 20-year-old, male patient, with no disclosed medical history, who experienced the serious, expected, AESI event of myocarditis. The event occurred on an unknown day after second dose of Spikevax. The rechallenge is unknown as no details on the first dose was given. The benefit-risk relationship of Spikevax is not affected by this report. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 11-Oct-2021 and was forwarded to Moderna on 11-Oct-2021.<br><br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (myocarditis) in a 20-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 3002335 and 3002335) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>In May 2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form.<br>On 27-Jun-2021, received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to 1 dosage form. On 29-Jun-2021, after starting mRNA-1273 (Spikevax), the patient experienced MYOCARDITIS (myocarditis) (seriousness criteria hospitalization and |

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| | | medically significant). At the time of the report, MYOCARDITIS (myocarditis) had not resolved.<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.<br><br>No concomitant medications were reported.<br><br>No treatment details were reported.<br><br>This case concerns a 20-year-old male patient with no relevant medical history who experienced serious expected event of Myocarditis. The event occurred approximately two days after the second dose of Spikevax. The rechallenge was not applicable as the event occurred following the second dose. Very limited information regarding clinical course of the event has been provided at this time. The benefit-risk relationship of Spikevax is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 11-Oct-2021: Translation document received on 13-Oct-2021 included no new information. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 11-Oct-2021 and was forwarded to Moderna on 11-Oct-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of PERICARDITIS (Pericarditis) in a 23-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3003604) for Vaccination.<br><br>No Medical History information was reported.<br><br>On 08-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to 1 dosage form.<br>On an unknown date, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 27-Sep-2021, the patient experienced PERICARDITIS (Pericarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, PERICARDITIS (Pericarditis) was resolving.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>In September 2021, Echocardiogram: normal (normal) Normal findings.<br>In September 2021, Electrocardiogram: consistent with pericarditis, no pericardial fluid (abnormal) Findings from clinical examination and ECG consistent with pericarditis, no pericardial fluid or specific sound (2/4 criteria for pericarditis fullfilled)..<br>In September 2021, Laboratory test: normal (normal) Normal results.<br>In September 2021, Physical examination: consistent with pericarditis, no pericardial fluid (abnormal) Findings from clinical examination and ECG consistent with pericarditis, no pericardial fluid or specific sound (2/4 criteria for pericarditis fullfilled)..<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered PERICARDITIS (Pericarditis) to be possibly related. |

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| | | No relevant concomitant medications were reported.<br><br>No treatment information was provided.<br><br>Company comment<br>This case concerns a 23 year old male patient, with no medical history reported, who experienced serious expected event of pericarditis (AESI) after second dose of mRNA-1273. The event occurred 20 days after second dose of mRNA-1273. The re-challenge is not applicable because further dose is not expected. The event was considered related to the product per the reporter's assessment. The benefit-risk relationship of Spikevax is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 11-Oct-2021: Translation received on 13-Oct-2021 included no new information |
| 4.1(b) | 4.1(b) | This case was initially received via European Medicines Agency (Reference number: 4.1(b) ) on 11-Oct-2021. The most recent information was received on 11-Oct-2021 and was forwarded to Moderna on 13-Oct-2021.<br>This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (Myocarditis) in a 38-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 10-Aug-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 14-Aug-2021, after starting mRNA-1273 (Spikevax), the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Myocarditis) outcome was unknown.<br><br>Concomitant medication was not provided.<br><br>Treatment information was not provided.<br><br>Patient Initial 4.1(b) and MRI of patient was confirmed CHD was ruled out.<br><br>company comment: This case concerns a 38-year-old male patient with no reported medical history, who experienced the expected event of myocarditis. The event occurred 4 days after the second dose of mRNA-1273 (Spikevax). The rechallenge was unknown as no details about the first dose was disclosed. Causality for the reported event was not provided by the reporter. myocarditis is consistent with the current understanding of the mechanism of action of the vaccine. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report. Events assessed as medically significant per regulatory authority reporting and required hospitalization. Myocarditis is an adverse event of special interest. |

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| | | Most recent FOLLOW-UP information incorporated above includes:<br>On 11-Oct-2021: Translation received on 13-OCT-21 and it included Patient Initial 4.1(b) and MRI result added in narrative. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) on 11-Oct-2021 and was forwarded to Moderna on 11-Oct-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myocarditis) in a 23-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 214021 and 3004738) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 14-Aug-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form.<br>On 04-Sep-2021, received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to 1 dosage form. On 07-Sep-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Myocarditis) had not resolved.<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.<br><br>Concomitan and treatment medication was not provided.<br><br>Company comment: This case concerns a 23-year-old male patient with no relevant medical history, who experienced the expected serious AESI event of Myocarditis. The events occurred approximately 5 days after the second dose of Spikevax administration. The rechallenge was not applicable since no events were reported after the first dose and no additional dosing was expected. Additional administrative event of inappropriate vaccination schedule was considered. The benefit-risk relationship is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 11-Oct-2021: Translation received on 14-OCT-2021: Contains no new information. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 12-Oct-2021 and was forwarded to Moderna on 12-Oct-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of PERICARDITIS (PERICARDITIS) in a 32-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3004498) for Vaccination.<br><br>No Medical History information was reported.<br><br>On 06-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to 1 dosage form.<br>On an unknown date, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 07-Sep-2021, the patient experienced PERICARDITIS (PERICARDITIS) (seriousness criteria |

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| | | hospitalization and medically significant). At the time of the report, PERICARDITIS (PERICARDITIS) was resolving.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 07-Sep-2021, Echocardiogram: abonormal (abnormal) No pleural effusion.<br>On 07-Sep-2021, Electrocardiogram: abnormal (abnormal) ECG changes..<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered PERICARDITIS (PERICARDITIS) to be possibly related.<br><br>Concomitant product use was not provided by the reporter.<br><br>No treatment information was provided.<br><br>Company Comment:<br>This case concerns a 32-year-old, male patient with no relevant medical history, who experienced the expected event of pericarditis. The event, which resulted in hospitalization, occurred 1 day after administration of the second dose of Spikevax. The rechallenge was not applicable as no additional dosing will be given. The patient's gender remains a confounder. The benefit-risk relationship of Spikevax is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 12-Oct-2021: Translation document received on 15-Oct-2021 with Sender's comments, dosage form text translated and updated. |
| 4.1(b) [redacted] | 4.1(b) [redacted] | This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 12-Oct-2021 and was forwarded to Moderna on 12-Oct-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Acute myocarditis) and PERICARDITIS (Acute pericarditis) in a 24-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3003604) for Vaccination. The occurrence of additional non-serious events is detailed below.<br><br>Previously administered products included for Vaccination: COMIRNATY.<br><br>On 02-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. In 2021, the patient experienced COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine). On 30-Sep-2021, the patient experienced MYOCARDITIS (Acute myocarditis) (seriousness criteria hospitalization and medically significant) and PERICARDITIS (Acute pericarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Acute myocarditis) and PERICARDITIS (Acute pericarditis) was resolving and COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine) had not resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): |

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| | | In 2021, C-reactive protein: crp elevation (High) CRP elevation..<br>In 2021, Electrocardiogram: abnormal (abnormal) Acute pericarditis with typical symptoms, ECG changes and CRP elevation..<br>In 2021, Troponin I: 7000 (High) Approx. 7000 at the highest.<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered MYOCARDITIS (Acute myocarditis), PERICARDITIS (Acute pericarditis) and COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine) to be possibly related.<br><br>Concomitant product use was not provided by the reporter.<br><br>No treatment information was provided.<br><br>Company Comment: This case concerns a 24-year-old male subject with no relevant medical history reported, who experienced the serious unexpected and AESI events of MYOCARDITIS and PERICARDITIS 29 days receiving the second dose of spikevax. Time to onset for the first dose is unknown, and this dose was a dose of COMIRNATY. Rechallenge is not applicable since the events occurred after the second dose and no further doses will be given. Previous vaccination with comirnaty remains as a counfounder/co-suspect for this event. The benefit-risk relationship of spikevax is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 12-Oct-2021: Translated document received on 15-Oct-2021. Translation Document contains no new information |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 12-Oct-2021 and was forwarded to Moderna on 12-Oct-2021.<br><br>This regulatory authority case was reported by a physician and describes the occurrence of CONGESTIVE CARDIOMYOPATHY (Dilated cardiomyopathy) and MYOCARDITIS (Myocarditis) in a 29-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 immunisation.<br><br>No Medical History information was reported.<br><br>On 27-May-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form.<br>On 08-Jul-2021, received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. On 11-Jul-2021, the patient experienced CONGESTIVE CARDIOMYOPATHY (Dilated cardiomyopathy) (seriousness criterion medically significant) and MYOCARDITIS (Myocarditis) (seriousness criterion medically significant). At the time of the report, CONGESTIVE CARDIOMYOPATHY (Dilated cardiomyopathy) and MYOCARDITIS (Myocarditis) had not resolved.<br><br>For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.<br><br>No Treatment informations were reported.<br><br>Company Comment: |

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| | | This case concerns Inappropriate schedule of vaccine administration in a 29 year-old male patient with no reported medical history, who experienced the expected serious event of Myocarditis (AESI) and the unexpected serious event of Dilated cardiomyopathy. The events occurred 3 days after the second dose of mRNA-1273 vaccine. Details of clinical presentation, diagnostic criteria, and clinical course were not provided. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 12-Oct-2021 and was forwarded to Moderna on 12-Oct-2021.<br>This regulatory authority case was reported by a pharmacist and describes the occurrence of MALAISE (Reported spiking fever and malaise after the administrationof SARS-CoV-2 vaccine with joint pain and nonspecificoppressive chest pain. Possible myopericarditis), CHEST PAIN (Reported spiking fever and malaise after the administrationof SARS-CoV-2 vaccine with joint pain and nonspecificoppressive chest pain. Possible myopericarditis.), PYREXIA (Reported spiking fever and malaise after the administrationof SARS-CoV-2 vaccine with joint pain and nonspecificoppressive chest pain. Possible myopericarditis), ARTHRALGIA (Reported spiking fever and malaise after the administrationof SARS-CoV-2 vaccine with joint pain and nonspecificoppressive chest pain. Possible myopericarditis.) and MYOCARDITIS (Reported spiking fever and malaise after the administration of SARS-CoV-2 vaccine with joint pain and nonspecific oppressive chest pain. Possible myopericarditis) in a 20-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 3005687) for Prophylactic vaccination.<br><br>No Medical History information was reported.<br><br>On 04-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) .5 milliliter. On 04-Sep-2021, the patient experienced MALAISE (Reported spiking fever and malaise after the administrationof SARS-CoV-2 vaccine with joint pain and nonspecificoppressive chest pain. Possible myopericarditis) (seriousness criterion hospitalization), CHEST PAIN (Reported spiking fever and malaise after the administrationof SARS-CoV-2 vaccine with joint pain and nonspecificoppressive chest pain. Possible myopericarditis.) (seriousness criterion hospitalization), PYREXIA (Reported spiking fever and malaise after the administrationof SARS-CoV-2 vaccine with joint pain and nonspecificoppressive chest pain. Possible myopericarditis) (seriousness criterion hospitalization), ARTHRALGIA (Reported spiking fever and malaise after the administrationof SARS-CoV-2 vaccine with joint pain and nonspecificoppressive chest pain. Possible myopericarditis.) (seriousness criterion hospitalization) and MYOCARDITIS (Reported spiking fever and malaise after the administration of SARS-CoV-2 vaccine with joint pain and nonspecific oppressive chest pain. Possible myopericarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, MALAISE (Reported spiking fever and malaise after the administrationof SARS-CoV-2 vaccine with joint pain and nonspecificoppressive chest pain. Possible myopericarditis), CHEST PAIN (Reported spiking fever and malaise after the administrationof SARS-CoV-2 vaccine with joint pain |

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| | | and nonspecificoppressive chest pain. Possible myopericarditis.), PYREXIA (Reported spiking fever and malaise after the administrationof SARS-CoV-2 vaccine with joint pain and nonspecificoppressive chest pain. Possible myopericarditis), ARTHRALGIA (Reported spiking fever and malaise after the administrationof SARS-CoV-2 vaccine with joint pain and nonspecificoppressive chest pain. Possible myopericarditis.) and MYOCARDITIS (Reported spiking fever and malaise after the administration of SARS-CoV-2 vaccine with joint pain and nonspecific oppressive chest pain. Possible myopericarditis) was resolving.<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.<br><br>Concomitant product use was not provided by the reporter.<br><br>On 08-Sep-2021, laboratory teste included chest x-ray, blood pressure, oxygen saturation, heart rate and emergency care examination and result was not reported. On 08-SEP-2021 patient visited physicians office.<br><br>No treatment information was provided.<br><br>On 29-Jul-2021 patient administered first dose of Spikevax vaccine Batch number.3004492.<br><br>Company Comment: This case concerns a 20 year-old female patient with no medical history provided, who experienced the unexpected events of Malaise, Chest pain, Pyrexia, Arthralgia, and Myocarditis(seriousness criterion hospitalization). These events occurred on the same day as the first dose of Spikevax.The rechallenge was not applicable since only information about the first dose was disclosed. The benefit-risk relationship of Spikevax is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 12-Oct-2021: Translation received on 14-OCT-2021 include translated verbatim. Sender's Comment added. Narrative updated accordingly.<br>On 29-Oct-2021: Follow-up information included no new information.<br>On 29-Oct-2021: Translation Received on 01-Nov-21 includes no new information. |
| 4.1(b) | 4.1(b) | This case was received via 4.1(b) (Reference number: 4.1(b) on 12-Oct-2021 and was forwarded to Moderna on 12-Oct-2021.<br>This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCARDITIS (Myocarditis) in a 39-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 05-Feb-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 08-Feb-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). The patient |

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| | | was hospitalized for 4 days due to MYOCARDITIS. At the time of the report, MYOCARDITIS (Myocarditis) had resolved.<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter considered MYOCARDITIS (Myocarditis) to be possibly related.<br><br>No concomitant medications were provided.<br>Treatment for the events were not provided.<br><br>Company Comment:<br>This case concerns a 39-year-old, male patient with no relevant medical history, who experienced the expected event of myocarditis. The event, which resulted in hospitalization, occurred 3 days after administration of the second dose of the Moderna COVID-19 Vaccine. The rechallenge was not applicable as no additional dosing will be given. The patient's gender remains a confounder. The benefit-risk relationship of Moderna COVID-19 Vaccine is not affected by this report. |
| 4.1(b) | 4.1(b) | This case was received via 4.1(b) (Reference number: 4.1(b) on 12-Oct-2021 and was forwarded to Moderna on 12-Oct-2021.<br>This regulatory authority case was reported by an other health care professional and describes the occurrence of ACUTE MYOCARDIAL INFARCTION (Acute myocardial infarction), AORTIC DISSECTION (Aortic dissection), BACK PAIN (Back pain), CARDIAC FAILURE (Cardiac failure), CORONARY ARTERY DISEASE (Coronary artery disease), DYSPNOEA (Dyspnoea, shortness of breath), MUSCULOSKELETAL PAIN (Musculoskeletal pain), SINUS TACHYCARDIA (Sinus tachycardia), ARTHRALGIA (Pain intermittently between the shoulder blades, Shoulder Pain) and MYOCARDITIS (Myocarditis) in a 29-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 012A21A and 012A21A) for COVID-19 vaccination.<br><br>The patient's past medical history included Obesity (BMI ~45).<br>Previously administered products included for Product used for unknown indication: Tdap.<br>Past adverse reactions to the above products included Fever with Tdap.<br>Family history included Coronary artery disease (Family history of elderly onset CAD of a maternal grandfather who smoked.).<br>Concurrent medical conditions included Allergy to vaccine (Allergy to Tdap vaccine (Fever)).<br><br>On 13-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form.<br>On 11-Apr-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. In June 2021, the patient experienced DYSPNOEA (Dyspnoea, shortness of breath) (seriousness criteria hospitalization and disability). On 19-Jun-2021, the patient experienced BACK PAIN (Back pain) (seriousness criteria hospitalization and disability) and MUSCULOSKELETAL PAIN (Musculoskeletal pain) (seriousness criteria hospitalization and disability). 19-Jun-2021, the patient experienced ARTHRALGIA (Pain intermittently between the shoulder blades, Shoulder Pain) (seriousness criteria hospitalization and disability). On 21-Jun-2021, the patient experienced |

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| | | ACUTE MYOCARDIAL INFARCTION (Acute myocardial infarction) (seriousness criteria hospitalization, disability and medically significant) and MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization, disability and medically significant). 21-Jun-2021, the patient experienced AORTIC DISSECTION (Aortic dissection) (seriousness criteria hospitalization, disability and medically significant), CARDIAC FAILURE (Cardiac failure) (seriousness criteria hospitalization, disability and medically significant), CORONARY ARTERY DISEASE (Coronary artery disease) (seriousness criteria hospitalization and disability) and SINUS TACHYCARDIA (Sinus tachycardia) (seriousness criteria hospitalization and disability). The patient was hospitalized on sometime in June 2021 due to ACUTE MYOCARDIAL INFARCTION, AORTIC DISSECTION, ARTHRALGIA, BACK PAIN, CARDIAC FAILURE, CORONARY ARTERY DISEASE, DYSPNOEA, MUSCULOSKELETAL PAIN, MYOCARDITIS and SINUS TACHYCARDIA. The patient was treated with ASA at an unspecified dose and frequency; CARVEDILOL at an unspecified dose and frequency; LISINOPRIL at an unspecified dose and frequency; KCL at an unspecified dose and frequency and IVABRADINE at an unspecified dose and frequency. At the time of the report, ACUTE MYOCARDIAL INFARCTION (Acute myocardial infarction), AORTIC DISSECTION (Aortic dissection), BACK PAIN (Back pain), CARDIAC FAILURE (Cardiac failure), CORONARY ARTERY DISEASE (Coronary artery disease), DYSPNOEA (Dyspnoea, shortness of breath), MUSCULOSKELETAL PAIN (Musculoskeletal pain), SINUS TACHYCARDIA (Sinus tachycardia), ARTHRALGIA (Pain intermittently between the shoulder blades, Shoulder Pain) and MYOCARDITIS (Myocarditis) had not resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 21-Jun-2021, Blood creatine phosphokinase: high (High) 223. Blood creatine phosphokinase increased..<br>On 21-Jun-2021, Catheterisation cardiac: abnormal (abnormal) 1) Markedly elevated left ventricular end-diastolic pressure. 2) Normal left anterior descending and right and dominant right coronary arteries. 3) Minimal (less than20%) coronary artery disease of the circumflex artery. 4) Severe diffuse hypokinesis of left ventricle. Estimated ejection fraction of 30% to 35%. 5) No significant mitral regurgitation. 6) Insignificant 9 mm gradient across the aortic valve..<br>On 21-Jun-2021, Computerised tomogram: abnormal (abnormal) CT aortic dissection protocol.<br>On 21-Jun-2021, Electrocardiogram: abnormal (abnormal) Abnormal.<br>On 21-Jun-2021, Electrocardiogram QRS complex: abnormal (abnormal) Sinus tachycardia (HR 107), abnormal QRS-T angle..<br>On 21-Jun-2021, Electrocardiogram T wave abnormal: abnormal (abnormal) Abnormal.<br>On 21-Jun-2021, Fibrin D dimer: low (Low) Less than 0.27 (normal)..<br>On 21-Jun-2021, Full blood count: abnormal (abnormal) Unremarkable outside of WBC 14.9 at time of NSTEMI..<br>On 21-Jun-2021, Left ventricular end-diastolic pressure: high (High) Left ventricular end-diastolic pressure increased..<br>On 21-Jun-2021, Metabolic function test: normal (normal) Unremarkable outside of WBC 14.9 at time of NSTEMI..<br>On 21-Jun-2021, Troponin: high (High) 514 -greater than 529 (4%) -greater than 587 (14%). |

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| | | On 21-Jun-2021, White blood cell count: high (High) White blood cell count increased..<br>On 22-Jun-2021, Blood magnesium: normal (normal) Blood magnesium normal..<br>On 22-Jun-2021, Blood thyroid stimulating hormone: normal (normal) Normal.<br>On 22-Jun-2021, Echocardiogram: abnormal (abnormal) Normal left ventricle size. Mild left ventricular hypertrophy. Moderate left ventricular systolic dysfunction. The ejection fraction, measured by Simpsons method, is 40 %. EF is reduced globally with no discrete regional wall motion abnormality. Normal diastolic left ventricular function. Mild enlargement of the left atrium. Mild mitral valve regurgitation. No mitral valve stenosis..<br>On 22-Jun-2021, Ejection fraction: 40 (Low) 40 percentage. Ejection fraction decreased..<br>On 22-Jun-2021, Free thyroxine index: normal (normal) Normal.<br>On 22-Jun-2021, Thyroxine free: normal (normal) Normal.<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments.<br><br>Concomitant medications were not reported.<br><br>Patient was taking Anticoagulant therapy since 19Jun2021.<br><br>Moderna COVID shot 1 given 3/13/21 and shot 2 given 4/11/21. Patient developed some vague back pain for last 2 days starting 6/19/21 intermittently between the shoulder blades. Patient states in last 24 hours he noticed increasing shortness of breath and shoulder pain worsened with exertion. Patient was found to have suspected myocarditis induced NSTEMI + Heart Failure with Reduced Ejection Fraction to 40%. Patient now requires several medications including ASA, carvedilol, lisinopril, KCl, and ivabradine. Patient only other past medical is obesity (BMI ~45), and family hx of elderly onset CAD of a maternal grandfather who smoked.<br><br>This case concerns a 29 year-old male patient with past medical history of obesity (BMI 45), who experienced the Serious Unexpected events of Acute myocardial infarction, Cardiac Failure and Coronary artery disease (Dissability, Hospitalisation, Medically significant/AESI), and the Serious Expected event of Myocarditis (Dissability, Hospitalisation, Medically significant/AESI). The events started approximately 71 days after the second dose of a proper schedule of administration of Moderna Covid-19 vaccine and the outcome is unknown. The rechallenge is not applicable since no information about further doses is provided. Medical history of past morbid obesity remains a confounder for the events. The benefit-risk relationship of Moderna covid-19 vaccine is not affected by this report. |
| 4.1(b) | 4.1(b) | This case was received via 4.1(b) (Reference number: 4.1(b) on 12-Oct-2021 and was forwarded to Moderna on 12-Oct-2021.<br>This regulatory authority case was reported by an other health care professional and describes the occurrence of PERICARDITIS (Pericarditis with pericardial effusion) and PERICARDIAL EFFUSION (Pericarditis with pericardial effusion) in a 26-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. |

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| | | Concurrent medical conditions included Peanut allergy.<br>Concomitant products included TESTOSTERONE CIPIONATE (TESTOSTERONE CYPIONATE), OXYCODONE HYDROCHLORIDE, PARACETAMOL (PERCOCET [OXYCODONE HYDROCHLORIDE;PARACETAMOL]), MELOXICAM and ACETYLSALICYLIC ACID (ASPRIN) for an unknown indication.<br><br>On 01-Jan-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 11-Sep-2021, the patient experienced PERICARDITIS (Pericarditis with pericardial effusion) (seriousness criteria hospitalization and medically significant) and PERICARDIAL EFFUSION (Pericarditis with pericardial effusion) (seriousness criteria hospitalization and medically significant). At the time of the report, PERICARDITIS (Pericarditis with pericardial effusion) and PERICARDIAL EFFUSION (Pericarditis with pericardial effusion) had not resolved.<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments.<br><br>No treatment information was provided by the reporter.<br><br>On 11-Sep-2021, the patient had undergone computerized tomogram and echocardiogram tests.<br><br>Company comment -This case concerns a 26-year old, male subject with a medical history of concomitant use of testosterone cypionate, who experienced the serious (Seriousness criteria-caused hospitalization, medically significant) expected event of Pericarditis(AESI) and serious unexpected event of Pericardial effusion. The events occurred approximately 8 months after the second dose of MODERNA COVID-19 VACCINE. Rechallenge is not applicable as no information about the first dose is available and no additional dose is expected to be given. The patient's concomitant use of testosterone cypionate remains a confounder. The benefit-risk relationship of MODERNA COVID-19 VACCINE is not affected by this report. |
| 4.1(b) [redacted] | 4.1(b) [redacted] | This spontaneous case was reported by a consumer and describes the occurrence of DYSPNOEA (could not breath), CHEST DISCOMFORT (pressure over the chest) and MYOCARDITIS (heart muscle inflammation) in a 19-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3005697) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below.<br><br>Previously administered products included for an unreported indication: PFIZER BIONTECH COVID-19 VACCINE (First dose Pfizer on 21Jul2021) on 21-Jul-2021.<br><br>On 08-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 08-Sep-2021, the patient experienced RHINORRHOEA (maybe a runny nose), PYREXIA (fever) and INTERCHANGE OF VACCINE PRODUCTS (First dose Pfizer on |

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| | | 21Jul2021 & Second dose Moderna on 08Sep2021). On 09-Sep-2021, the patient experienced MYOCARDITIS (heart muscle inflammation) (seriousness criterion medically significant). On an unknown date, the patient experienced DYSPNOEA (could not breath) (seriousness criteria hospitalization and medically significant), CHEST DISCOMFORT (pressure over the chest) (seriousness criterion hospitalization) and DEPRESSED MOOD (was not good during those two weeks). The patient was hospitalized from 09-Sep-2021 to 09-Sep-2021 due to CHEST DISCOMFORT and DYSPNOEA. The patient was treated with IBUPROFEN at an unspecified dose and frequency. On 08-Sep-2021, INTERCHANGE OF VACCINE PRODUCTS (First dose Pfizer on 21Jul2021 & Second dose Moderna on 08Sep2021) had resolved. At the time of the report, DYSPNOEA (could not breath), CHEST DISCOMFORT (pressure over the chest) and MYOCARDITIS (heart muscle inflammation) had not resolved and RHINORRHOEA (maybe a runny nose), DEPRESSED MOOD (was not good during those two weeks) and PYREXIA (fever) outcome was unknown.<br><br>For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.<br><br>No Concomitant medications were reported.<br><br>They performed tests and they mentioned to patient that he has heart muscle inflammation and he received a sick leave for 2 weeks. Patient not good during those two weeks, so he went to the healthcare center and they told him that he still has the heart muscle inflammation and extended the sick leave with another month. Patient still experiences the pressure on the chest and the breathlessness during physical activity.<br><br>Company comment: This case of vaccine interchange concerning a 19-year-old male patient, who had prior administration of Pfizer Biontech Covid-vaccine and with no other reported medical history, who experienced the expected event of heart muscle inflamed (myocarditis) and unexpected events of dyspnoea and chest discomfort. The events occurred 1 day after the second dose of mRNA-1273 (COVID-19 Vaccine Moderna). The rechallenge was not applicable as the events occurred after the second dose. Causality for the reported events were not provided by the reporter. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Myocarditis is consistent with the current understanding of the mechanism of action of the vaccine. Events were assessed as serious as both chest discomfort and dyspnoea resulted in hospitalization. Heart muscle inflamed was noted as medically significant and is an adverse event of special interest. |
| 4.1(b) | 4.1(b) | This case was received via 4.1(b) (Reference number: 4.1(b) on 12-Oct-2021 and was forwarded to Moderna on 12-Oct-2021.<br>This regulatory authority case was reported by an other health care professional and describes the occurrence of ASTHENIA (Asthenia), CHEST DISCOMFORT (Chest discomfort), CHEST PAIN (Chest pain), INFLUENZA LIKE ILLNESS (Influenza like illness), CHILLS (Chills), PRESYNCOPE (Presyncope), VOMITING (Vomiting) and MYOCARDITIS (Myocarditis) in a 33-year-old male patient who received mRNA-1273 |

| Case ID | WW Identifier | Narrative |
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| | | (Moderna COVID-19 Vaccine) (batch no. 002F21A) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 20-Sep-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 21-Sep-2021, the patient experienced ASTHENIA (Asthenia) (seriousness criterion hospitalization), CHEST DISCOMFORT (Chest discomfort) (seriousness criterion hospitalization), CHEST PAIN (Chest pain) (seriousness criterion hospitalization), INFLUENZA LIKE ILLNESS (Influenza like illness) (seriousness criterion hospitalization), CHILLS (Chills) (seriousness criterion hospitalization), PRESYNCOPE (Presyncope) (seriousness criterion hospitalization), VOMITING (Vomiting) (seriousness criterion hospitalization) and MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). The patient was hospitalized from 23-Sep-2021 to 24-Sep-2021 due to ASTHENIA, CHEST DISCOMFORT, CHEST PAIN, CHILLS, INFLUENZA LIKE ILLNESS, MYOCARDITIS, PRESYNCOPE and VOMITING. At the time of the report, ASTHENIA (Asthenia), CHEST DISCOMFORT (Chest discomfort), CHEST PAIN (Chest pain), INFLUENZA LIKE ILLNESS (Influenza like illness), CHILLS (Chills), PRESYNCOPE (Presyncope), VOMITING (Vomiting) and MYOCARDITIS (Myocarditis) had resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 21-Sep-2021, Troponin: increased (High) Increased.<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments.<br><br>Laboratory data on 21-Sep-2021 included C-reactive protein, Chest X-ray, Echocardiogram, Electrocardiogram, Full blood count, Metabolic function test, Red blood cell sedimentation rate with unknown results.<br><br>On 23-Sep-2021 admitted for chest pain w/detectable troponin. his troponin quickly trended down and chest pain felt second to probable myocarditis presumed from COVID vaccine.<br><br>Patient developed flu-like symptoms approximately 12 hr. after vaccine which included, chills, rigors, emesis x4-5, weakness, near syncope, and chest pain. His pain was initially mild but then became moderate, was centrally located, sharp and tight. Patient was presented to the ER dur to the degree of pain.<br><br>This case concerns a 33-year-old, male patient with no relevant medical history, who experienced the unexpected events of Asthenia, Chest discomfort, Chest pain, Influenza like illness, Chills, Presyncope, Vomiting, and the expected event of Myocarditis. The events of vomiting and chills are unexpected as they are retained as serious per the source document Authority reporting. The events occurred 1 day after the second dose of Spikevax. Laboratory data included troponin increased. The |

| Case ID | WW Identifier | Narrative |
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| | | rechallenge was not applicable as no additional dose is expected to be given, and no details were provided about the first dose. The benefit-risk relationship of Spikevax is not affected by this report. |
| 4.1(b) | 4.1(b) | This case was received via 4.1(b) (Reference number: 4.1(b) on 12-Oct-2021 and was forwarded to Moderna on 12-Oct-2021.<br>This regulatory authority case was reported by an other health care professional and describes the occurrence of CHEST DISCOMFORT (Chest discomfort), CHILLS (Chills), COUGH (Cough), DYSPNOEA (Dyspnoea), FATIGUE (Fatigue/ tiredness), PYREXIA (Pyrexia) and MYOCARDITIS (Myocarditis) in a 35-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 004F21A and 046C21A) for COVID-19 vaccination.<br><br>Concomitant products included FLUTICASONE PROPIONATE (FLONASE [FLUTICASONE PROPIONATE]) for an unknown indication.<br><br>On 20-Sep-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form.<br>On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 21-Sep-2021, the patient experienced CHEST DISCOMFORT (Chest discomfort) (seriousness criteria hospitalization and disability), CHILLS (Chills) (seriousness criteria hospitalization and disability), COUGH (Cough) (seriousness criteria hospitalization and disability), DYSPNOEA (Dyspnoea) (seriousness criteria hospitalization and disability), FATIGUE (Fatigue/ tiredness) (seriousness criteria hospitalization and disability), PYREXIA (Pyrexia) (seriousness criteria hospitalization and disability) and MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization, disability and medically significant). At the time of the report, CHEST DISCOMFORT (Chest discomfort), CHILLS (Chills), COUGH (Cough), DYSPNOEA (Dyspnoea), FATIGUE (Fatigue/ tiredness), PYREXIA (Pyrexia) and MYOCARDITIS (Myocarditis) outcome was unknown.<br><br>The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown.<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments.<br><br>The patient had shortness of breath, chest pressure and tightness, chills, fever, fatigue, tiredness, cough, chest tightness when stand and outcome was myocarditis.<br><br>No treatment information was provided.<br><br>Company Comment: This case concerns a 35-year-old male patient, with no relevant details on medical history provided, who experienced the serious expected AESI of MYOCARDITIS. The event occurred one day after receiving the second dose of SPIKEVAX. The rechallenge is not applicable since no additional dose of Spikevax will be administered. The benefit-risk relation of Spikevax is not affected by this report. Seriousness |

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| | | criteria was assessed as per Regulatory Authority report, even if there is no evidence confirming the events met the disability criteria. |
| 4.1(b) | 4.1(b) | This case was received via 4.1(b) (Reference number: 4.1(b) on 12-Oct-2021 and was forwarded to Moderna on 12-Oct-2021.<br>This regulatory authority case was reported by an other health care professional and describes the occurrence of ANAPHYLACTIC REACTION (Anaphylactic reaction) and MYOCARDITIS (Myocarditis) in a 40-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 026L20A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below.<br><br>The patient's past medical history included Childhood asthma (History of childhood asthma).<br>Concurrent medical conditions included Drug allergy (Allergic to Sulfa).<br>Concomitant products included MULTIVITAMINS [VITAMINS NOS], CALCIUM, ZINC and VITAMIN C [ASCORBIC ACID] for an unknown indication.<br><br>On 01-Jan-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form.<br>On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 03-Feb-2021, the patient experienced ANAPHYLACTIC REACTION (Anaphylactic reaction) (seriousness criterion medically significant), MYOCARDITIS (Myocarditis) (seriousness criterion medically significant), BRONCHOSPASM (Bronchospasm) and HYPOTENSION (Hypotension).<br>On an unknown date, the patient experienced CHEST PAIN (chest pain), PALPITATIONS (palpitations), DYSPNOEA (shortness of breath), VERTIGO (vertigo) and HEADACHE (Headaches). The patient was treated with COLCHICINE for Myocarditis, at an unspecified dose and frequency. At the time of the report, ANAPHYLACTIC REACTION (Anaphylactic reaction), MYOCARDITIS (Myocarditis), BRONCHOSPASM (Bronchospasm) and HYPOTENSION (Hypotension) had resolved and CHEST PAIN (chest pain), PALPITATIONS (palpitations), DYSPNOEA (shortness of breath), VERTIGO (vertigo) and HEADACHE (Headaches) outcome was unknown.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 03-Feb-2021, Blood pressure measurement: 64/40 (Low) severe hypotension.<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments.<br><br>Patient reported full cardiac work up, ekg, echocardiogram, chest Vt, chest X-ray, etc. On 03-FEB-2021 Lab data included Cardiovascular examination, Chest X-ray, Computerized tomogram thorax, Echocardiogram, Electrocardiogram and results were not reported.<br>First dose: patient had chest pain, palpitations, shortness of breath, Headaches and vertigo symptoms. |

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| | | After 2nd: dose, patient had anaphylactic reaction with associated sxs bronchospasm and severe hypotension, 64/40. Later developed myopericarditis requiring treatment with colchicine.<br><br>This case concerns a 40 year-old female patient with history of childhood asthma, who experienced the expected serious events of Anaphylactic reaction and Myocarditis (AESI). The events occurred approximately one month after the second dose of mRNA-1273 vaccine. The patient's history of asthma remains a confounder for the non-serious event of bronchospasm reported as an associated symptom of anaphylaxis. Regarding the event of Myocarditis, patient reported full cardiac workup, however the details of clinical presentation, results of assessments/diagnostic criteria, and clinical course were not provided. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. |
| 4.1(b) | 4.1(b) | This case was received via 4.1(b) (Reference number: 4.1(b) on 12-Oct-2021 and was forwarded to Moderna on 12-Oct-2021.<br>This regulatory authority case was reported by an other health care professional (subsequently medically confirmed) and describes the occurrence of PERICARDITIS (Pericarditis) in a 32-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below.<br><br>Concurrent medical conditions included Fever ('flu like symptoms') since 23-Sep-2021, Malaise ('flu like symptoms') since 23-Sep-2021 and Myalgia ('flu like symptoms') since 23-Sep-2021.<br><br>On 23-Sep-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 25-Sep-2021, the patient experienced PERICARDITIS (Pericarditis) (seriousness criterion medically significant) and CHEST PAIN (Chest pain). The patient was treated with COLCHICINE at an unspecified dose and frequency. At the time of the report, PERICARDITIS (Pericarditis) and CHEST PAIN (Chest pain) outcome was unknown.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 25-Sep-2021, Angiogram: normal (normal) Normal.<br>On 25-Sep-2021, Blood test: negative (Negative) Patient had negative cardiac biomarkers.<br>On 25-Sep-2021, Chest X-ray: normal (normal) Normal.<br>On 25-Sep-2021, Echocardiogram: normal (normal) Normal.<br>On 25-Sep-2021, Electrocardiogram: normal (normal) Electrocardiogram.<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments.<br><br>No relevant concomitant medications were reported.<br><br>Treatment information included NSAIDs. |

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| | | Company Comment: This case concerns a 32-year-old, male patient with concurrent flu like symptoms, who experienced the unexpected events of pericarditis and chest pain. The event occurred approximately 3 days after the second dose of Moderna Covid-19 vaccine and had a unknown outcome. The rechallenge is not applicable, as no information was provided of the first dose. The benefit-risk relationship of the vaccine is not affected by this report. |
| 4.1(b) | 4.1(b) | This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) ) on 05-Oct-2021 and was forwarded to Moderna on 13-Oct-2021.<br>This case, reported by a physician, was received by Takeda via Moderna's adverse reaction reporting site (4.1(b) and reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref, 4.1(b)<br><br>On 14-Jul-2021, the patient received the 1st dose of this vaccine.<br><br>On an unknown date, body temperature before the vaccination: 36.2 degrees Celsius.<br><br>On 11-Aug-2021, at 16:00, the patient received the 2nd dose of this vaccine. At night, headache developed.<br><br>On 12-Aug-2021, in the morning, chest pain developed. Headache persisted.<br><br>On 13-Aug-2021, pyrexia of 38.4 degrees Celsius developed, and the patient took loxoprofen sodium hydrate.<br><br>On 14-Aug-2021, the symptoms were exacerbated in the early morning, and the patient was hospitalized. Suspected myocarditis was diagnosed.<br><br>On 18-Aug-2021, the symptoms were resolving, and the patient was discharged from the hospital.<br><br>On 02-Sep-2021, the symptoms resolved.<br><br>The outcome of pyrexia, chest pain, headache, and suspected myocarditis was reported as resolved.<br><br>Follow-up investigation was attempted, but follow-up investigation was impossible because of the non-cooperation of the reporter.<br><br>Follow-up received on 09-NOV-2021<br><br>Updated: Lab Data, Narrative<br><br>Company Comment:<br>The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. |
| 4.1(b) | 4.1(b) | This spontaneous case was reported by a consumer and describes the occurrence of MYOCARDITIS (Myocarditis) in a 24-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 022C21A and 022C21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. |

| Case ID | WW Identifier | Narrative |
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| | | No Medical History information was reported.<br><br>On 31-Aug-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form.<br>On 01-Oct-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 05-Oct-2021, after starting mRNA-1273 (Moderna COVID-19 Vaccine), the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). In October 2021, the patient experienced IMPAIRED WORK ABILITY (cannot do strenuous work or exercise for a month). The patient was hospitalized from sometime in October 2021 to sometime in October 2021 due to MYOCARDITIS. At the time of the report, MYOCARDITIS (Myocarditis) was resolving and IMPAIRED WORK ABILITY (cannot do strenuous work or exercise for a month) outcome was unknown.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>In October 2021, Electrocardiogram: normal (normal) EKG looked normal.<br>In October 2021, Troponin: high (High) High troponin levels.<br><br>No concomitant medications were provided.<br><br>Patient had no prior history for the symptoms nor a history of COVID-19 infection. He had no medical or family history for myocarditis/pericarditis.<br><br>Patient experienced strong chest pain in the morning. He would rate the pain about 7 out of 10; 10 being the strongest pain. Walking or stretching would not make it better or worse. It was a constant stable pain. It was quite noticeable. The pain lasted 2-3 hours. The symptoms started on 05 Oct 2021 from 7 AM to 10:30 AM. The symptoms repeated everyday. On 06 Oct 2021, at about 9 AM to10:30 AM, the pain was less than on 05 Oct 2021. On 07 Oct 2021, it was less noticeable, but he could still feel the pain. Patient was kept under observation for a day and then they discharged him. He felt better and he did not have any symptoms now. He could not do strenuous work or exercise for a month. The hospital summary suspected the second dose of Moderna COVID-19 vaccine as the cause.<br><br>Patient received an injection in his belly that made his blood flow better. He was given a blood thinner injection. He reported that the hospital told him he could take Tylenol but he never did.<br><br>Company Comment : This case concerns a 24-year-old male patient with no relevant medical history, who experienced the serious expected event of Myocarditis. The event occurred approximately 5 days after the Moderna COVID-19 Vaccine. The patient had high troponin levels and EKG was normal. The patient was under observation for a day then got discharged. The rechallenge was not applicable as the event occurred after the second dose. The patient received the second dose |

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| | | approximately a month after the first dose. The benefit-risk relationship of COVID-19 Vaccine is not affected by this report. |
| 4.1(b) | | This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) ) on 29-Sep-2021 and was forwarded to Moderna on 13-Oct-2021.<br>This case, initially reported to the 4.1(b) 4.1(b) by a (physician), was received via the 4.1(b) (Ref, 4.1(b)<br><br>On an unknown date, the patient received the 1st dose of this vaccine.<br><br>On 19-Sep-2021, at 15:00, the patient received the 2nd dose of this vaccine.<br><br>On 21-Sep-2021, at 12:00, pyrexia of 40 degrees Celsius developed. Thereafter, chest pain developed. The patient was raced to the reporting hospital and hospitalized. Electrocardiogram showed 1, aVL, and ST-T elevation from V4 to V6. Echocardiography showed decreased wall motion of the inferior wall of the left ventricle and LVEF of 47%. Blood test showed increased CK 600 IU/L. The patient was diagnosed with myocarditis. The patient rested, and oral administration of bisoprolol fumarate and losartan potassium were performed.<br><br>On 27-Sep-2021, left ventricular systolic performance became normal.<br><br>On 28-Sep-2021, the symptoms were resolving. The patient was discharged from the hospital.<br><br>The outcome of pyrexia, chest pain, and myocarditis was reported as resolving.<br><br>Follow-up investigation will be made.<br><br>Company Comment:<br><br>The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. |
| 4.1(b) | 4.1(b) | This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 30-Sep-2021 and was forwarded to Moderna on 13-Oct-2021.<br><br>This case, initially reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref, 4.1(b)<br><br>On an unknown date, the patient received the 1st dose of the vaccine.<br><br>On 19-Sep-2021, the patient received the 2nd dose of the vaccine. After the vaccination, the patient experienced pyrexia.<br><br>On 21-Sep-2021, at 16:12, the patient visited the reporting hospital. From around 17:00, the patient had chest pain. An electrocardiogram showed low levels in I, II, and III. ST elevations were found in from V3 through V6. The result of blood sampling revealed elevations such as CK of 678 IU/L and CK-MB of 51 IU/L. There were also increases as WBC was |

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| | | 12,400 with CRP of 15.7 mg/dL. PEAK CK: 2,294 IU/L, CK-MB: 148 IU/L. Heart CT showed no abnormalities in the coronary artery while heart MRI revealed delayed imaging of the posterior wall of the left ventricle. Based on the above, the patient was diagnosed with myocarditis and was hospitalized.<br><br>On 29-Sep-2021, the symptom was relieved, and the patient was discharged from the hospital.<br><br>The outcome of myocarditis was reported as resolving.<br><br>Follow-up investigation will be made.<br><br>Company Comment:<br><br>The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. |
| 4.1(b) | 4.1(b) | This case was initially received via Takeda Pharmaceuticals (Reference number: 4.1(b) ) on 06-Oct-2021. The most recent information was received on 11-Nov-2021 and was forwarded to Moderna on 22-Nov-2021.<br>This case, initially reported to the 4.1(b) by a (physician), was received via the 4.1(b) (Ref, 4.1(b)<br><br>On 11-Nov-2021, follow-up information, initially reported by a physician, was received by Takeda Pharmaceutical Company Limited via Modernas adverse reaction reporting site (4.1(b)<br><br>On an unknown date, the patient received the 1st dose of this vaccine.<br><br>On an unknown date, body temperature before the vaccination: 36.2 degrees Celsius.<br><br>On 29-Sep-2021, at 11:00, the patient received the 2nd dose of this vaccine. At around 23:00, pyrexia developed.<br><br>On 30-Sep-2021, at around 03:00, chest pain developed. Pyrexia was in 39 degrees Celsius level. The symptom did not improve, and the patient visited a hospital. Breathlessness or oedema was not observed. The patient was diagnosed with acute pericarditis based on chest pain exacerbated by inhalation and recumbent position and PR depression on an electrocardiogram. The patient was hospitalized. There was no elevated cardiac deviation enzyme in the blood test. During the course, no pericardial effusion or progression to myocarditis was observed. The patient was treated with aspirin and colchicine during hospitalization.<br><br>On 09-Oct-2021, the symptoms were resolving, and the patient was discharged from the hospital.<br><br>On 26-Oct-2021, the symptoms was resolving.<br><br>The outcome of acute pericarditis was reported as resolving. |

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| | | No Follow-up investigation will be made.<br><br>Follow-up received on 11-NOV-2021<br><br>Updated: Other Relevant History, Lab Data, Event Information, Narrative, Reporter Comments<br><br>Company Comment:<br><br>The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. |
| 4.1(b) | 4.1(b) | This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) ) on 07-Oct-2021 and was forwarded to Moderna on 14-Oct-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Acute myocarditis) in an 18-year-old male patient who received mRNA-1273 (COVID 19 Vaccine Moderna) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 27-Sep-2021, the patient received second dose of mRNA-1273 (COVID 19 Vaccine Moderna) (Intramuscular) dosage was changed to 1 dosage form.<br>On an unknown date, the patient received first dose of mRNA-1273 (COVID 19 Vaccine Moderna) (Intramuscular) 1 dosage form. On 29-Sep-2021, after starting mRNA-1273 (COVID 19 Vaccine Moderna), the patient experienced MYOCARDITIS (Acute myocarditis) (seriousness criteria hospitalization and medically significant). On 06-Oct-2021, MYOCARDITIS (Acute myocarditis) had resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 29-Sep-2021, Alanine aminotransferase: 56 enzyme unit per litre 56.<br>On 29-Sep-2021, Aspartate aminotransferase: 88 enzyme unit per litre 88.<br>On 29-Sep-2021, Blood creatine phosphokinase: 770 Test Result:770.<br>On 29-Sep-2021, Blood lactate dehydrogenase: 246 enzyme unit per litre 246.<br>On 29-Sep-2021, Brain natriuretic peptide: 20.6 picogram per millilitre 20.6.<br>On 29-Sep-2021, C-reactive protein increased: 1.17 milligram per decilitre 1.17.<br>On 29-Sep-2021, Echocardiogram: preserved ef, no asynergy, no valvular disease, an Echocardiography showed preserved EF, no asynergy, no valvular disease, and no pericardial and pleural effusion.<br>On 29-Sep-2021, Electrocardiogram: st elevation in v2-6 Electrocardiogram showed ST elevation in V2-6..<br>On 29-Sep-2021, Polymerase chain reaction: negative (Negative) PCR test for SARS-CoV-2 was negative..<br>On 29-Sep-2021, Troponin: 10.2922 milliliter 10.2922.<br>On 29-Sep-2021, White blood cell count: 6200 u/l U/L Test Result: 6,200 U/L. |

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| | | On 30-Sep-2021, Blood creatine phosphokinase: 988 Test Result:988 (CK-MB 84.2).<br><br>For mRNA-1273 (COVID 19 Vaccine Moderna) (Intramuscular), the reporter considered MYOCARDITIS (Acute myocarditis) to be possibly related.<br><br>This case refers to a 18-year-old male patient with no known medical history who experienced the expected event of Myocarditis approximately 1 day after the second dose of Moderna COVID-19 Vaccine. Rechallenge was assessed as not applicable. The event was considered related to the vaccine per the reporter's assessment. The benefit-risk relationship of Moderna COVID-19 Vaccine is not affected by this report. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 14-Oct-2021 and was forwarded to Moderna on 14-Oct-2021.<br>This regulatory authority prospective pregnancy case was reported by a physician and describes the occurrence of MYOCARDITIS (Myocarditis) and MATERNAL EXPOSURE DURING PREGNANCY (Maternal exposure during pregnancy) in a 29-year-old female patient who received mRNA-1273 (Spikevax) (batch nos. 3004955 and 214001) for COVID-19 vaccination.<br><br>The patient's past medical history included Myocarditis in 2018.<br><br>On 15-Jul-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form.<br>On 31-Aug-2021, received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. Last menstrual period and estimated date of delivery were not provided. On 01-Oct-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization prolonged and medically significant). On an unknown date, the patient experienced MATERNAL EXPOSURE DURING PREGNANCY (Maternal exposure during pregnancy) (seriousness criterion hospitalization prolonged). The patient was hospitalized on 01-Oct-2021 due to MYOCARDITIS. At the time of the report, MYOCARDITIS (Myocarditis) and MATERNAL EXPOSURE DURING PREGNANCY (Maternal exposure during pregnancy) was resolving.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On an unknown date, SARS-CoV-2 test: negative (Negative) negative.<br><br>For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.<br><br>No concomitant and treatment medication were provided<br>Gestation period when reaction/event was observed in the fetus was 15 weeks<br><br>This case concerns a 29 year old female patient, with medical history of myocarditis 3 years ago, who experienced serious expected event of |

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| | | myocarditis and unexpected event of maternal exposure during pregnancy. The patient received the second dose of vaccine at 11 weeks of gestation. The event myocarditis occurred at 15 weeks of gestation (1 month after second dose of mRNA-1273). The re-challenge is not applicable since no information is available. Patient´s past medical history of myocarditis remains a confounder. The benefit-risk relationship of Spikevax in not affected by this report. Events seriousness captured as per Regulatory Authority assessment in the Source Document.<br><br>Upon internal review on 02-Dec-2021, gestation period at event onset was corrected to 15 weeks.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 14-Oct-2021: Translation document received on 15-Oct-2021 include NNI<br>On 15-Oct-2021: Follow up received on 15-Oct-2021 it contains no new information |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 14-Oct-2021 and was forwarded to Moderna on 14-Oct-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myocarditis) in a 15-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19.<br><br>No Medical History information was reported.<br><br>On 23-Sep-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 25-Sep-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Myocarditis) had not resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 28-Sep-2021, Serum ferritin: 133 (normal) 133 ng/mL.<br>On 29-Sep-2021, Troponin I: 243.8 (High) 243.8 pg/ml.<br>On 30-Sep-2021, Troponin I: 67.7 (High) 67.7 pg/ml.<br>On 01-Oct-2021, Troponin I: 32.9 (High) 32.9 pg/ml.<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments.<br><br>Concomitant information was not provided.<br>Treatment information was not provided.<br><br>Company comment:<br>The case concerns a 15-year-old-male patient with no relevant medical history, who experienced the expected event of myocarditis. The event occurred approximately 2 days after the first dose of Spikevax, with the highest level of Troponin I on day 4 after the vaccination. The rechallenge was unknown since there's no information about the first dose. The benefit-risk relationship of Spikevax is not affected by this report. |

| Case ID | WW Identifier | Narrative |
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| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 14-Oct-2021 and was forwarded to Moderna on 14-Oct-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myocarditis) in a 33-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3004217) for Prophylactic vaccination.<br><br>No Medical History information was reported.<br><br>On 12-Jul-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form.<br>On 23-Aug-2021, received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. On 24-Aug-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization, medically significant and life threatening). At the time of the report, MYOCARDITIS (Myocarditis) outcome was unknown.<br><br>For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.<br><br>There is an Inappropriate schedule of vaccine administered as the gap between the doses was 42 days.<br>No concomitant medications reported by reporter.<br><br>No treatment medications provided by the reporter.<br><br>Company comment:<br>This case concerns a 33 year old male with no reported history who experienced the serious, listed event of Myocarditis the day after the second dose of Spikevax. Re-challenge is not applicable as this was dose 2. Benefit-risk relationship of Spikevax is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 14-Oct-2021: Translation received on 18-OCT-2021: Contains No new information. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 14-Oct-2021 and was forwarded to Moderna on 14-Oct-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myocarditis) in a 34-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3005238) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 23-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 30-Sep-2021, after starting mRNA-1273 (Spikevax), the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Myocarditis) was resolving. |

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| | | For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.<br><br>Concomitant product use was not provided by the reporter.<br>Treatment information was not provided.<br><br>Company comment: This case concerns a 34-year-old, male patient with no relevant medical history, who experienced the expected serious event of Myocarditis. The event occurred approximately 08 days after the second dose of Spikevax. The rechallenge was not applicable. The event is consistent with the current understanding of the mechanism of action of the vaccine. The benefit-risk relationship of Spikevax is not affected by this report. Event term, onset date, outcome and seriousness captured per SD from Regulatory Authority reporting.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 14-Oct-2021: Translation document received on 16-OCT-2021, contains translated event verbatim, and product dose information. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 14-Oct-2021 and was forwarded to Moderna on 14-Oct-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Perimyocarditis), CHEST PAIN (Chest discomfort after the 2nd vaccination) and MALAISE (Malaise after the 2nd vaccination) in a 29-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 3004954 and 3004954) for COVID-19 immunisation.<br><br>No Medical History information was reported.<br><br>On 23-Aug-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form.<br>On 20-Sep-2021, received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to 1 dosage form. On 20-Sep-2021, the patient experienced MYOCARDITIS (Perimyocarditis) (seriousness criteria hospitalization and medically significant), CHEST PAIN (Chest discomfort after the 2nd vaccination) (seriousness criterion hospitalization) and MALAISE (Malaise after the 2nd vaccination) (seriousness criterion hospitalization). At the time of the report, MYOCARDITIS (Perimyocarditis) had not resolved and CHEST PAIN (Chest discomfort after the 2nd vaccination) and MALAISE (Malaise after the 2nd vaccination) outcome was unknown.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 23-Sep-2021, C-reactive protein: 18 (abnormal) 18 Unit not specified.<br>On 23-Sep-2021, Electrocardiogram: unknown (abnormal) Compatible with perimyocarditis.<br>On 23-Sep-2021, Troponin T: 243-465 (High) Increasing, unit not specified.<br>On 23-Sep-2021, White blood cell count: 5.8 (abnormal) 5.8 Unit not specified. |

| Case ID | WW Identifier | Narrative |
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| | | For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.<br><br>No concomitant medication provided.<br>No treatment information mentioned.<br><br>Company comment: This case concerns a 29-year-old, male patient with no relevant medical history, who experienced the serious unexpected events of Chest pain and Malaise and the serious expected (AESI) of Myocarditis. The events occurred on the same day after the 2nd dose of mRNA-1273. Relevant labs like ECG result was suggestive of perimyocarditis, other lab results include an increase in Troponin T, abnormal C-reactive protein, and an abnormal leukocyte count. The rechallenge was not applicable since the event occurred after the second dose. The benefit-risk relationship of mRNA-1273 is not affected by this report. Event seriousness assessed as per Regulatory Authority reporting and retained for consistency with the RA report. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 14-Oct-2021 and was forwarded to Moderna on 14-Oct-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (acute myocarditis) in a 37-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination.<br><br>Concurrent medical conditions included Ulcer peptic, Alcohol use (1 glass per week), Cannabis use (1 joint/3 days), Tabaquism (3 cigarettes per day) and Obesity (BMI = 30.5).<br>Concomitant products included ESOMEPRAZOLE for an unknown indication.<br><br>On 24-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 25-Sep-2021, the patient experienced MYOCARDITIS (acute myocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (acute myocarditis) was resolving.<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.<br><br>No treatment medication was provided.<br>The patient received vaccine on unknown deltoid.<br><br>Company Comment:<br>This case concerns a 37-year-old, male patient with relevant medical history of Alcohol use, Cannabis use, Tabaquism and Obesity, who experienced the unexpected AESI event of Myocarditis. The event occurred approximately 1 day after the second dose of Spikevax, which resulted in an outcome of Hospitalization. The rechallenge was unknown since no information about the events of the first dose was disclosed. The patient's medical history of Alcohol use, Cannabis use, Tabaquism and Obesity remain as confounders for the occurrence of the event. The |

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| | | benefit-risk relationship of Moderna CoviD-19 Vaccine is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 14-Oct-2021: Translated document received on 18-Oct-2021 included suspect product route of administration updated and relevant medical history, concurrent conditions related and comments updated. |
| 4.1(b) | 4.1(b) | This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) ) on 08-Oct-2021 and was forwarded to Moderna on 14-Oct-2021.<br>This case, initially reported to the 4.1(b) by a pharmacist, was received via the 4.1(b) (Ref, 4.1(b)<br><br>On an unknown date, the patient received the 1st dose of this vaccine.<br><br>On 28-Sep-2021, the patient received the 2nd dose of this vaccine. Only on the same day, the patient had low-grade fever.<br><br>On 01-Oct-2021, at 06:30, myocarditis developed. The patient felt pressure in the precordium after waking up. Because the symptoms persisted for about 1 hour and a half, the patient visited a medical institution. The symptoms had disappeared by the time the patient left home. The negative T wave of V1 was noted in the electrocardiogram. The patient had no medical or medication history and had no problems with other collagen diseases. The patient was hospitalized.<br><br>On 05-Oct-2021, the symptoms were resolving, and the patient was discharged from the hospital.<br><br>The outcome of low-grade fever was reported as recovered. The outcome of myocarditis was reported as resolving.<br><br>Follow-up investigation will be made.<br><br>Company Comment:<br><br>The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 14-Oct-2021 and was forwarded to Moderna on 14-Oct-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myocarditis) in an 18-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination.<br><br>Concurrent medical conditions included Strength training with creatine supplementation.<br><br>On 31-Aug-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 01-Sep-2021, after starting mRNA-1273 (Spikevax), the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically |

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| | | significant). At the time of the report, MYOCARDITIS (Myocarditis) was resolving.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 04-Sep-2021, SARS-CoV-2 test: negative (Negative) Negative.<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered MYOCARDITIS (Myocarditis) to be possibly related.<br><br>No concomitant medication was reported.<br>Treatment medication was not provided by the reporter.<br>Patient was under strength training with creatine supplementation.<br><br>Company Comment: This case concerns an 18-year-old, male patient with no relevant medical history, who experienced the expected serious event of myocarditis. The event, which resulted in hospitalization, occurred 1 day after administration of the second dose of the Moderna COVID-19 Vaccine. The rechallenge was not applicable as no additional dosing will be given. The benefit-risk relationship of the Moderna COVID-19 Vaccine is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 14-Oct-2021: Translation document was received on 15-Oct-2021 which contains text for relevant medical history and concurrent conditions was translated. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 14-Oct-2021 and was forwarded to Moderna on 14-Oct-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myocarditis) in a 17-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3005888) for COVID-19 vaccination.<br><br>The patient's past medical history included Papillomatosis (Cutaneous Papillomatosis) in July 2020.<br>Concurrent medical conditions included Disorders of refraction and accommodation, other since 2012.<br><br>On 20-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 23-Sep-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Myocarditis) was resolving.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 23-Sep-2021, Echocardiogram: abnormal (abnormal) VI non-dilated, non-hypertrophic with preserved SF. Normal global and segmental contractility. Non-dilated aortic root and LA. Structurally preserved mitral valve with good opening and without MI. Non-thickened tricuspid aortic valve with good opening and without aortic insufficiency. Non-dilated right heart cavities with good RV systolic function. Tricuspid valve with normal |

| Case ID | WW Identifier | Narrative |
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| | | TI and normal sPAP. Normal pericardium. Non-dilated IVC with adequate inspiratory collapse. Normal diastolic function. Normal aortic arch and normal position of coronary arterial ostia. Normal PA..<br>On 24-Sep-2021, Magnetic resonance imaging heart: abnormal (abnormal) VI non-dilated, non-hypertrophic with preserved SF. Normal global and segmental contractility. Non-dilated aortic root and LA. Structurally preserved mitral valve with good opening and without MI. Non-thickened tricuspid aortic valve with good opening and without aortic insufficiency. Non-dilated right heart cavities with good RV systolic function. Tricuspid valve with normal TI and normal sPAP. Normal pericardium. Non-dilated IVC with adequate inspiratory collapse. Normal diastolic function. Normal aortic arch and normal position of coronary arterial ostia. Normal PA..<br><br>For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.<br><br>No concomitant medications were provided.<br>No treatment medications were reported.<br><br>company comment:<br>This case concerns a 17 year-old, male patient with no relevant medical history, who experienced the serious (due to hospitalization) unexpected AESI event of Myocarditis. The event occurred approximately 4 days after the second dose of Spikevax. The rechallenge was not applicable, as the event was reported exclusively after the second dose. The benefit-risk relationship of Spikevax is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 14-Oct-2021: Translation received date 18OCT2021 Medical history comment ,Lab data result , Dosage text updated |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 14-Oct-2021 and was forwarded to Moderna on 14-Oct-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of PERICARDITIS ( 4.1(b) ) in a 25-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3003604) for COVID-19 vaccination.<br><br>Previously administered products included for Vaccination: Spikevax.<br><br>On 27-Aug-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to 1 dosage form.<br>On an unknown date, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 29-Sep-2021, the patient experienced PERICARDITIS ( 4.1(b) ) (seriousness criteria hospitalization and medically significant). At the time of the report, PERICARDITIS ( 4.1(b) ) was resolving.<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered PERICARDITIS ( 4.1(b) ) to be possibly related.<br><br>No relevant concomitant and treatment medications were reported. |

| Case ID | WW Identifier | Narrative |
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| | | Company Comment: This case concerns a 25-year-old male patient with no reported medical history, who experienced the expected event of pericarditis. The event occurred I month 2 days after the second dose of mRNA-1273 (Spikevax). The rechallenge was unknown as no details about the first dose was disclosed. Causality for the reported event was assessed as related by the reporter. Pericarditis is consistent with the current understanding of the mechanism of action of the vaccine. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report. Events assessed as medically significant per regulatory authority reporting. Pericarditis is an adverse event of special interest.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 14-Oct-2021: Translation of follow up document received on 18-OCT-2021, which contains no new information<br>On 22-Oct-2021: Non-significant follow up |
| 4.1(b) | 4.1(b) | This case was initially received via European Medicines Agency (Reference number: 4.1(b) ) on 14-Oct-2021. The most recent information was received on 15-Oct-2021 and was forwarded to Moderna on 15-Oct-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (4.1(b) ) in a 39-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 3005835 and 3004218) for COVID-19 vaccination.<br><br>The patient's past medical history included Graves' disease.<br><br>On 23-Jul-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form.<br>On 28-Sep-2021, received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. On 30-Sep-2021, after starting mRNA-1273 (Spikevax), the patient experienced MYOCARDITIS (4.1(b) ) (seriousness criterion hospitalization). At the time of the report, MYOCARDITIS (4.1(b) ) was resolving.<br><br>For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.<br><br>Concomitant medication use was unknown. Treatment information was unknown.<br><br>Company comment:<br>This case concerns a 39-year-old male patient with relevant medical history of Basedow's disease, who experienced the expected serious AESI event of Myocarditis. The event occurred approximately 3 days after the second dose of Spikevax administration. The rechallenge was not applicable since no events were reported after the first dose and no additional dosing was expected. The administrative event of Inappropriate schedule of vaccine administered was considered. The benefit-risk relationship is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes: |

| Case ID | WW Identifier | Narrative |
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| | | On 14-Oct-2021: Translation document received on 15-oct-21 include dosage text, history<br>On 15-Oct-2021: Translated document received on 15-OCT-2021 contains updated dose 1 and dose 2 lot number. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 14-Oct-2021 and was forwarded to Moderna on 14-Oct-2021.<br>This regulatory authority case was reported by a consumer and describes the occurrence of PERICARDITIS (Pericarditis), CHEST PAIN (Chest pains) and HOSPITALISATION (hospitalised) in a 25-year-old female patient who received mRNA-1273 (Spikevax) for Vaccination.<br><br>Concurrent medical conditions included Abstains from alcohol and Non-smoker.<br>Concomitant products included DROSPIRENONE, ETHINYLESTRADIOL (YASMIN) for Contraception.<br><br>On 01-Sep-2021 at 12:00 PM, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 03-Sep-2021, the patient experienced PERICARDITIS (Pericarditis) (seriousness criteria hospitalization, medically significant and life threatening) and CHEST PAIN (Chest pains) (seriousness criteria hospitalization and medically significant). On an unknown date, the patient experienced HOSPITALISATION (hospitalised) (seriousness criterion hospitalization). At the time of the report, PERICARDITIS (Pericarditis) was resolving and CHEST PAIN (Chest pains) and HOSPITALISATION (hospitalised) outcome was unknown.<br><br>No treatment medication details was reported.<br>On 03 Sep 2021, the patient developed acute chest pain. She was hosptalised with acute pericarditis.<br>Company comment: This case concerns a 25 year-old female patient with a reported medical history of non-tobacco, non-alcohol use, on drospirenone and ethinyl lestradiol who experienced the unexpected serious events of pericarditis, which is an AESI, chest pain and hospitalization. The events occurred approximately 2 days after the second dose of mRNA-1273 (Spikevax). The rechallenge was not applicable as no additional dosing will be administered. The benefit-risk relationship of mRNA-1273 (Spikevax) is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 14-Oct-2021: Translation document received on 18 Oct 2021 and event verbatims was translated. |
| 4.1(b) | 4.1(b) | This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myocarditis) in a 31-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination.<br><br>No Medical History information was reported. |

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| | | On 23-Aug-2021, the patient received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 200 microgram. On 27-Aug-2021, after starting mRNA-1273 (COVID-19 Vaccine Moderna), the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). On 31-Aug-2021, MYOCARDITIS (Myocarditis) was resolving.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 28-Aug-2021, Blood creatine phosphokinase: 297 u/ml (High) 297 U/ml.<br>On 28-Aug-2021, Troponin: 581 ng/l (High) 581 ng/l.<br><br>For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered MYOCARDITIS (Myocarditis) to be possibly related.<br><br>Concomitant product use was not provided by reporter.<br>Treatment information was not provided.<br><br>Company comment: This case concerns a 31-year-old, male patient, with no disclosed medical history, who experienced the serious, expected, AESI event of Myocarditis. The events occurred 4 days after second dose of Moderna vaccine. The event was considered related to the product per the reporter's assessment. The rechallenge is not applicable as a third dose is not expected. The benefit-risk relationship of Moderna vaccine is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 14-Oct-2021: Translated document received on 18-Oct-2021 included Updated Event Verbatim, Updated lab data from initial version. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 15-Oct-2021 and was forwarded to Moderna on 15-Oct-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myopericarditis) in a 23-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 214020 and 214010) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 18-Jul-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form.<br>On 15-Aug-2021, received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. On 17-Aug-2021, the patient experienced MYOCARDITIS (Myopericarditis) (seriousness criterion medically significant). At the time of the report, MYOCARDITIS (Myopericarditis) was resolving.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 18-Aug-2021, Troponin T (0-14): 160 pg/ml (High) 160 pg/ml. |

| Case ID | WW Identifier | Narrative |
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| | | For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.<br><br>Concomitant product use was not provided by the reporter.<br>Treatment information was not provided.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 15-Oct-2021: Translation received on 18 Oct 2021 included: Event as reported by primary source has changed, dosage text updated. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 15-Oct-2021 and was forwarded to Moderna on 15-Oct-2021.<br>This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (I had the second dose of the Moderna vaccine on 22-Jun-2021 and 3 4 days I started having symptoms (final diagnosis, acute perimyocarditis). Admitted to hospital for 1 month) in a 37-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 214003) for COVID-19 immunization.<br><br>No Medical History information was reported.<br><br>On 22-Jun-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form in total. On 26-Jun-2021, after starting mRNA-1273 (Spikevax), the patient experienced MYOCARDITIS (I had the second dose of the Moderna vaccine on 22-Jun-2021 and 3 4 days I started having symptoms (final diagnosis, acute perimyocarditis). Admitted to hospital for 1 month) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (I had the second dose of the Moderna vaccine on 22-Jun-2021 and 3 4 days I started having symptoms (final diagnosis, acute perimyocarditis). Admitted to hospital for 1 month) had not resolved.<br><br>Concomitant product use was not provided by the reporter.<br>Treatment medication was not provided by the reporter.<br><br>Before the second dose the patient was in good health, and was sporty and used to play basketball.<br><br>This case concerns a 37-year-old male patient with no relevant medical history, who experienced the expected serious AESI event of Myocarditis. The event occurred approximately 5 days after the second dose of Spikevax administration. The rechallenge was not applicable since no events were reported after the first dose and no additional dosing was expected. The benefit-risk relationship is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 15-Oct-2021: Translation received on 18-Oct-2021, included significant information ( Event verbatim translated ).<br>On 29-Oct-2021: follow up received on 29-OCT-2021 contains no new information<br>On 29-Oct-2021: Translation for follow-up received on 02-Nov-2021, containing no new information |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 15-Oct-2021 and was forwarded to Moderna on 15-Oct-2021. |

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| | | This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (Pressure on the chest, increased inspiratory, perimyocarditis) in an 18-year-old male patient who received mRNA-1273 (Spikevax) for Prophylactic vaccination.<br><br>No Medical History information was reported.<br><br>On 23-Aug-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form.<br>On an unknown date, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 26-Aug-2021, the patient experienced MYOCARDITIS (Pressure on the chest, increased inspiratory, perimyocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Pressure on the chest, increased inspiratory, perimyocarditis) was resolving.<br><br>Concomitant medication information was not provided by the reporter.<br>Treatment information was not provided by the reporter.<br><br>Patient has allergies to Strawberry or Apple.<br><br>It was reported that inpatient admission to the hospital, as part of the diagnostics (TTE / laboratory / MR) then evidence of peri myocarditis.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 15-Oct-2021: Translation received on 19-Oct-2021 contains Significant Information. Reaction/event as reported by primary source is updated. Sender's comments is updated. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 15-Oct-2021 and was forwarded to Moderna on 15-Oct-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myopericarditis) in an 18-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 23-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 25-Sep-2021, the patient experienced MYOCARDITIS (Myopericarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Myopericarditis) was resolving.<br><br>For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.<br><br>No concomitant medications was reported.<br>No treatment information was provided. |

| Case ID | WW Identifier | Narrative |
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| | | Company Comment: This case concerns an 18-year-old male patient with no relevant medical history who experienced serious expected event of Myocarditis. The event occurred two days after the patient had received the second dose of Spikevax. Except that the event was resolving at the time of the report, no further information was provided regarding the clinical course of the event. The rechallenge is not applicable as the event occurred after the second dose of Spikevax. The benefit-risk relationship of Spikevax is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 15-Oct-2021: Translation received on 20-OCT-2021 included Event verbatim translated. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) on 15-Oct-2021 and was forwarded to Moderna on 15-Oct-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Perimyocarditis) in a 33-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 3004730 and 3004959) for COVID-19 immunisation.<br><br>No Medical History information was reported.<br><br>On 21-Aug-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form.<br>On 02-Oct-2021, received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to 1 dosage form. On 04-Oct-2021, after starting mRNA-1273 (Spikevax), the patient experienced MYOCARDITIS (Perimyocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Perimyocarditis) had not resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>In October 2021, Ejection fraction: low (Low) Decreased LVEF.<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.<br><br>On OCT-2021 patient went through Blood test and Echocardiography with unknown results<br><br>No relevant concomitant and treatment medications were reported<br><br>Company Comment: This authority report concerns a 33 year old male patient with no relevant medical history who experienced a serious expected event of peri myocarditis. The event occurred 2 days after the second dose and nearly 1.5 months after the first dose of mRNA-1273 respectively. The patient was administered second dose 42 days (which is more than the 25-35 days window period) after the first dose of mRNA-1273. Hence, an additional non-serious event of inappropriate schedule of vaccine administration was considered. As per the report, the patient was hospitalized for the event and was noted to have decreased left ventricular ejection fraction. The report also states that blood tests and echocardiography were performed but the results were not provided. Re- |

| Case ID | WW Identifier | Narrative |
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| | | challenge is not applicable as the event happened after the second dose and no additional dosing will be given. The patient had not recovered from the event at the time of the report. The benefit-risk relationship of mRNA-1273 is not affected by this report. |
| 4.1(b) | 4.1(b) | This case was initially received via European Medicines Agency (Reference number: 4.1(b) ) on 15-Oct-2021. The most recent information was received on 02-Nov-2021 and was forwarded to Moderna on 02-Nov-2021.<br>This regulatory authority case was reported by a consumer and describes the occurrence of PERICARDITIS (Pericarditis) and MYOCARDITIS (Heart Inflammation, Acute Myocarditis) in a 21-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 3005242 and 3003659) for COVID-19 vaccination.<br><br>The patient's past medical history included Adverse reaction to antibiotics (AT 5 YEARS OF AGE).<br>Concurrent medical conditions included Taste loss (Covid symptoms remain), COVID-19 since January 2021, Intestinal inflammation, Smell loss (Covid symptoms remain), General physical condition decreased (COVID SYMPTOMS REMAIN.) and Ulcerative colitis (AFTER COVID, 9 MONTHS AGO, CAME TO THE GASTROENTEROLOGY DEPARTMENT,TOTAL ULCERATIVE COLITIS) since August 2021.<br>Concomitant products included MESALAZINE (ASACOL) for an unknown indication.<br><br>On 07-Jul-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form.<br>On 29-Aug-2021, received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. On 15-Sep-2021, the patient experienced PERICARDITIS (Pericarditis) (seriousness criteria hospitalization, disability, medically significant and life threatening) and MYOCARDITIS (Heart Inflammation, Acute Myocarditis) (seriousness criteria hospitalization, disability, medically significant and life threatening). At the time of the report, PERICARDITIS (Pericarditis) and MYOCARDITIS (Heart Inflammation, Acute Myocarditis) was resolving.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 16-Sep-2021, SARS-CoV-2 test: negative (Negative) negative.<br><br>For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.<br><br>Treatment information was not provided.<br><br>Company Comment: This case concerns a 21-year-old, male patient with a history of COVID-19, and concomitant use of Mesalazine, who experienced the serious, expected (AESI) of Pericarditis and Myocarditis. The events occurred approximately 17 days after the second dose of Moderna COVID-19 vaccine. The rechallenge was not applicable, as the events were reported exclusively after the second dose. The medical history of COVID-19, and concomitant use of Mesalazine remain as confounders. The benefit-risk relationship of Moderna COVID-19 vaccine is not affected by this report. |

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| | | Most recent FOLLOW-UP information incorporated above includes: On 02-Nov-2021: Follow-up received contains new reporter details, added patient's medical conditions (ulcerative colitis) and updated additional information to all medical conditions), added lab data and event of cardiac disorder deleted as it is updated to Acute Myocarditis as per SD and added concomitant product Asacol<br>On 02-Nov-2021: Translated document received on 05-Nov-2021, included medical History translated and event verbatim translated. |
| 4.1(b) | 4.1(b) | This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) ) on 08-Oct-2021 and was forwarded to Moderna on 15-Oct-2021.<br>This case, initially reported to the 4.1(b) by a (physician), was received via the 4.1(b) (Ref, 4.1(b)<br><br>On 03-Sep-2021, the patient received the 1st dose of the vaccine.<br><br>On an unknown date, body temperature before the vaccination: 36.4 degrees Celsius.<br><br>On 01-Oct-2021, at 15:00, the patient received the 2nd dose of the vaccine. At night, pyrexia developed.<br><br>On 02-Oct-2021, fever subsided.<br><br>On 03-Oct-2021, the patient had chest pain.<br><br>On 04-Oct-2021, the symptom was aggravated, and the patient was emergently transported to hospital. There were elevated cardiac enzymes as troponin T was positive (1.300 ng/mL) with CK of 762 U/L and CKMB of 72 U/L. Diffuse hypokinesis in the wall was shown by echocardiography (left ventricular ejection fraction: 46%). The patient was diagnosed with perimyocarditis and was hospitalized. Steroid pulse therapy was started on the same day.<br><br>On 05-Oct-2021, mild lymphocyte infiltration was found by myocardial biopsy, which led to definitive diagnosis of myocarditis.<br><br>On 07-Oct-2021, steroid therapy was effective, and CK/CKMB were normalized with a decrease in troponin T to 0.551 ng/mL. The general condition of the patient was stable, and relief of the symptom was confirmed. The patient was to be discharged from the hospital after troponin T was normalized, and an ambulant follow was scheduled.<br><br>The outcome of pyrexia and perimyocarditis was reported as resolving.<br><br>Follow-up investigation will be made.<br><br>Reporter comments continuation:<br><br>In addition, considering the favorable response to steroid therapy (steroid therapy is less effective in viral myocarditis), the event was likely to be caused by administration of this vaccine. As other contributing factors, viral myocarditis should be distinguished, but administration of this |

| Case ID | WW Identifier | Narrative |
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| | | vaccine is considered as highly possible cause of the event based on the timing of onset.<br><br>Company Comment:<br><br>The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 15-Oct-2021 and was forwarded to Moderna on 15-Oct-2021.<br>This regulatory authority case was reported by a consumer and describes the occurrence of COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine), CONCOMITANT DISEASE AGGRAVATED (Concomitant disease aggravated), CHEST DISCOMFORT (Chest pressure) and PERICARDITIS (Pericarditis) in a 39-year-old male patient who received mRNA-1273 (Spikevax) for Vaccination. The occurrence of additional non-serious events is detailed below.<br><br>The patient's past medical history included Emergency care examination (No findings.), Chest pressure on 12-Jul-2021 and Chest discomfort on 12-Jul-2021.<br>Previously administered products included for Vaccination: COMIRNATY.<br><br>On 13-Aug-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 23-Sep-2021, the patient experienced PERICARDITIS (Pericarditis) (seriousness criterion medically significant). On an unknown date, the patient experienced COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine) (seriousness criterion medically significant), CONCOMITANT DISEASE AGGRAVATED (Concomitant disease aggravated) (seriousness criterion medically significant), CHEST DISCOMFORT (Chest pressure) (seriousness criterion medically significant) and DIZZINESS (Dizziness). At the time of the report, COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine), CONCOMITANT DISEASE AGGRAVATED (Concomitant disease aggravated) and DIZZINESS (Dizziness) outcome was unknown and CHEST DISCOMFORT (Chest pressure) and PERICARDITIS (Pericarditis) had not resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>In September 2021, Emergency care examination: normal (normal) Normal No findings.<br>On 23-Sep-2021, Ultrasound scan: abnormal (abnormal) Abnormal Diagnosed with PERICARDITIS..<br>On an unknown date, Electrocardiogram: normal (normal) Normal No findings.<br><br>No concomitant medication was reported.<br>No treatment medication was reported. |

| Case ID | WW Identifier | Narrative |
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| | | Company Comment:<br>This is a case of revaccination with different Covid -19 vaccine for this 39-year-old, male patient with relevant medical history of chest pressure and chest discomfort and relevant vaccine history of receiving other brand of Covid 19 vaccine (Comirnaty), who experienced the unexpected events of concomitant disease aggravated and chest discomfort and expected event of pericarditis. The event pericarditis occurred 42 days after a dose of mRNA-1273 vaccine administration while the occurrence of the events concomitant disease aggravated and chest discomfort exact occurrence unknown but stated that the events occurred after the administration of mRNA-1273 vaccine administration. The rechallenge is not applicable because the patient received other brand of Covid-19 vaccine (Comirnaty), prior to receiving mRNA-1273 vaccine. The medical history of chest pressure and chest discomfort and vaccine history of receiving other brand of Covid 19 vaccine (Comirnaty) remains confounders. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.<br><br>This case was linked to 4.1(b) (E2B Linked Report).<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 15-Oct-2021: Translation document received on 19-OCT-2021 contains no new information. |
| 4.1(b) | 4.1(b) | This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 09-Oct-2021 and was forwarded to Moderna on 15-Oct-2021.<br><br>This case, initially reported to the 4.1(b) by a (physician), was received via the 4.1(b) (Ref, 4.1(b)<br><br>Acute pericarditis was assessed as serious by the MAH.<br><br>On an unknown date, the patient received the 1st dose of this vaccine.<br>On 18-Sep-2021, the patient received the 2nd dose of this vaccine.<br>On 19-Sep-2021, at 12:00, symptoms of respiratory discomfort and chest pain were noted.<br>On 20-Sep-2021, the patient visited the reporting hospital. Although no elevation of cardiac enzymes was noted, ST decreased in 2, 3, aVF, and V2-5 leads was found. The physician made the diagnosis of acute pericarditis based on symptoms and examination findings.<br>On 30-Sep-2021, symptoms were confirmed to be improving.<br><br>The outcome of acute pericarditis was reported as resolving.<br><br>Follow-up investigation will be made.<br><br>Company Comment:<br>The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 15-Oct-2021 and was forwarded to Moderna on 15-Oct-2021. |

| Case ID | WW Identifier | Narrative |
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| | | This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (Myocarditis) in a 16-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 300423) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 21-Aug-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form.<br>On 25-Sep-2021, received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. On 27-Sep-2021, after starting mRNA-1273 (Spikevax), the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization prolonged and medically significant). At the time of the report, MYOCARDITIS (Myocarditis) had not resolved.<br><br>Patient had undergone Laboratory tests, echo, ECG, cardiac MRI, results were not provided.<br><br>No concomitant medication provided.<br><br>No treatment information mentioned.<br><br>Company comment: This is a regulatory authority case concerning a 16-year-old male patient with no relevant medical history reported, who experienced serious unexpected event of Myocarditis. The event occurred 2 days after the second dose of mRNA-1273. The rechallenge was not applicable as no additional dosing is expected. The benefit-risk relationship of mRNA-1273 is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 15-Oct-2021: Significant follow-up received, Patient's age updated.<br>On 15-Oct-2021: Translation received on 18-10-2021 contains significant information: lab data was updated in Inarrative supplement. |
| 4.1(b) | 4.1(b) | This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 09-Oct-2021 and was forwarded to Moderna on 15-Oct-2021.<br><br>This case, initially reported to the 4.1(b) by a nurse, was received via the 4.1(b) (Ref, 4.1(b)<br><br>On 31-Aug-2021, the patient received the 1st dose of the vaccine.<br>On an unknown date, body temperature before the vaccination: 36.4 degrees Celsius.<br>On 28-Sep-2021, at 16:30, the patient received the 2nd dose of the vaccine.<br>On 29-Sep-2021, at 18:00, median chest discomfort persisted intermittently from the early evening.<br>On 01-Oct-2021, around 05:30, the patient woke up with intense median chest discomfort. The symptom persisted for slightly less than 10 minutes, and thus the patient visited a hospital. As the symptom had |

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| | | been alleviated when an electrocardiography was performed, no change was showed in the electrocardiographic waveform. However, elevated cardiac enzymes were found in a blood test. The patient was transported to a medical institution. Elevated cardiac enzymes and ST elevation in aVL and V4-6 in electrocardiogram were revealed. The patient was hospitalized with a diagnosis of myopericarditis.<br>On 08-Oct-2021, improvements in cardiac enzymes and ST waveform in electrocardiogram were shown. No problems were found in the results of cardiac MRI and echocardiography, and resolution of the symptom was confirmed. The patient was discharged from the hospital.<br><br>The outcome of chest discomfort and myopericarditis was reported as resolving.<br><br>Follow-up investigation will be made.<br><br>Company Comment:<br>The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) on 15-Oct-2021 and was forwarded to Moderna on 15-Oct-2021.<br>This regulatory authority case was reported by a consumer and describes the occurrence of ASTHENIA (Weakness), CHEST PAIN (Chest pain), GAIT DISTURBANCE (Difficulty in walking), PERIPHERAL COLDNESS (Ice cold feet), PALPITATIONS (Strong heart pounding), CHILLS (Chills), PYREXIA (Fever), NAUSEA (Nausea) and MYOCARDITIS (Heart muscle inflammation) in a 34-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3005697) for COVID-19 vaccination.<br><br>Concurrent medical conditions included Asthma.<br><br>On 27-Aug-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 27-Aug-2021, the patient experienced PERIPHERAL COLDNESS (Ice cold feet) (seriousness criterion life threatening), CHILLS (Chills) (seriousness criterion life threatening) and PYREXIA (Fever) (seriousness criterion life threatening). On 28-Aug-2021, the patient experienced ASTHENIA (Weakness) (seriousness criterion life threatening), CHEST PAIN (Chest pain) (seriousness criterion life threatening), GAIT DISTURBANCE (Difficulty in walking) (seriousness criterion life threatening), PALPITATIONS (Strong heart pounding) (seriousness criterion life threatening), NAUSEA (Nausea) (seriousness criterion life threatening) and MYOCARDITIS (Heart muscle inflammation) (seriousness criteria medically significant and life threatening). On 28-Aug-2021, PERIPHERAL COLDNESS (Ice cold feet), CHILLS (Chills), PYREXIA (Fever) and NAUSEA (Nausea) had resolved. On 29-Aug-2021, ASTHENIA (Weakness), CHEST PAIN (Chest pain), GAIT DISTURBANCE (Difficulty in walking), PALPITATIONS (Strong heart pounding) and MYOCARDITIS (Heart muscle inflammation) had resolved. |

| Case ID | WW Identifier | Narrative |
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| | | Concomitant product use was not provided by the reporter.<br><br>Treatment information was not provided.<br><br>Company comment: This case concerns a 34-year-old, male patient with no relevant medical history, who experienced the serious unexpected events of Asthenia, Chest pain, Gait disturbance, Peripheral coldness, Palpitations, Chills, Pyrexia and Nausea and serious expected AESI of Myocarditis. The events of Peripheral coldness, Chills and pyrexia occurred on the same day after the second dose of mRNA-1273, while the events of Asthenia, Chest pain, Gait disturbance, Palpitations, Nausea and Myocarditis occurred one day after the second dose of mRNA-1273. The rechallenge is not applicable as the event occurred after the second dose. The benefit-risk relationship of mRNA-1273 is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 15-Oct-2021: Translated document received on 18-Oct-2021, included translated event verbatim and updated the dose number |
| 4.1(b) | 4.1(b) | This regulatory authority case was reported by a physician and describes the occurrence of PERICARDITIS (Pericarditis) in a 25-year-old female patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination.<br><br>Concurrent medical conditions included Endometriosis, Asthma (bronchial asthma) and Hypothyroidism.<br><br>On 11-Aug-2021, the patient received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form. On 12-Aug-2021, after starting mRNA-1273 (COVID-19 Vaccine Moderna), the patient experienced PERICARDITIS (Pericarditis) (seriousness criteria hospitalization and medically significant). The patient was hospitalized from 13-Aug-2021 to 14-Aug-2021 due to PERICARDITIS. At the time of the report, PERICARDITIS (Pericarditis) had not resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On an unknown date, Electrocardiogram: typical ecg changes (abnormal) Typical ECG changes.<br><br>For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered PERICARDITIS (Pericarditis) to be possibly related.<br><br>Concomitant medications were not provided.<br>No Treatment Information was provided.<br><br>Lab data included Elevated inflammatory parameters.<br><br>Company comment -This case concerns a 25 year old female with no relevant history who experienced the serious, listed AESI of Pericarditis the day after the second dose of mRNA-1273. Re-challenge is not applicable as this was dose 2 and the event is not reported for dose 1. Benefit-risk relationship of mRNA-1273 is not affected by this report. |

| Case ID | WW Identifier | Narrative |
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| | | Most recent FOLLOW-UP information incorporated above includes: On 15-Oct-2021: Translation recived on 18-Oct-21- Age of the patient was updated. Medical history was added, Laboratory tests added in the I-narrative, Sender's comment, Reporter's comments added. Event verbatim term translated and hospitalization dates were updated. Dosing details of the vaccine was updated. |
| 4.1(b) | 4.1(b) | This regulatory authority case was reported by a physician and describes the occurrence of PERICARDITIS (Pericarditis) in a 33-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for SARS-CoV-2 immunisation.<br><br>No Medical History information was reported.<br><br>On 02-Aug-2021, the patient received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form. On 02-Aug-2021, after starting mRNA-1273 (COVID-19 Vaccine Moderna), the patient experienced PERICARDITIS (Pericarditis) (seriousness criterion medically significant). At the time of the report, PERICARDITIS (Pericarditis) was resolving.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 08-Aug-2021, Chest X-ray: normal (normal) Non-pathological, no pneumothorax.<br>On 08-Aug-2021, Electrocardiogram: abnormal (abnormal) PR descending in DII, DIII and AVF, no repolarization disorders..<br>On 08-Aug-2021, Troponin T (Unknown-< 14): < 3 (abnormal) Troponin T-hs < 3 ng/L.<br>On 10-Aug-2021, Echocardiogram: abnormal (abnormal) minimal pericardial effusion.<br>On 10-Aug-2021, Ejection fraction: normal (normal) Normal.<br><br>For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered PERICARDITIS (Pericarditis) to be probably related.<br><br>Lab tests C-reactive protein, Leucocyte count was done on 8-AUG-2021. The patient had good health, athletic, active smoker. Patient received 1st dose in July 2021, precise date unknown and the 2nd dose of the on Aug 2, 2021. In the night, a few hours after the vaccination, he was woken by a hot-cold sensation and intermittent oppressive chest pain for around 1 hour 30 minutes which decreased with anteflexion of the trunk. From slight unusual dyspnea during intense exercise. The chest pain almost disappeared. In the night of Aug 07, 2021, he was again woken by oppressive chest pain that lasted 2 hours before spontaneously resolving. A sitting position helped alleviate the pain. On Aug 8, 2021, he went to the emergency room with a feeling of very slight tightness in the chest. His vitals are within normal, the ECG shows no pathologies, same for the chest radiography. Troponins are negative (troponin T hs <3 ng/L, normal <14 ng/L). The cardiological status shows that the sounds are normal without murmur or perceived pericardial friction. The patient was in less pain with anteflexion of the trunk. Faced with the typical clinical case, a diagnosed with acute pericarditis, treatment with ibuprofen and |

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| | | dextromethorphan was started the same day. On Aug 10, 2021 during the cardiological exam, he described the disappearance of the retrosternal pains but the persistence of the cough and orthopnea. The transthoracic ultrasound showed a slight pericardial effusion. A regressive treatment of colchicine for 3 months and NSAIDs was introduced.<br>This case refers to a 33-year-old male patient with no known medical history who experienced the expected event of Pericarditis on the same day after receiving the second dose of Moderna COVID-19 Vaccine. Rechallenge was assessed as not applicable. The event was considered related to the vaccine per the reporter's assessment. The benefit-risk relationship of Moderna COVID-19 Vaccine is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 15-Oct-2021: Translation received on 19-OCT-2021. Lab data added. Event verbatim updated. Narrative supplement updated. |
| 4.1(b) | 4.1(b) | This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 11-Oct-2021 and was forwarded to Moderna on 18-Oct-2021.<br>This case was reported by a hospital personnel and physician via a medical representative.<br><br>On an unknown date, the patient received the 1st dose of this vaccination.<br><br>On 09-Oct-2021, the patient received the 2nd dose of this vaccination.<br><br>On 10-Oct-2021, the patient had a pyrexia of around 39 degrees Celsius.<br><br>On 11-Oct-2021, around 12:00, chest pain developed, and the patient was requested an emergency transport, because the patients condition that cannot take a meal continued. The patient was hospitalized with a diagnosis of myocarditis on the same day.<br><br>The outcome of pyrexia and myocarditis was reported as unknown.<br><br>Follow-up investigation will be made.<br><br>Company Comment:<br><br>The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.. |
| 4.1(b) | 4.1(b) | This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) ) on 11-Oct-2021 and was forwarded to Moderna on 18-Oct-2021. |

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| | | This case, initially reported to the 4.1(b) by a (physician), was received via the 4.1(b) (Ref, 4.1(b)<br><br>On an unknown date, the patient received the 1st dose of this vaccine.<br><br>On 02-Oct-2021, the patient received the 2nd dose of this vaccine.<br><br>On 04-Oct-2021, chest pain and vomiting developed.<br><br>On 05-Oct-2021, the patient visited the reporting hospital. The patient was diagnosed with myocarditis due to abnormally high troponin I level. The patient was transported to an advanced treatment hospital and was hospitalized.<br><br>On 09-Oct-2021, the symptoms were resolving, and the patient was discharged from the hospital.<br><br>The outcome of myocarditis was reported as resolving.<br><br>Follow-up investigation will be made.<br><br>Company Comment:<br><br>The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. |
| 4.1(b) | 4.1(b) | This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) ) on 11-Oct-2021 and was forwarded to Moderna on 18-Oct-2021.<br><br>This case, initially reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref 4.1(b)<br><br>On an unknown date, the patient received the 1st dose of the vaccine.<br><br>On 05-Oct-2021, the patient received the 2nd dose of the vaccine.<br><br>On 06-Oct-2021, pyrexia developed.<br><br>On 07-Oct-2021, at 02:00, chest pain developed, and an emergency call was made. As ST elevation was shown by electrocardiogram and cardiac effusion was showed by CT, the patient was diagnosed with myocarditis.<br><br>On an unspecified date, the patient was hospitalized.<br><br>The outcome of pyrexia and myocarditis was unknown.<br><br>Follow-up investigation will be made.<br><br>Company Comment:<br><br>The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. |

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| 4.1(b) | 4.1(b) | This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 12-Oct-2021 and was forwarded to Moderna on 18-Oct-2021.<br>This case, initially reported to the 4.1(b) ) by a physician, was received via the 4.1(b) (Ref, 4.1(b)<br><br>Suspected myocarditis was assessed as serious by the MAH.<br><br>On an unknown date, the patient received the 1st dose of this vaccine.<br><br>On 03-Oct-2021, the patient received the 2nd dose of this vaccine. The patient had pyrexia of 38.0-38.9 degrees Celsius.<br><br>On 05-Oct-2021, around 00:00, left precordial pain persisted for 2 hours, and dyspnea also developed. Body temperature was 37 degrees Celsius at this time.<br><br>On 06-Oct-2021, in the morning, the patient had chest pain and palpitations for 30 minutes. The patient visited the reporting hospital because the patient was suffered from the symptoms. At the time of medical consultation, although the patient had mild precordial pain, but had no pyrexia, and there was no problem in cardiopulmonary physical findings. SpO2 98% and pulse 74/min. Chest X-ray was normal. Elevations in ST, 1, 2, and V2-6 were noted on ECG. Blood test showed elevated levels including GOT 44, GPT 47, CK 362, and CRP 4.7. Myocarditis was suspected. No medication was prescribed.<br><br>On 07-Oct-2021, subjective symptoms subsided. The symptoms were confirmed to be resolving.<br><br>The outcome of pyrexia, left precordial pain, dyspnoea, palpitations, and suspected myocarditis was reported as resolving.<br><br>Follow-up investigation will be made.<br><br>Company Comment:<br><br>The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. |
| 4.1(b) | 4.1(b) | This case was initially received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 13-Oct-2021. The most recent information was received on 05-Jan-2022 and was forwarded to Moderna on 11-Jan-2022.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (myocarditis) in a 22-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna Intramuscular Injection) (batch nos. 3005788 and 3005693) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 10-Sep-2021, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna Intramuscular Injection) (Intramuscular) 1 dosage form. |

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| | | On 08-Oct-2021, received second dose of mRNA-1273 (COVID-19 Vaccine Moderna Intramuscular Injection) (Intramuscular) dosage was changed to 1 dosage form. On 10-Oct-2021, the patient experienced MYOCARDITIS (myocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (myocarditis) was resolving.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 09-Oct-2021, Body temperature: 37 (normal) Test Result:37s.<br>On 10-Oct-2021, Blood creatine phosphokinase (62-287): 118 (normal) 118 [iU]/L (international unit per litre), 280 (normal) 280 [iU]/L (international unit per litre), 562 (High) 562 [iU]/L (international unit per litre) and 551 (High) 551 [iU]/L (international unit per litre).<br>On 10-Oct-2021, Blood creatine phosphokinase MB (Unknown-4.0): 3.90 (normal) 3.90 ng/mL (nanogram per millliiter), 15.70 (High) 15.70 ng/mL (nanogram per millliiter), 33.30 (High) 33.30 ng/mL (nanogram per millliiter) and 36.10 (High) 36.10 ng/mL (nanogram per millliiter).<br>On 10-Oct-2021, Brain natriuretic peptide: 8.8 (normal) 8.8 pg/ml (picogram per millilitre).<br>On 10-Oct-2021, C-reactive protein (Unknown-0.3): 2.70 (abnormal) 2.70 mg/dl (MILLIGRAM PER DECILITRE).<br>On 10-Oct-2021, Echocardiogram: no particular findings were observed. (normal) No particular findings were observed..<br>On 10-Oct-2021, Fibrin D dimer: 0.80 (High) 0.80 microgram per millilitre.<br>On 10-Oct-2021, Heart rate: 63 (normal) 63/min (per minute).<br>On 10-Oct-2021, Troponin I (Unknown-26.2): 585.2 (High) 585.2 pg/ml (picogram per millilitre), 3950.03 (High) 3950.03 pg/ml (picogram per millilitre), 11504 (High) 11504 pg/ml (picogram per millilitre) and 10922.04 (High) 10922.04 pg/ml (picogram per millilitre).<br>On 11-Oct-2021, Blood creatine phosphokinase (62-287): 493 (High) 493 [iU]/L (international unit per litre), 467 (High) 467 [iU]/L (international unit per litre), 416 (High) 416 [iU]/L (international unit per litre), 319 (High) 319 [iU]/L (international unit per litre), 229 229 [iU]/L (international unit per litre) and 182 (normal) 182 [iU]/L (international unit per litre).<br>On 11-Oct-2021, Blood creatine phosphokinase MB (Unknown-4.0): 31.90 (High) 31.90 ng/mL (nanogram per millliiter), 31.50 (High) 31.50 ng/mL (nanogram per millliiter), 27.40 (High) 27.40 ng/mL (nanogram per millliiter), 19.30 (High) 19.30 ng/mL (nanogram per millliiter), 13.60 (High) 13.60 ng/mL (nanogram per millliiter) and 9.40 (High) 9.40 ng/mL (nanogram per millliiter).<br>On 11-Oct-2021, Troponin I (Unknown-26.2): 9433.05 (High) 9433.05 pg/ml (picogram per millilitre), 7481.02 (High) 7481.02 pg/ml (picogram per millilitre), 6535.01 (High) 6535.01 pg/ml (picogram per millilitre), 5097.05 (High) 5097.05 pg/ml (picogram per millilitre), 3068.01 (High) 3068.01pg/ml (picogram per millil and 3298.03 (High) 3298.03 pg/ml (picogram per millilitre).<br>On 12-Oct-2021, Blood creatine phosphokinase (62-287): 125 (normal) 125 [iU]/L (international unit per litre).<br>On 12-Oct-2021, Blood creatine phosphokinase MB (Unknown-4.0): 5.30 (High) 5.30 ng/mL (nanogram per millliiter).<br>On 12-Oct-2021, Troponin I (Unknown-26.2): 4194.09 (High) 4194.09 pg/ml (picogram per millilitre). |

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| | | On 13-Oct-2021, Magnetic resonance imaging: high signals (t2 black blood) in the apical epicar (abnormal) High signals (T2 black blood) in the apical epicardium..<br>On 14-Oct-2021, Blood creatine phosphokinase (62-287): 46 (Low) 46 [iU]/L (international unit per litre).<br>On 14-Oct-2021, Blood creatine phosphokinase MB (Unknown-4.0): 0.50 (Low) 0.50 ng/mL (nanogram per millliiter).<br>On 14-Oct-2021, C-reactive protein (Unknown-0.3): 0.13 (normal) 0.13 mg/dl (MILLIGRAM PER DECILITRE).<br>On 14-Oct-2021, Troponin I (Unknown-26.2): 339.9 (High) 339.9 pg/ml (picogram per millilitre).<br>On 16-Oct-2021, Chest X-ray: normal range (normal) Test Result:Normal range.<br>On 16-Oct-2021, Electrocardiogram: st elevation in the lateral and anterior wall. (abnormal) ST elevation in the lateral and anterior wall..<br>On 16-Oct-2021, Heart rate: 72 (normal) 72/min (per minute).<br><br>For mRNA-1273 (COVID-19 Vaccine Moderna Intramuscular Injection) (Intramuscular), the reporter considered MYOCARDITIS (myocarditis) to be possibly related.<br><br>Company Comment - This regulatory authority case concerns a 22 year old male patient with no relevant medical history, who experienced the AESI myocarditis, an expected event. The event occurred 2 days after the second dose of mRNA-1273 vaccine, and was resolving at the time of the report. Patient complained of chest pain and was hospitalized. The rechallenge was not applicable. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report.<br><br>Since the onset of myocarditis occurred two days after the vaccination, it cannot be denied that it was caused by this vaccine. Since the onset of symptoms occurred about two days after the 2nd vaccination, the occurrence of the adverse event was related to the timing of the administration of the vaccine. The occurrence of the adverse event was related to concomitant drugs because there had been reports about it.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 05-Jan-2022: Significant follow up information received -Event details, outcome updated, tests details updated. |
| 4.1(b) | 4.1(b) | This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 12-Oct-2021 and was forwarded to Moderna on 18-Oct-2021.<br><br>This case, reported by a physician, was received by Takeda via Moderna's adverse reaction reporting site (4.1(b) and reported to the 4.1(b) )by a physician, was received via the 4.1(b) (Ref, 4.1(b)<br><br>Myocarditis was assessed as a serious by the MAH.<br><br>The patient had a history of pyrexia with 4.1(b) encephalitis vaccination. |

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| | | On 07-Sep-2021, at 16:45, the patient received the 1st dose of this vaccination.<br><br>On 05-Oct-2021, at 16:45, the patient received the 2nd dose of this vaccination.<br><br>On 07-Oct-2021, at 09:00, myocarditis developed. Chest pain, dyspnea, and feeling of fatigue were observed.<br><br>On 11-Oct-2021, the symptoms resolved.<br><br>The outcome of myocarditis was reported as resolving.<br><br>Follow-up investigation will be made.<br><br>Company Comment:<br><br>The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 18-Oct-2021 and was forwarded to Moderna on 18-Oct-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of VENTRICULAR EXTRASYSTOLES (Ventricular extrasystoles) and MYOCARDITIS (Acute myocarditis) in a 19-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 06-Jul-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form.<br>On 03-Aug-2021, received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. In July 2021, the patient experienced VENTRICULAR EXTRASYSTOLES (Ventricular extrasystoles) (seriousness criterion medically significant). On 03-Aug-2021, the patient experienced MYOCARDITIS (Acute myocarditis) (seriousness criterion medically significant). At the time of the report, VENTRICULAR EXTRASYSTOLES (Ventricular extrasystoles) and MYOCARDITIS (Acute myocarditis) was resolving.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 03-Aug-2021, Magnetic resonance imaging heart: abnormal (abnormal) myocarditis.<br>On 12-Aug-2021, Troponin: negative (Negative) negative.<br><br>For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.<br><br>No concomitant medications provided.<br>No treatment medications provided. |

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| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 18-Oct-2021 and was forwarded to Moderna on 18-Oct-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Perimyocarditis) in a 31-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 06-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 08-Sep-2021, the patient experienced MYOCARDITIS (Perimyocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Perimyocarditis) was resolving.<br><br>For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.<br><br>Concomitant medication was not provided.<br>Treatment information was not provided.<br><br>Company comment: This case concerns a 31-year-old, male patient with no medical history reported, who experienced the expected event of myocarditis which required hospitalization. The event occurred approximately 2 days after the second dose of Moderna COVID-19 Vaccine. The rechallenge was not applicable as event occurred after second dose and no further dosing was reported or planned, based on information provided. No information regarding patient's symptoms or diagnostic findings was provided. The benefit-risk relationship of Moderna COVID-19 Vaccine is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 18-Oct-2021: Translation document received on 20-Oct-2021 contains event as reported by primary source updated and Dosage text translated. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 18-Oct-2021 and was forwarded to Moderna on 18-Oct-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Perimyocarditis) in an 18-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination.<br><br>Concurrent medical conditions included Pollen allergy and Asthma.<br><br>On 10-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 23-Sep-2021, after starting mRNA-1273 (Spikevax), the patient experienced MYOCARDITIS (Perimyocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Perimyocarditis) was resolving. |

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| | | For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.<br><br>Concomitant medications were not reported.<br>Treatment medications were not reported.<br><br>Company Comment:<br>This case concerns a 18-year-old, male with no relevant medical history, who experienced the serious, expected and AESI event of myocarditis. The events occurred 13 days after second dose of Spikevax. The rechallenge was not applicable, as no additional dosing will be given. The benefit-risk relationship of Spikevax is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 18-Oct-2021: Translation received on 19-OCT-2021 contains: Dose number of vaccination added and Event verbatim updated. |
| 4.1(b) | 4.1(b) | This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) ) on 13-Oct-2021 and was forwarded to Moderna on 18-Oct-2021.<br>This case, initially reported to the 4.1(b) ) by a physician, was received via the 4.1(b) (Ref, 4.1(b)<br><br>Suspected cardiac failure and myocarditis was assessed as serious by the MAH.<br><br>On an unknown date, the patient received the 1st dose of this vaccine.<br><br>On 29-Aug-2021, at 14:00, the patient received the 2nd dose of this vaccine.<br><br>On 27-Sep-2021, at 07:00, generalized malaise and oedema of the lower limbs developed. Myocarditis was considered to developed.<br><br>On 30-Sep-2021, the patient visited the reporting hospital. In X-ray, mild bilateral congestion was found. Cardiac failure was suspected. Combined with the echocardiographic findings, viral myocarditis or myocarditis due to this vaccine was considered.<br><br>On 07-Oct-2021, the course of the symptoms was unknown.<br><br>The outcome of suspected cardiac failure and myocarditis was unknown.<br><br>Follow-up investigation will be made.<br><br>Company Comment:<br><br>The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. |
| 4.1(b) | 4.1(b) | This case was initially received via Takeda Pharmaceuticals (Reference number: 4.1(b) ) on 12-Oct-2021. The most recent information was received on 10-Nov-2021 and was forwarded to Moderna on 17-Nov-2021.<br><br>On 10-Nov-2021, follow-up information was received from a physician. |

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| | | On an unknown date, the patient received the 1st dose of this vaccine.<br>On an unknown date, body temperature before the vaccination: 36.4 degrees Celsius.<br>On 04-Oct-2021, at 17:00, the patient received the 2nd dose of this vaccine. Pyrexia developed.<br>On 06-Oct-2021, chest pain developed<br>On 07-Oct-2021, at 06:00, the patient had chest discomfort, chest pain, pyrexia, and dyspnoea. At 07:30, the patient visited the reporting hospital as an emergency.<br>Chest X-ray: mild cardiomegaly was noted, CTR: approximately 50%. Electrocardiogram: ST-T increased in V3-6. Echocardiography: left ventricular ejection fraction (EF) decreased to 53%. Pericardial effusion was noted. Blood test: CK-MB 46 IU/L, CRP 6.0 mg/dL. Elevated cardiac enzymes were observed, and the patient was hospitalized with a diagnosis of myocarditis. The patient was placed at rest and received fluid replacement. The patient started taking acetaminophen 200 mg by 3 tablets per day and furosemide 20 mg by 1 tablet per day regularly. Cardiac failure was treated with diuretics.<br>On 08-Oct-2021, blood collection: BNP 361 pg/mL.<br>On 11-Oct-2021, chest X-ray: there was no abnormality, and CTR was approximately 44%. Electrocardiogram: increased ST-T improved. Echocardiography: left ventricular ejection fraction (EF) improved to 67%, and pericardial effusion disappeared. The symptoms were resolving, and the patient was discharged from the hospital. The patient finished taking acetaminophen and furosemide.<br>On 13-Oct-2021, the patient was judged to have recovered completely at the outpatient department.<br><br>The outcome of myocarditis was reported as resolved.<br><br>No follow-up investigation will be made.<br><br>Follow-up received on 10-NOV-2021<br>Updated: Patient Information, Other Relevant History, Lab Data, Product Information, Event Information, Narrative, Reporter Comments<br><br>Company Comment:<br>The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. |
| 4.1(b) | 4.1(b) | This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) ) on 13-Oct-2021 and was forwarded to Moderna on 18-Oct-2021.<br>This case, initially reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref, 4.1(b)<br><br>Myocarditis was assessed as serious by the MAH.<br><br>On an unknown date, the patient received the 1st dose of this vaccine.<br><br>On an unknown date, body temperature before vaccination: 35.8 degrees Celsius.<br><br>On 28-Sep-2021, the patient received the 2nd dose of this vaccine. |

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| | | On 01-Oct-2021, in the morning, the patient had left chest pain and visited the hospital. No abnormalities in the chest X-ray, double master stress electrocardiogram, and echocardiography were noted. Blood test showed increases with CRP 2.46, high-sensitivity troponin I 1,938, and CK 446. The patient was diagnosed with myocarditis after vaccination with this vaccine.<br><br>On 02-Oct-2021, left chest pain showed a tendency of improvement at return visit.<br><br>On 07-Oct-2021, the patient visited another hospital.<br><br>On an unknown date, the improvement of symptom was confirmed.<br><br>The outcome of myocarditis was reported as resolving.<br><br>Follow-up investigation will be made.<br><br>Company Comment:<br><br>The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. |
| 4.1(b) | 4.1(b) | This case was initially received via Takeda Pharmaceuticals (Reference number: 4.1(b) ) on 14-Oct-2021. The most recent information was received on 11-Nov-2021 and was forwarded to Moderna on 19-Nov-2021.<br>This case, initially reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref, 4.1(b)<br><br>On 11-Nov-2021, follow-up information was received from a physician.<br><br>Ileocecal inflammation was assessed as serious by the MAH.<br><br>On an unknown date, the patient received the 1st dose of the vaccine.<br><br>On an unknown date, body temperature before the vaccination: 36.4 degrees Celsius.<br><br>On 09-Oct-2021, the patient received the 2nd dose of the vaccine.<br><br>On 10-Oct-2021, pyrexia of 39.0-39.9 degrees Celsius developed. The patient took acetaminophen and was followed up at home.<br><br>On 11-Oct-2021, around 12:00, precordial pain developed. The patient was unable to control it, and thus an emergency call was made. The patient was transported to the reporting hospital. Chest x-ray showed no cardiomegaly, extravasation, or congestion. ST elevations were noted in leads other than the aVR on the electrocardiogram. Echocardiography showed mild hypokinesis with mild encircling. Mild pericarditis was noted. Chest CT was performed, and no abnormalities were noted. Blood test showed positive for troponin T. The patient was hospitalized for treatment with a diagnosis of acute pericarditis and myocarditis. After |

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| | | hospitalization, intravenous fluid replacement and oral administration of NSAIDs (celecoxib) and colchicine were started.<br><br>On 12-Oct-2021, blood test showed positive for troponin.<br><br>On 13-Oct-2021, blood test showed positive for troponin. Echocardiography was normal. Precordial pain disappeared.<br><br>On 15-Oct-2021, blood test showed positive for troponin.<br><br>On 18-Oct-2021, troponin became negative, but there was an increase in CRP. Chest x-ray showed no cardiomegaly, extravasation, or congestion. Pericarditis and acute myocarditis disappeared. Right lower abdominal pain developed. Abdominal ultrasonography showed enlarged intestinal lymph nodes with pus in the right lower abdomen. CT showed coprolites and intestinal fluid retention in the appendix, but no obvious adipose tissue turbidity was noted. The patient was diagnosed with ileocecal inflammation and was treated with antibiotics.<br><br>On 19-Oct-2021, oral administration of NSAIDs and colchicine was completed.<br><br>On 20-Oct-2021, CRP decreased, and abdominal symptoms disappeared. Persistent negative troponin was confirmed.<br><br>On Oct-2021, the symptoms were resolving, and the patient was discharged from the hospital.<br><br>The outcome of pericarditis, acute myocarditis, and ileocecal inflammation was reported as resolving.<br><br>No follow-up investigation will be made.<br><br>Reporter comments continuation:<br><br>Based on the changes in electrocardiogram, echocardiography, and blood test findings, the symptoms are considered to be myocarditis, which is consistent with adverse reactions to this vaccine. Therefore, the occurrence of adverse events is temporally related to the timing of the administration of this vaccine. The causality between this vaccine and ileocecal inflammation is unknown.<br><br>Follow-up received on 11-NOV-2021<br><br>Updated: Patient Information, Lab Data, Event Information, Narrative, Reporter Comments<br><br>Company Comment:<br><br>The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) on 19-Oct-2021 and was forwarded to Moderna on 19-Oct-2021. |

| Case ID | WW Identifier | Narrative |
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| | | This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myocarditis) in a 17-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 3005238 and 3004670) for COVID-19 vaccination.<br><br>The patient's past medical history included Myocarditis in 2019.<br><br>On 06-Sep-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form.<br>On 27-Sep-2021, received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. On 28-Sep-2021, after starting mRNA-1273 (Spikevax), the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Myocarditis) was resolving.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 30-Sep-2021, SARS-CoV-2 test: negative (Negative) Negative.<br><br>For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.<br><br>No concomitant medications reported by reporter.<br><br>No treatment medications provided by the reporter.<br><br>Company Comment: This case concerns a 17 year-old male patient with a history of myocarditis who experienced the expected serious event of myocarditis, an AESI, and the non-serious event of inappropriate schedule of vaccine administered. The event occurred approximately 1 day after the second dose of mRNA-1273, which was administered 22 days after the first dose. The rechallenge was not applicable as no additional dosing will be administered. The medical history of myocarditis and of inappropriate schedule of vaccine administered remain confounders. The benefit-risk relationship of mRNA-1273 (Spikevax) is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 19-Oct-2021: Translation document received on 20-Oct-2021 and event verbatim updated. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 19-Oct-2021 and was forwarded to Moderna on 19-Oct-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of PERICARDITIS (Pericarditis, acute inflammatory reaction post-vaccination) and INFLAMMATION (Pericarditis, acute inflammatory reaction post-vaccination) in a 20-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3002545) for SARS-CoV-2 vaccination.<br><br>No Medical History information was reported. |

| Case ID | WW Identifier | Narrative |
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| | | On 26-May-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) .5 milliliter.<br>On 30-Jun-2021, received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to .5 milliliter. On 10-Jul-2021, the patient experienced PERICARDITIS (Pericarditis, acute inflammatory reaction post-vaccination) (seriousness criteria hospitalization and medically significant) and INFLAMMATION (Pericarditis, acute inflammatory reaction post-vaccination) (seriousness criterion hospitalization). At the time of the report, PERICARDITIS (Pericarditis, acute inflammatory reaction post-vaccination) and INFLAMMATION (Pericarditis, acute inflammatory reaction post-vaccination) had resolved.<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.<br><br>No concomitant medications were mentioned.<br>No treatment details were reported.<br><br>Reported that Intramuscular administration of the second dose, deltoid. time of administration: 01:13 p.m.<br><br>Company comment: This case concerns a 20-year-old, male patient with no relevant medical history, who experienced the unexpected events of Pericarditis and Acute Inflammatory Reaction post-vaccination. The events occurred approximately 11 days after the second dose of Spikevax. The rechallenge was not applicable since evets occurred after second dose. The benefit-risk relationship of Spikevax is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 19-Oct-2021: Translation received on 21-OCT-2021 contained translated event verbatim term , Reporters comment translated, time and anatomical position of injection has been updated. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 19-Oct-2021 and was forwarded to Moderna on 19-Oct-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myocarditis) and PERICARDITIS (Pericarditis) in a 23-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 immunisation.<br><br>The patient's past medical history included Chronic diarrhoea and Ferropenic anaemia.<br><br>On 19-Aug-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 milliliter. On 27-Sep-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant) and PERICARDITIS (Pericarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Myocarditis) and PERICARDITIS (Pericarditis) was resolving. |

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| | | For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered MYOCARDITIS (Myocarditis) and PERICARDITIS (Pericarditis) to be possibly related.<br><br>No concomitant medication details was reported.<br>No treatment medication details was reported.<br><br>Company comment: This case concerns a 23 year old female patient with no relevant medical history reported, who experienced serious expected AESI of myocarditis and pericarditis after second dose of mRNA-1273. The events occurred 40 days after second dose of mRNA-1273. The re-challenge is unknown as the events occurred after second dose and the outcome is recovering at the time of report. The benefit risk relationship of vaccine is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 19-Oct-2021: Translation received on 20-OCT-2021 contains significant information that include all event description as reported updated and suspected product dose text updated.<br>On 20-Oct-2021: Follow-up received and added other relevant medical history. |
| 4.1(b) | 4.1(b) | This case was received via an unknown source (no reference has been entered for a health authority or license partner) on 19-Oct-2021 and was forwarded to Moderna on 19-Oct-2021.<br><br>This regulatory authority case was reported by a physician and describes the occurrence of CARDIAC FAILURE (Cardiac Insufficiency), MYOCARDITIS (Acute myocarditis) and PERICARDITIS (Pericarditis) in a 22-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3005885) for COVID-19 immunisation.<br><br>No Medical History information was reported.<br><br>On 27-Jul-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 ml. On 29-Jul-2021, the patient experienced CARDIAC FAILURE (Cardiac Insufficiency) (seriousness criteria hospitalization and medically significant), MYOCARDITIS (Acute myocarditis) (seriousness criteria hospitalization and medically significant) and PERICARDITIS (Pericarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, CARDIAC FAILURE (Cardiac Insufficiency), MYOCARDITIS (Acute myocarditis) and PERICARDITIS (Pericarditis) was resolving.<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered MYOCARDITIS (Acute myocarditis) to be probably related. No further causality assessments were provided for CARDIAC FAILURE (Cardiac Insufficiency) and PERICARDITIS (Pericarditis).<br><br>No concomitant medications were reported.<br>Treatment information was not provided.<br><br>Company Comment: This is a Regulatory case concerning a 22-year-old male patient with no relevant medical history who experienced serious |

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| | | unexpected event of Cardiac failure and serious expected events of Myocarditis and Pericarditis (AESI). The events occurred approximately two days after the second dose of Spikevax. The rechallenge was not applicable as the events occurred following the second dose. Very limited information regarding clinical course of the events has been provided at this time. The benefit-risk relationship of Spikevax is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 19-Oct-2021: Translation document received on 20-Oct-2021, added dose number of vaccine, updated event verbatim and causality of acute myocarditis changed to probable.<br>On 20-Oct-2021: Follow up received contains No-new information. |
| 4.1(b) | 4.1(b) | This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 14-Oct-2021 and was forwarded to Moderna on 20-Oct-2021.<br>This case, initially reported to the 4.1(b) by a (physician), was received via the 4.1(b) (Ref, 4.1(b)<br><br>On an unknown date, the patient received the 1st dose of this vaccine.<br><br>On an unknown date, body temperature before the vaccination: 36.6 degrees Celsius.<br><br>On 11-Oct-2021, at 10:00, the patient received the 2nd dose of this vaccine. Pyrexia of BT 37.5 degrees Celsius developed in the early evening. Since the body temperature rose to 38.3 degrees Celsius, the patient took over-the-counter aspirin.<br><br>On 12-Oct-2021, after waking up, the patient's body temperature was in the 39 degrees Celsius range. At 12:00, the patient took aspirin. At the same time, respiratory discomfort, throbbing chest pain, chest tightness, and cough developed.<br><br>Around 18:00, because the symptoms persisted, an emergency call was made. The patient was transported with BP of 99/64, HR of 155, Sat of 98 (room air), and eardrum temperature of 37.2 degrees Celsius. After arriving, 12 lead electrocardiogram showed negative T waves in 2, 3 and aVf, and there was no arrhythmia. No previous ECG was recorded. Vital signs were stable with BP of 134/83, HR of 90, Sat of 98 (room air), and axillary BT of 38.5 degrees Celsius.<br><br>The patient was raced to a hospital due to persistent symptoms and abnormal electrocardiogram. After transport, 12 lead electrocardiogram, blood sampling, chest Xp, and echocardiography were performed. Echocardiography showed pericardial effusion, and the patient was diagnosed with suspected acute pericarditis based on the clinical course and electrocardiographic findings and was hospitalized. Afterwards, the symptoms were resolving.<br><br>On 13-Oct-2021, respiratory discomfort remained but tended to improve. |

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| | | The outcome of pyrexia, suspected acute pericarditis, respiratory discomfort, throbbing chest pain, chest tightness, cough, and pericardial effusion was reported as resolving.<br><br>Follow-up investigation will be made.<br><br>Company Comment:<br><br>The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. |
| 4.1(b) | 4.1(b) | This case was received via 4.1(b) (Reference number: 4.1(b) on 19-Oct-2021 and was forwarded to Moderna on 19-Oct-2021.<br>This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCARDITIS (Myocarditis) in a 27-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 010D9A) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 03-Oct-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 04-Oct-2021, after starting mRNA-1273 (Moderna COVID-19 Vaccine), the patient experienced MYOCARDITIS (Myocarditis) (seriousness criterion medically significant). At the time of the report, MYOCARDITIS (Myocarditis) had not resolved.<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments.<br><br>Concomitant product use was not provided by the reporter.<br>No treatment information was provided.<br><br>Company Comment: This case concerns a 27-year-old, female patient with no relevant medical history, who experienced the expected event of myocarditis. The event myocarditis occurred 1 day after the second dose of mRNA-1273 vaccine administration. The rechallenge was unknown as there's no information available about the first dose. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. |
| 4.1(b) | 4.1(b) | This case was received via 4.1(b) (Reference number: 4.1(b) on 19-Oct-2021 and was forwarded to Moderna on 19-Oct-2021.<br>This regulatory authority case was reported by an other health care professional and describes the occurrence of CHEST PAIN (Chest pain) and MYOCARDITIS (Myocarditis) in an 18-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 038C21A) for COVID-19 vaccination.<br><br>No Medical History information was reported. |

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| | | On 23-Jul-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form.<br>On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 25-Jul-2021, the patient experienced CHEST PAIN (Chest pain) (seriousness criterion hospitalization) and MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). The patient was hospitalized on 25-Jul-2021 due to CHEST PAIN and MYOCARDITIS. The patient was treated with IBUPROFEN for Chest pain, at an unspecified dose and frequency. At the time of the report, CHEST PAIN (Chest pain) had resolved and MYOCARDITIS (Myocarditis) outcome was unknown.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 25-Jul-2021, Magnetic resonance imaging heart: abnormal (abnormal) visualized regions of epicardial delayed gadolinium enhancement consistent with myocarditis.<br>On 25-Jul-2021, Pain assessment: 7/10 (High) Stabbing chest pain rated it a 7/10 on the pain scale..<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments.<br><br>Concomitant medications was not reported.<br><br>On an unknown date, after receiving the first dose, 2 weeks later patient received the TDAP (tetanus, diphtheria, and pertussis) and typhoid vaccines.<br><br>On 25-Jul-2021, the patient developed stabbing chest pain rated it as 7/10 on the pain scale at which point the patient went to the local ER (emergency room) and was transported to another medical facility for further evaluation and management due to concerns for myocarditis. Cardiology visualized regions of epicardial delayed gadolinium enhancement consistent with myocarditis. The patient had follow-up with cardiology in 2-3 weeks.<br><br>Company comment<br>This case concerns a 18-year-old, male with no reported medical history, who experienced the serious, unexpected event of chest pain and serious, expected and AESI event of myocarditis. The events occurred 2 days after second dose of Spikevax. The rechallenge was not applicable, as no additional dosing will be given. Previous vaccination with TDAP and Typhoid vaccines could be potentially confounders. The benefit-risk relationship of Spikevax is not affected by this report. |
| 4.1(b) | 4.1(b) | This case was received via 4.1(b) (Reference number: 4.1(b) on 19-Oct-2021 and was forwarded to Moderna on 19-Oct-2021.<br>This regulatory authority case was reported by an other health care professional and describes the occurrence of ACUTE MYOCARDIAL INFARCTION (Acute myocardial infarction), CHEST PAIN (Chest pain/Left upper chest pain/Pain began to radiate down left arm), |

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| | | MYOCARDIAL INFARCTION (Myocardial infarction), PAIN (Pain), PAIN IN EXTREMITY (Pain in extremity), LIMB DISCOMFORT (Felt like I layed on my arm wrong) and MYOCARDITIS (Myocarditis/Focal Myocarditis) in a 37-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 012M20A) for COVID-19 vaccination.<br><br>No medical history was reported.<br>Concurrent medical conditions included Asthma, Arthritis and Drug allergy.<br>Concomitant products included BUDESONIDE, FORMOTEROL FUMARATE (SYMBICORT), ALBUTEROL [SALBUTAMOL], PARACETAMOL (TYLENOL) and IBUPROFEN for an unknown indication.<br><br>On 01-Feb-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 25-Sep-2021, the patient experienced PAIN (Pain) (seriousness criteria hospitalization and life threatening) and PAIN IN EXTREMITY (Pain in extremity) (seriousness criteria hospitalization and life threatening). On 26-Sep-2021, the patient experienced CHEST PAIN (Chest pain/Left upper chest pain/Pain began to radiate down left arm) (seriousness criteria hospitalization and life threatening) and LIMB DISCOMFORT (Felt like I layed on my arm wrong) (seriousness criteria hospitalization and life threatening). On 27-Sep-2021, the patient experienced ACUTE MYOCARDIAL INFARCTION (Acute myocardial infarction) (seriousness criteria hospitalization, medically significant and life threatening), MYOCARDIAL INFARCTION (Myocardial infarction) (seriousness criteria hospitalization, medically significant and life threatening) and MYOCARDITIS (Myocarditis/Focal Myocarditis) (seriousness criteria hospitalization, medically significant and life threatening). At the time of the report, ACUTE MYOCARDIAL INFARCTION (Acute myocardial infarction), CHEST PAIN (Chest pain/Left upper chest pain/Pain began to radiate down left arm), MYOCARDIAL INFARCTION (Myocardial infarction), PAIN (Pain), PAIN IN EXTREMITY (Pain in extremity), LIMB DISCOMFORT (Felt like I layed on my arm wrong) and MYOCARDITIS (Myocarditis/Focal Myocarditis) outcome was unknown.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 25-Sep-2021, Angiocardiogram: abnormal (abnormal) No occlusions found. Diagnosed with Focal Myocarditis..<br>On 25-Sep-2021, Electrocardiogram: abnormal (abnormal) Showed inferion MI.<br>On 25-Sep-2021, Fibrin D dimer: high (High) EKG showed STEMI Troponins + d-dimer+..<br>On 25-Sep-2021, Troponin: high (High) EKG showed STEMI Troponins + d-dimer+..<br>On 27-Sep-2021, Electrocardiogram: abnormal (abnormal) EKG showed STEMI Troponins + d-dimer+..<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. |

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| | | Lab tests include Chest X-ray, CTA chest, Differential white blood cell count, Full blood count, Glycosylated hemoglobin, Lipids, Metabolic function test, SARS-CoV-2 test, performed on 25-Sep-2021 with unknown results.<br><br>Treatment information include patient took 1 gm Tylenol and 400 mg Ibuprofen.<br><br>On 26-Sep-2021 21:00, patient had left upper chest pain which got resolved with 1gm Tylenol and a warm bath.<br>On 27-Sep-2021 03:30, pain returned and took 1gm Tylenol and 400mg ibuprofen but pain did not resolve. At 04:30, pain began to radiate down to left arm and thus went to hospital. After EKG was done, patient sat in room for 1hour, pain got resolved and then left the facility to seek help at another facility.<br>Again pain returned and EKG was done which showed STEMI Troponins + d-dimer+.<br><br>Patient was then sent to Cath lab for cardiac catheterization. No occlusions found. Diagnosed with Focal Myocarditis.<br><br>Company Comment: This case concerns a 37-year-old, male patient with no relevant medical history, who experienced the serious unexpected events of Pain in extremity, Chest pain, Limb discomfort, Acute Myocardial infarction, and the serious expected event of Myocarditis.The events occurred approximately 7 months after the second dose of Moderna CoviD-19 Vaccine which resulted in Hospitalization and a Life threatening outcome . The rechallenge was unknown since no information about the events of the first dose was disclosed. The benefit-risk relationship of Moderna CoviD-19 Vaccine is not affected by this report. |
| 4.1(b) | 4.1(b) | This case was received via 4.1(b) Reference number: 4.1(b) on 19-Oct-2021 and was forwarded to Moderna on 19-Oct-2021.<br>This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCARDITIS (Myocarditis), PRESYNCOPE (Presyncope), CHEST PAIN (Chest pain), DIZZINESS (Dizziness), DYSPNOEA (Dyspnoea) and FEELING ABNORMAL (Feeling abnormal) in a 37-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination.<br><br>Concurrent medical conditions included Hashimoto's thyroiditis and Hypocalcemia.<br>Concomitant products included LEVOTHYROXINE, LIOTHYRONINE (NP THYROID), OMEPRAZOLE (4.1(b) [OMEPRAZOLE]), VITAMIN D3, CALCIUM, MAGNESIUM OXIDE and CALCITRIOL for an unknown indication.<br><br>On 31-Aug-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 03-Sep-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant), PRESYNCOPE (Presyncope) (seriousness criterion hospitalization), CHEST PAIN (Chest pain) (seriousness criterion hospitalization), |

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| | | DIZZINESS (Dizziness) (seriousness criterion hospitalization), DYSPNOEA (Dyspnoea) (seriousness criterion hospitalization) and FEELING ABNORMAL (Feeling abnormal) (seriousness criterion hospitalization). The patient was hospitalized for 3 days due to CHEST PAIN, DIZZINESS, DYSPNOEA, FEELING ABNORMAL, MYOCARDITIS and PRESYNCOPE. At the time of the report, MYOCARDITIS (Myocarditis), PRESYNCOPE (Presyncope), CHEST PAIN (Chest pain), DIZZINESS (Dizziness), DYSPNOEA (Dyspnoea) and FEELING ABNORMAL (Feeling abnormal) had not resolved.<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments.<br><br>No treatment information was provided.<br>On 03-Sep-2021, Multiple EKG, Angiogram, CT chest, X-rays, laboratory test, ECHO, ultrasound scan were performed. Results not provided. |
| 4.1(b) | 4.1(b) | This case was received via 4.1(b) (Reference number: 4.1(b) on 19-Oct-2021 and was forwarded to Moderna on 19-Oct-2021.<br>This regulatory authority case was reported by an other health care professional and describes the occurrence of CHEST DISCOMFORT (Chest discomfort), CHEST PAIN (Chest pain), DYSPNOEA (Dyspnoea), EJECTION FRACTION DECREASED (Ejection fraction decreased), MYOCARDIAL OEDEMA (Myocardial oedema), MYOCARDITIS (Myocarditis), PAIN (Pain), PAIN IN JAW (Pain in jaw), PERICARDIAL EFFUSION (Pericardial effusion), PYREXIA (Pyrexia), SLEEP DISORDER (Sleep disorder), VENTRICULAR HYPOKINESIA (Ventricular hypokinesia) and PERICARDITIS (Pericarditis) in a 21-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 939901) for COVID-19 vaccination.<br><br>Concomitant products included FENTANYL for Pain, ACETYLSALICYLIC ACID (ASPIRIN (E.C.)), COLCHICINE, IBUPROFEN and METOPROLOL SUCCINATE for an unknown indication.<br><br>On 24-Aug-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form.<br>On 23-Sep-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 24-Sep-2021, the patient experienced CHEST DISCOMFORT (Chest discomfort) (seriousness criterion hospitalization), CHEST PAIN (Chest pain) (seriousness criterion hospitalization), DYSPNOEA (Dyspnoea) (seriousness criterion hospitalization), EJECTION FRACTION DECREASED (Ejection fraction decreased) (seriousness criterion hospitalization), MYOCARDIAL OEDEMA (Myocardial oedema) (seriousness criteria hospitalization and medically significant), MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant), PAIN (Pain) (seriousness criterion hospitalization), PAIN IN JAW (Pain in jaw) (seriousness criterion hospitalization), PERICARDIAL EFFUSION (Pericardial effusion) (seriousness criteria hospitalization and medically significant), PYREXIA (Pyrexia) (seriousness criterion hospitalization), SLEEP DISORDER (Sleep disorder) (seriousness criterion hospitalization), VENTRICULAR HYPOKINESIA (Ventricular hypokinesia) (seriousness criteria |

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| | | hospitalization and medically significant) and PERICARDITIS (Pericarditis) (seriousness criteria hospitalization and medically significant). The patient was hospitalized from 27-Sep-2021 to 29-Sep-2021 due to CHEST DISCOMFORT, CHEST PAIN, DYSPNOEA, EJECTION FRACTION DECREASED, MYOCARDIAL OEDEMA, MYOCARDITIS, PAIN, PERICARDIAL EFFUSION, PERICARDITIS, PYREXIA, SLEEP DISORDER and VENTRICULAR HYPOKINESIA. At the time of the report, CHEST DISCOMFORT (Chest discomfort), CHEST PAIN (Chest pain), DYSPNOEA (Dyspnoea), EJECTION FRACTION DECREASED (Ejection fraction decreased), MYOCARDIAL OEDEMA (Myocardial oedema), MYOCARDITIS (Myocarditis), PAIN (Pain), PAIN IN JAW (Pain in jaw), PERICARDIAL EFFUSION (Pericardial effusion), PYREXIA (Pyrexia), SLEEP DISORDER (Sleep disorder), VENTRICULAR HYPOKINESIA (Ventricular hypokinesia) and PERICARDITIS (Pericarditis) had resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 24-Sep-2021, Blood potassium: decreased (Low) decreased.<br>On 24-Sep-2021, Cardiac imaging procedure: abnormal (abnormal) abnormal.<br>On 27-Sep-2021, Electrocardiogram: st elevations (abnormal) ST elevations and st elevations (abnormal) ST elevations.<br>On 27-Sep-2021, Troponin: 5ng/ml (High) 5ng/ml, 10.6 ng/ml (High) 10.6 ng/ml, 9.5 ng/ml (High) 9.5 ng/mL, 10.5 ng/ml (High) 10.5 ng/mL and 25.9 ng/ml (High) 25.9 ng/ml.<br>On 28-Sep-2021, Magnetic resonance imaging heart: normal lv cavity si (abnormal) Normal LV cavity si.<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments.<br><br>On 24-SEP-2021 Chest x ray,Echocardiogram normal, Electrocardiogram ST segment elevation,Magnetic resonance imaging heart, Right ventricular ejection fraction decreased,SARS-CoV-2 test,Troponin increased was performed, results not reported however outcome is reported as recovered/resolved.<br>ON 27-SEP-2021 at 06.32 Chest X-Raywas done ,On same day at 10.56 Covid PCR was done,results not provided.<br>It wa reported that the patient also received (see continuation) 40 mEq of potassium to replete electrolytes (potassium level upon arrival 3.4 mmol/L).<br><br>No treatment medications were provided.<br><br>Company Comment:<br>This case concerns a 21-year-old, male patient with no relevant medical history, who experienced the unexpected events of Chest discomfort, Chest pain, Dyspnea, Ejection fraction decreased, Myocardial edema, Myocarditis, Pain, Pain in jaw, Pericardial effusion, Pyrexia, Sleep disorder, Ventricular hypokinesia, and Pericarditis. The events occurred approximately 2 days after the second dose of mRNA-1273 (Moderna Covid-19 vaccine). The rechallenge was not applicable as events |

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| | | occurred after the second dose. The benefit-risk relationship of mRNA-1273 (Moderna Covid-19 vaccine) is not affected by this report. |
| 4.1(b) | 4.1(b) | This case was received via 4.1(b) (Reference number: 4.1(b) on 19-Oct-2021 and was forwarded to Moderna on 19-Oct-2021.<br>This regulatory authority case was reported by an other health care professional and describes the occurrence of BACK PAIN (Back pain), CHEST PAIN (Chest pain), DYSPNOEA (Dyspnoea), PAIN (Pain), PAIN IN EXTREMITY (Pain in extremity) and MYOCARDITIS (Myocarditis) in a 19-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 048F21A) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 28-Sep-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 29-Sep-2021, the patient experienced BACK PAIN (Back pain) (seriousness criterion hospitalization), CHEST PAIN (Chest pain) (seriousness criterion hospitalization), DYSPNOEA (Dyspnoea) (seriousness criterion hospitalization), PAIN (Pain) (seriousness criterion hospitalization), PAIN IN EXTREMITY (Pain in extremity) (seriousness criterion hospitalization) and MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). The patient was hospitalized on sometime in September 2021 due to BACK PAIN, CHEST PAIN, DYSPNOEA, MYOCARDITIS, PAIN and PAIN IN EXTREMITY. At the time of the report, BACK PAIN (Back pain), CHEST PAIN (Chest pain), DYSPNOEA (Dyspnoea), PAIN (Pain), PAIN IN EXTREMITY (Pain in extremity) and MYOCARDITIS (Myocarditis) had resolved.<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments.<br><br>No concomitant product was provided by the reporter.<br>No treatment medication was provided.<br><br>Chest pain started at 5am, approximately 19 hours after vaccination. Patient's symptoms mimicked those of a hear attack. Patient taken to the hospital on Thursday morning after shortness of breath developed. Pain was radiating down his arm and to his back. Patient was admitted on Thursday after being at the ER.<br><br>Company Comment: This case concerns a 19-year-old, male patient, with no relevant medical history, who experienced the serious, expected, AESI event of myocarditis and other serious unexpected events of back pain, chest pain, dyspnea, pain and pain in extremity. The events occurred 1 day after second dose of Moderna vaccine. The rechallenge is not applicable as a third dose is not expected. The benefit-risk relationship of Moderna vaccine is not affected by this report. |
| 4.1(b) | 4.1(b) | This case was received via 4.1(b) (Reference number: 4.1(b) on 19-Oct-2021 and was forwarded to Moderna on 19-Oct-2021.<br>This regulatory authority case was reported by an other health care professional and describes the occurrence of ARTHRALGIA (Arthralgia), |

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| | | BACK PAIN (Back pain), CHEST PAIN (Chest pain), HYPOPNOEA (Hypopnoea), MUSCULOSKELETAL PAIN (Musculoskeletal pain), PAIN (Pain), PAINFUL RESPIRATION (Painful respiration) and PERICARDITIS (Pericarditis) in a 35-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 006C21) for COVID-19 vaccination.<br><br>Concurrent medical conditions included High cholesterol and Migraine. Concomitant products included FEXOFENADINE HYDROCHLORIDE (ALLEGRA) and CAFFEINE, PARACETAMOL (EXCEDRIN [CAFFEINE;PARACETAMOL]) for an unknown indication.<br><br>On 24-Apr-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 03-Aug-2021, the patient experienced BACK PAIN (Back pain) (seriousness criterion hospitalization). On 04-Aug-2021, the patient experienced ARTHRALGIA (Arthralgia) (seriousness criterion hospitalization), CHEST PAIN (Chest pain) (seriousness criterion hospitalization), HYPOPNOEA (Hypopnoea) (seriousness criterion hospitalization), MUSCULOSKELETAL PAIN (Musculoskeletal pain) (seriousness criterion hospitalization), PAIN (Pain) (seriousness criterion hospitalization), PAINFUL RESPIRATION (Painful respiration) (seriousness criterion hospitalization) and PERICARDITIS (Pericarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, ARTHRALGIA (Arthralgia), BACK PAIN (Back pain), CHEST PAIN (Chest pain), HYPOPNOEA (Hypopnoea), MUSCULOSKELETAL PAIN (Musculoskeletal pain), PAIN (Pain), PAINFUL RESPIRATION (Painful respiration) and PERICARDITIS (Pericarditis) had resolved.<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments.<br><br>No treatment medications were provided.<br>Company Comment: This case concerns a 35-year-old, male patient with no relevant medical history, who experienced the expected serious adverse event of special interest of pericarditis and unexpected serious events of arthralgia, back pain, chest pain, hypopnea, musculoskeletal pain, pain, painful respiration. The events occurred approximately 3 months and 11 days after the second dose of Spikevax (Moderna COVID-19 vaccine). The rechallenge was assessed as not applicable as the AEs occurred after the second dose. The benefit-risk relationship of Spikevax (Moderna COVID-19 vaccine) is not affected by this report. |
| 4.1(b) [redacted] | 4.1(b) [redacted] | This case was received via 4.1(b) [redacted] (Reference number: 4.1(b) [redacted] on 19-Oct-2021 and was forwarded to Moderna on 19-Oct-2021.<br>This regulatory authority case was reported by an other health care professional and describes the occurrence of CHEST PAIN (Chest pain), DYSPNOEA (Dyspnoea) and MYOCARDITIS (Myocarditis) in a 23-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 048F21A) for COVID-19 vaccination.<br><br>No Medical History information was reported. |

| Case ID | WW Identifier | Narrative |
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| | | On 03-Oct-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 05-Oct-2021, the patient experienced CHEST PAIN (Chest pain) (seriousness criteria hospitalization and medically significant), DYSPNOEA (Dyspnoea) (seriousness criteria hospitalization and medically significant) and MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, CHEST PAIN (Chest pain), DYSPNOEA (Dyspnoea) and MYOCARDITIS (Myocarditis) outcome was unknown.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 05-Oct-2021, Electrocardiogram: normal (normal) normal.<br>On 05-Oct-2021, Laboratory test: normal (normal) normal.<br>On 05-Oct-2021, Troponin (8000-10.3000): increased (High) Increased, high sensitivity troponins with value of 10,337.<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments.<br><br>No concomitant medications were reported<br>No treatment medications were reported.<br><br>The patient had Myocarditis - developed chest pain, shortness of breath quite suddenly the morning of 10/5/2021.<br><br>This case concerns a 23-year-old, male patient with no relevant medical history, who experienced the unexpected events of chest pain and dyspnea and expected event of myocarditis. The events chest pain, dyspnea and myocarditis occurred 2 days after the second dose of mRNA-1273 vaccine administration. The rechallenge was unknown as there's no information available about the first dose. The patient's age and gender remain confounders. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. |
| 4.1(b) | 4.1(b) | This case was received via 4.1(b) (Reference number: 4.1(b) on 19-Oct-2021 and was forwarded to Moderna on 19-Oct-2021.<br><br>This regulatory authority case was reported by an other health care professional and describes the occurrence of PERICARDITIS (Pericarditis) in a 35-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination.<br><br>The patient's past medical history included High cholesterol and Swollen lymph nodes (tender swollen lymph nodes following flu vaccine (but not every time)).<br>Concomitant products included COLECALCIFEROL (VITAMIN D [COLECALCIFEROL]) for an unknown indication.<br><br>On 30-Apr-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 03-May-2021, after starting mRNA-1273 (Moderna COVID-19 Vaccine), the patient experienced PERICARDITIS (Pericarditis) (seriousness criterion |

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| | | medically significant). At the time of the report, PERICARDITIS (Pericarditis) had not resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 03-May-2021, Blood cholesterol increased: increased (High) Blood cholesterol increased.<br>On 03-May-2021, Blood magnesium: decreased (Low) decreased Blood magnesium.<br>On 03-May-2021, Blood test: abnormal (abnormal) abnormal.<br>On 03-May-2021, Electrocardiogram: normal (normal) Normal.<br>On 03-May-2021, Ultrasound scan: normal (normal) Normal.<br>On 03-May-2021, Vitamin D: decreased (Low) decreased.<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments.<br><br>The patient experienced pericarditis heart racing/pounding heavily especially when laying down at night.<br><br>The patient had sonogram that he believed came back normal. blood panels showing low vit D high cholesterol, low magnesium he believed. since, He had a long term (1 week) heart monitor ecg, another blood panel pending results. Stress test scheduled. The patient had Cardiac monitoring with unknown result.<br><br>No treatment medication reported.<br><br>Company Comment - This case concerns a 35-year-old, male patient with no relevant medical history, who experienced the unexpected event of palpitations and the expected event of pericarditis. The events palpitations and pericarditis occurred 3 days after the second dose of mRNA-1273 vaccine administration. The rechallenge was not applicable, as the event occurred after the second dose and no additional dose is expected at this moment. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. |
| 4.1(b) | 4.1(b) | This case was received via 4.1(b) (Reference number: 4.1(b) ) on 19-Oct-2021 and was forwarded to Moderna on 19-Oct-2021.<br>This regulatory authority case was reported by an other health care professional and describes the occurrence of FATIGUE (Fatigue), CHEST PAIN (Chest Pain), PALPITATIONS (Palpitations), TACHYCARDIA (Tachycardia) and PERICARDITIS (Pericarditis) in a 23-year-old female patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 08-Sep-2021, the patient received second dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 04-Oct-2021, after starting mRNA-1273 (Moderna CoviD-19 Vaccine), the patient experienced PERICARDITIS (Pericarditis) (seriousness criterion medically significant). On an unknown date, the patient experienced FATIGUE (Fatigue) (seriousness criterion medically significant), CHEST |

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| | | PAIN (Chest Pain) (seriousness criterion medically significant), PALPITATIONS (Palpitations) (seriousness criterion medically significant) and TACHYCARDIA (Tachycardia) (seriousness criterion medically significant). At the time of the report, FATIGUE (Fatigue), CHEST PAIN (Chest Pain), PALPITATIONS (Palpitations) and TACHYCARDIA (Tachycardia) outcome was unknown and PERICARDITIS (Pericarditis) was resolving.<br><br>The action taken with mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown) was unknown.<br><br>For mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown), the reporter considered PERICARDITIS (Pericarditis) to be possibly related. No further causality assessments were provided for FATIGUE (Fatigue), CHEST PAIN (Chest Pain), PALPITATIONS (Palpitations) and TACHYCARDIA (Tachycardia).<br><br>Concomitant product use was not provided by the reporter. No treatment information was provided.<br><br>The patient had chest pain for one day after the first vaccine. Followed by two weeks of chest pain after the second dose. Confirmed as pericarditis as a result of the vaccine.<br><br>Patient had not tested positive for COVID-19 since having the vaccine. Patient was not enrolled in clinical trial.<br><br>Company Comment : This case concerns a 23-year-old, female patient with no reported medical history, who experienced the unexpected, serious events of palpitations, tachycardia, chest pain, fatigue and expected, serious and AESI event of Pericarditis. The event pericarditis occurred 26 days after the second dose of Spikevax. The events palpitations, chest pain and fatigue occurred after second dose of Spikevax, time to onset from vaccination was not reported. Regulatory authority captured the rechallenge as unknown, as it should for Pericarditis, as outcome is recovering and no information disclosed about other doses, however, for events palpitations, tachycardia, chest pain, fatigue, the outcome is not recovered, hence rechallenge should be not applicable. The benefit-risk relationship of Spikevax vaccine is not affected by this report. |
| 4.1(b) | 4.1(b) | This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) ) on 13-Oct-2021 and was forwarded to Moderna on 20-Oct-2021.<br>This case, reported by a physician, was received by Takeda via Moderna's adverse reaction reporting site (4.1(b)<br><br>On 03-Sep-2021, at 15:00, the patient received the 1st dose of this vaccine.<br><br>On an unknown date, body temperature before the vaccination: 36.4 degrees Celsius.<br><br>On 01-Oct-2021, at 15:00, the patient received the 2nd dose of this vaccine. Pyrexia developed at night. |

| Case ID | WW Identifier | Narrative |
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| | | On 02-Oct-2021, pyrexia went down.<br><br>On 03-Oct-2021, at 21:00, chest pain developed.<br><br>On 04-Oct-2021, the symptoms were exacerbated, and the patient was urgently transported to a medical institution. Troponin T was positive (1.300 ng/mL), CK: 762 U/L, CKMB: 72 U/L, and cardiac enzymes were elevated. Echocardiography showed diffuse wall hypokinesis (left ventricular ejection fraction: 46%). The patient was diagnosed with perimyocarditis and was urgently hospitalized. Steroid pulse therapy was started.<br><br>On 05-Oct-2021, myocardial biopsy showed mild lymphocytic infiltration, leading to a definitive diagnosis of myocarditis.<br><br>On 07-Oct-2021, steroid treatment was effective, CK/CKMB were normalized, and troponin T decreased to 0.551 ng/mL.<br><br>On 12-Oct-2021, colchicine was additionally administered. The patient's general condition was stabilized thereafter.<br><br>On 13-Oct-2021, the symptoms were resolving.<br><br>The outcome of pyrexia was reported as recovered. The outcome of perimyocarditis and diffuse wall hypokinesis was reported as resolving.<br><br>Follow-up investigation will be made.<br><br>Company Comment:<br>The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. |
| 4.1(b) | 4.1(b) | This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) ) on 16-Oct-2021 and was forwarded to Moderna on 20-Oct-2021.<br>This case, initially reported to the 4.1(b) by a (pharmacist), was received via the 4.1(b) (Ref, 4.1(b)<br><br>The patient had a history of epilepsy and was taking levetiracetam.<br><br>On an unknown date, the patient received the 1st dose of this vaccine.<br><br>On 12-Oct-2021, the patient received the 2nd dose of this vaccine.<br><br>On 13-Oct-2021, chest pain and queasy developed.<br><br>On 15-Oct-2021, in the morning, the patient was raced to a hospital with a pain scale of 10/10. No pericardial effusion was confirmed by ultrasound. Electrocardiogram and blood test showed increased cardiac enzymes, and acute pericarditis was suspected. The patient was hospitalized.<br><br>The outcome of chest pain, queasy, and suspected myocarditis was unknown. |

| Case ID | WW Identifier | Narrative |
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| | | Follow-up investigation will be made.<br><br>Company Comment:<br>The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. |
| 4.1(b) | 4.1(b) | This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 13-Oct-2021 and was forwarded to Moderna on 20-Oct-2021.<br>This case, reported by a pharmacist via a medical representative, and reported to the 4.1(b) by a pharmacist, was received via the 4.1(b) (Ref, 4.1(b)<br><br>On 02-Sep-2021, at 14:00, the patient received the 1st dose of this vaccine.<br><br>On 30-Sep-2021, at 14:00, the patient received the 2nd dose of this vaccine.<br><br>On 01-Oct-2021, chest pain developed.<br><br>On 03-Oct-2021, in the early hours, an emergency call was made, and the patient visited a hospital. Increased cardiac enzymes, increased inflammatory reaction, and abnormality in the electrocardiogram were noted, and the patient was hospitalized for suspected myocarditis. Oral administration of 6 tablets of aspirin in 3 divided doses was started.<br><br>On an unknown date, myocardial enzymes improved over time, and test values returned to normal.<br><br>On 13-Oct-2021, the patient recovered but remained hospitalized for examinations.<br><br>The outcome of chest pain and suspected myocarditis was reported as resolved.<br><br>Follow-up investigation will be made.<br><br>Company Comment:<br><br>The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. |
| 4.1(b) | 4.1(b) | This case was initially received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 15-Oct-2021. The most recent information was received on 10-Nov-2021 and was forwarded to Moderna on 17-Nov-2021.<br>This case, initially reported to the 4.1(b) by a (physician), was received via the 4.1(b) (Ref, 4.1(b)<br><br>On 10-Nov-2021, follow-up information was received from the physician.<br><br>On an unknown date, the patient received the 1st dose of this vaccine.<br><br>On 26-Sep-2021, the patient received the 2nd dose of this vaccine. |

| Case ID | WW Identifier | Narrative |
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| | | On 27-Sep-2021, pyrexia in the 38 degrees Celsius developed.<br><br>On 28-Sep-2021, in the morning, acute myocarditis and pericarditis developed. Chest tightness developed. The patient visited a nearby physician. Electrocardiogram showed extensive ST elevation. Blood test showed increased CK, CK-MB, CRP, and WBC. Oral administration of acetaminophen 200 mg 3 times/day was started.<br><br>On 29-Sep-2021, the patient was referred to the reporting department. Physical findings showed no abnormal pulsus paradoxus or pericardial friction rub. Chest x-ray and echocardiography showed no abnormalities, but troponin I was elevated at 8.40 ng/mL. BNP 65.1 pg/mL, CK-MB 47.5 ng/mL, CRP 5.95 mg/dL. Electrocardiogram showed ST elevation in multiple leads. The patient was hospitalized with a diagnosis of acute myocarditis. Chest tightness disappeared. Oral administration of acetaminophen 200 mg 3 times/day was completed.<br><br>On 30-Sep-2021, electrocardiogram showed ST elevation in multiple leads.<br><br>On 01-Oct-2021, electrocardiogram showed ST elevation in multiple leads.<br><br>On 02-Oct-2021, the symptoms were confirmed as resolving. Spontaneously improved, and acute myocarditis and pericarditis disappeared.<br><br>The outcome of acute myocarditis and pericarditis was reported as resolving.<br><br>No follow-up investigation will be made.<br><br>Follow-up received on 10-NOV-2021<br><br>Updated: Patient Information, Lab Data, Event Information, Narrative, Reporter Comments<br><br>Company Comment:<br><br>The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. |
| 4.1(b) | 4.1(b) | This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 16-Oct-2021 and was forwarded to Moderna on 20-Oct-2021.<br>This case, initially reported to the 4.1(b) by a (physician), was received via the 4.1(b) (Ref, 4.1(b)<br><br>On an unknown date, the patient received the 1st dose of this vaccine.<br><br>On an unknown date, body temperature before the vaccination: 36.5 degrees Celsius. |

| Case ID | WW Identifier | Narrative |
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| | | On 07-Oct-2021, at 15:00, the patient received the 2nd dose of this vaccine. At 19:00, it was thought that acute myocarditis devloped. During the night, pyrexia and chest pain developed.<br><br>On an unknown date, the symptoms did not improve, and the patient visited the reporting hospital emergently.<br><br>On 10-Oct-2021, the patient was hospitalized for treatment. Acute myocarditis was diagnosed based on abnormal electrocardiogram and increased CK.<br><br>On an unknown date, the symptoms improved with oral treatment with anti-inflammatory agent.<br><br>On 14-Oct-2021, the symptoms improved, and the patient was discharged from the hospital.<br><br>The outcome of acute myocarditis was reported as resolved.<br><br>Follow-up investigation will be made.<br><br>Company Comment:<br><br>The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. |
| 4.1(b) | 4.1(b) | This case was received via 4.1(b) Reference number: 4.1(b) on 19-Oct-2021 and was forwarded to Moderna on 19-Oct-2021.<br>This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCARDITIS (Myocarditis/Pericarditis) in a 22-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination.<br><br>No relevant medical history was provided by the reporter.<br>Concomitant products included IBUPROFEN for an unknown indication.<br><br>On 30-Sep-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 02-Oct-2021, after starting mRNA-1273 (Moderna COVID-19 Vaccine), the patient experienced MYOCARDITIS (Myocarditis/Pericarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Myocarditis/Pericarditis) outcome was unknown.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 02-Oct-2021, Chest X-ray: normal (normal) chest x-ray normal.<br>On 02-Oct-2021, Echocardiogram: normal (normal) echocardiogram normal.<br>On 02-Oct-2021, Electrocardiogram: abnormal (abnormal) consistent with pericarditis.<br>On 02-Oct-2021, Troponin: increased (High) Elevated. |

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| | | For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments.<br><br>Patient had myopericarditis. symptoms included chest pain, shortness of breath, dyspnea on exertion starting 2 days after the second dose of Moderna COVID-19 vaccine.<br><br>No treatment medications were reported.<br><br>Company Comment: This case concerns a 22-year-old, male patient with no relevant medical history, who experienced the unexpected event of myocarditis. The events occurred approximately 2 days after the second dose of Moderna Covid-19 vaccine when patient was hospitalized. At the time of report outcome is still unknown. The rechallenge was unknown since no information about the first dose was disclosed. The benefit-risk relationship of the vaccine is not affected by this report. |
| 4.1(b) [redacted] | 4.1(b) [redacted] | This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 20-Oct-2021 and was forwarded to Moderna on 20-Oct-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of CHEST PAIN (Chest pain/Pericarditis) and PERICARDITIS (Chest pain/Pericarditis) in a 30-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3003604) for Vaccination. The occurrence of additional non-serious events is detailed below.<br><br>Previously administered products included for Vaccination: Comirnaty. Past adverse reactions to the above products included No adverse reaction with Comirnaty.<br><br>On 04-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 27-Sep-2021, the patient experienced CHEST PAIN (Chest pain/Pericarditis) (seriousness criterion hospitalization) and PERICARDITIS (Chest pain/Pericarditis) (seriousness criteria hospitalization and medically significant). On an unknown date, the patient experienced COVID-19 IMMUNISATION (Chest pain/Pericarditis). At the time of the report, CHEST PAIN (Chest pain/Pericarditis), PERICARDITIS (Chest pain/Pericarditis) and COVID-19 IMMUNISATION (Chest pain/Pericarditis) outcome was unknown.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 27-Sep-2021, Electrocardiogram: abnormal (abnormal) Findings consistent with pericarditis.<br>On 27-Sep-2021, Investigation: abnormal (abnormal) No myocardial affection.<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered CHEST PAIN (Chest pain/Pericarditis) and PERICARDITIS (Chest pain/Pericarditis) to be possibly related. No further causality assessment was provided for COVID-19 IMMUNISATION (Chest pain/Pericarditis).<br><br>No concomitant medications were reported. |

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| | | No treatment medications were reported.<br><br>This is a regulatory case concerning a 30 year-old, male patient with clinical history of<br>previously administered Comirnaty products for Vaccination without adverse reaction, who experienced the unexpected serious event of CHEST PAIN, the expected (AESI) serious event of PERICARDITIS and other non-serious adverse event.<br>The events occurred 24 days after the first dose of Spikevax vaccine, second doses of COVID-19 vaccine.<br>The rechallenge was not applicable since only information about the first dose was disclosed<br>The benefit-risk relationship of Spikevax is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 20-Oct-2021: Translation received on 21-Oct-2021: Event verbatim was updated. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 20-Oct-2021 and was forwarded to Moderna on 20-Oct-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (PERIMYOCARDITIS) in an 18-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3006273) for COVID-19 vaccination.<br><br>No medical history was provided by the reporter.<br><br>On 05-Oct-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 08-Oct-2021, after starting mRNA-1273 (Spikevax), the patient experienced MYOCARDITIS (PERIMYOCARDITIS) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (PERIMYOCARDITIS) was resolving.<br><br>For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.<br><br>No concomitant medication listed.<br><br>No treatment information provided.<br><br>Company comment -This is a regulatory case concerning a 18 year-old, male patient with no clinical history who experienced the expected (AESI) serious event of PERICARDITIS.<br>The event occurred 4 days after the second dose of Spikevax vaccine<br>The rechallenge is not applicable" as the events occurred after the second dose and no details were provided about the first dose<br>The benefit-risk relationship of Spikevax is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 20-Oct-2021: Translation Received on 21-Oct-2021 includes event verbatim updated. |

| Case ID | WW Identifier | Narrative |
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| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 20-Oct-2021 and was forwarded to Moderna on 20-Oct-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (MYOCARDITIS) in a 19-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3005835) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 22-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 25-Sep-2021, after starting mRNA-1273 (Spikevax), the patient experienced MYOCARDITIS (MYOCARDITIS) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (MYOCARDITIS) was resolving.<br><br>For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.<br><br>No concomitant medication was reported.<br>No treatment history was reported.<br><br>Company Comment : This case concerns a 19-year-old, male patient with no relevant medical history, who experienced the expected serious event of Myocarditis. The event occurred approximately 04 days after the second dose of Spikevax. The rechallenge was not applicable. The event is consistent with the current understanding of the mechanism of action of the vaccine. The benefit-risk relationship of Spikevax is not affected by this report. Event term, onset date, outcome and seriousness captured per SD from Regulatory Authority reporting.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 20-Oct-2021: Translation received on 21 Oct 2021 included event verbatim and dosage text updated. |
| 4.1(b) | 4.1(b) | This case was received via an unknown source (no reference has been entered for a health authority or license partner) on 20-Oct-2021 and was forwarded to Moderna on 20-Oct-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of INFLUENZA LIKE ILLNESS (flu-like symptoms), ABDOMINAL PAIN UPPER (Epigastric pain) and MYOCARDITIS (Peri-/Myocarditis) in a 38-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 immunisation.<br><br>The patient's past medical history included Nephrolithiasis (History of nephrolithiasis, spontaneous resolution Aug 26, 2020; calcium oxalate concrement) on 26-Aug-2020, Hidradenitis suppurativa (Acne inversa) and Ex-smoker.<br>Concurrent medical conditions included Allergy (Dyshidrotic finger/hand eczema without spread; idiopathic, possible atopic diathesis).<br><br>In July 2021, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 100 microgram. |

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| | | On 02-Aug-2021, received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) dosage was changed to 100 microgram. On 02-Aug-2021, the patient experienced INFLUENZA LIKE ILLNESS (flu-like symptoms) (seriousness criterion hospitalization), ABDOMINAL PAIN UPPER (Epigastric pain) (seriousness criterion hospitalization) and MYOCARDITIS (Peri-/Myocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, INFLUENZA LIKE ILLNESS (flu-like symptoms), ABDOMINAL PAIN UPPER (Epigastric pain) and MYOCARDITIS (Peri-/Myocarditis) had not resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 05-Aug-2021, Angiocardiogram: abnormal (abnormal) Stenosis-free coronary vessels, LVEF 55%; mid-ventricular hypokinesis.<br>On 05-Aug-2021, Echocardiogram: abnormal (abnormal) mildly impaired systolic LV function EF visual 45% with diffuse hypokinesis, diastolic dysfunction, LA dilatation, no relevant valve defects, normal RV function and dimension, the pulmonary pressure cannot be captured, no indirect signs of a pulmonary hypertension, no pericardial effusion..<br>On 05-Aug-2021, Electrocardiogram: abnormal (abnormal) normal cardiac sinus rhythm, HR 60/min, PQinterval 191ms, QRS 86ms, R/S transition V4, STelevations I, II, aVL, V4-V6, ST-depressions aVR, V1, Negative T waves III, QTc 368ms.<br>On 07-Aug-2021, Electrocardiogram: normal (normal) normal cardiac SR, 63/min, indifferent type, preterminal anterolateral negative T waves, PQ 196ms, QRS 90ms, QTc 401ms..<br>On 07-Aug-2021, Laboratory test: abnormal (abnormal) CK peak of 489 U/L and Troponin-T peak of 1003 ng/L then regressive cardiac enzymes and regressive CRP..<br><br>For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered INFLUENZA LIKE ILLNESS (flu-like symptoms), ABDOMINAL PAIN UPPER (Epigastric pain) and MYOCARDITIS (Peri-/Myocarditis) to be possibly related.<br><br>No concomitant medications reported<br>Patient was treated with Ibuprofen 600 mg 3x/day as well as a heart failure therapy with candesartan and metoprolol ,Pantoprazole and Metamizole for epigastric pain .<br>Company Comment : This case concerns a 38-year-old, male patient with medical history of smoking (ex-smoker), who experienced the unexpected events of abdominal pain upper, influence like illness and expected event of myocarditis. The events occurred on the same day after the second dose of Moderna COVID-19 Vaccine. The patient developed fever of 37.5°C and limb pain and epigastric pain. Also patient had palpitation, rapid breathing. To alleviate the pain, the patient independently took pantoprazole and metamizole, which did not relieve the symptoms. At that point the patient presented to the primary care doctor, who detected elevated cardiac enzymes and D-dimers and referred the patient to the emergency department for a suspected myocarditis. The ECG showed a sinus rhythm with diffuse ST-elevations. Coronary angiography showed no stenoses in the coronary arteries. The TTE showed a mildly impaired systolic LVEF of 45% with diffuse hypokinesis, without pericardial |

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| | | effusion. The treating physicians diagnosed a perimyocarditis most likely in the context of the COVID vaccination. Lab data included CK of 386 U/L, Troponin-T of 782 ng/L, CRP of 42mg/L.with leukocytes in normal ranges. The patient was successfully treated with ibuprofen, candesartan and metoprolol and discharged two days later. The rechallenge was not applicable as events occurred after second dose and no further dosing was reported or planned, based on information provided. The reporter assessed the events as related to the product. The medical history of smoking remains a confounder. The benefit-risk relationship of Moderna COVID-19 Vaccine is not affected by this report.<br><br>It was reported that Patient was hospitalized on 05AUG2021 and discharged on 07AUG2021 . Lab data included CK of 386 U/L, Troponin<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 20-Oct-2021: Translation received on 24OCT2021 Contains Medical history, Lab data, Treatment drugs, Translated narrative and Sender comments |
| 4.1(b) | 4.1(b) | This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCARDITIS (4.1(b)) in a 19-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) (batch nos. 3004219 and 3003606) for COVID-19 vaccination.<br><br>No medical history was reported.<br>Concurrent medical conditions included Non-smoker, Alcohol use (Occasional), Renal disease and Liver disorder (Liver Disease).<br><br>On 29-Jun-2021, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 200 microgram.<br>On 27-Jul-2021, received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) dosage was changed to 200 microgram. On 29-Jul-2021, after starting mRNA-1273 (COVID-19 Vaccine Moderna), the patient experienced MYOCARDITIS (4.1(b)) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (4.1(b)) was resolving.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On an unknown date, Electrocardiogram: high (High) ECG inferior and latest ST segment elevation without mirror.<br>On an unknown date, Magnetic resonance imaging: abnormal (abnormal) evidence of moderate multifocal lateral myopericardtitis.<br>On an unknown date, Troponin: high (High) 11779 ng/L.<br><br>For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered MYOCARDITIS (4.1(b)) to be possibly related.<br><br>Concomitant product use was not provided by the reporter.<br>No treatment information was provided.<br>Approximately 2.5 days after second vaccination from 29-Jul-2021, the patient developed the first symptoms of Perimyocarditis in the form of mild |

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| | | chest pain. Initially the pain was almost completely gone following rest. However the same evening (about 4 hours later), he again experienced very severe chest symptoms and presented as an emergency. A diagnosis of Perimyocarditis was made. Clinically he presented very groggy and pale in the face. He was hospitalized where analgesic as well as antiphlogistic therapy was initiated and continuous monitoring performed. The ECG showed ST elevation inferiorly and laterally without mirror changes(ST depressions) in the anterior leads. Lab tests revealed a ma imum troponin I (hs) of 11,779 ng/L, which regressed over the course. MRI revealed evidence of moderate multifocal lateral myocarditis, with no evidence of dysfunction (LVEF 56%, no focal wall motility disturbance) or pericardial effusion. Differential diagnosis: a viral genesis was discussed. There were no known cardiovascular risk factors. In addition to NSAIDs and colchicine, low-dose cardioprotective therapy was installed with an ACE inhibitor and a cardio-selective beta blocker. The further course was without complications and after 5 days the patient could be discharged in improved condition. At discharge, the following medications were prescribed: Pantoprazole, Ramipril, Bisoprolol, Acetylsalicylic acid and Colchicine. No known allergies.<br>Company Comment: This case refers to a 19yearold male patient with no relevant medical history who experienced the unexpected event of Myocarditis approximately 2 days after the second dose of Moderna COVID-19 Vaccine. Rechallenge was assessed as not applicable. The event was considered related to the vaccine per the reporter's assessment. The benefit-risk relationship of Moderna COVID-19 Vaccine is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes: On 20-Oct-2021: Translation received on 21-Oct-2021. Concurrent conditions, Lab tests added. Case narrative and Sender comments updated and added in inarrative supplement. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 20-Oct-2021 and was forwarded to Moderna on 20-Oct-2021.<br>This regulatory authority case was reported by a consumer and describes the occurrence of HYPERTENSION (An ECG was taken and I had high blood pressure and a high pulse, plus severe pain NRS 7-9.), PAIN (An ECG was taken and I had high blood pressure and a high pulse, plus severe pain NRS 7-9.), HYPERHIDROSIS (That same evening I felt extremely nauseous and sweated, and that lasted about 3-5 hours.), CHEST PAIN (I was awake for about 1.5 hours before I had acute stabbing chest pains on my left side.), NAUSEA (Nausea), LYMPHADENOPATHY (Swollen lymph nodes under arm) and PERICARDITIS (Pericarditis) in a 26-year-old female patient who received mRNA-1273 (Spikevax) for Vaccination. The occurrence of additional non-serious events is detailed below.<br><br>No Medical History information was reported.<br><br>On 04-May-2021 at 11:30 AM, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to 1 dosage form.<br>On an unknown date, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 04-May-2021, the patient experienced HYPERHIDROSIS (That same evening I felt extremely |

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| | | nauseous and sweated, and that lasted about 3-5 hours.) (seriousness criterion hospitalization), NAUSEA (Nausea) (seriousness criterion hospitalization) and LYMPHADENOPATHY (Swollen lymph nodes under arm) (seriousness criterion hospitalization). On 05-May-2021, the patient experienced HYPERTENSION (An ECG was taken and I had high blood pressure and a high pulse, plus severe pain NRS 7-9.) (seriousness criterion hospitalization), PAIN (An ECG was taken and I had high blood pressure and a high pulse, plus severe pain NRS 7-9.) (seriousness criterion hospitalization), CHEST PAIN (I was awake for about 1.5 hours before I had acute stabbing chest pains on my left side.) (seriousness criterion hospitalization), PERICARDITIS (Pericarditis) (seriousness criteria hospitalization and medically significant) and HEART RATE INCREASED (An ECG was taken and I had high blood pressure and a high pulse, plus severe pain NRS 7-9.). On 05-May-2021, HYPERHIDROSIS (That same evening I felt extremely nauseous and sweated, and that lasted about 3-5 hours.) and NAUSEA (Nausea) had resolved. On 07-May-2021, LYMPHADENOPATHY (Swollen lymph nodes under arm) had resolved. At the time of the report, HYPERTENSION (An ECG was taken and I had high blood pressure and a high pulse, plus severe pain NRS 7-9.), PAIN (An ECG was taken and I had high blood pressure and a high pulse, plus severe pain NRS 7-9.), CHEST PAIN (I was awake for about 1.5 hours before I had acute stabbing chest pains on my left side.), PERICARDITIS (Pericarditis) and HEART RATE INCREASED (An ECG was taken and I had high blood pressure and a high pulse, plus severe pain NRS 7-9.) outcome was unknown.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On an unknown date, Electrocardiogram: abnormal (abnormal) Patient reports had high pulse..<br><br>No concomitant medications were reported<br>No treatment medications were reported.<br><br>Patient experienced strong pain in arm (dose no. 1), and axillary lymph nodes enlarged (dose no.1) after receiving the 1st covid-19 vaccination dose from Moderna. Patient reported nausea and sweating on the evening after receiving the vaccine on 04/May/2021, this lasted for approximately 3-5 hours. The patient developed axillary lymph nodes enlarged on 04/MAY/2021. The morning after, 05/May/2021, the patient felt ok. 1.5 hours later the patient experienced stabbing acute chest pain left side. it became worse in intensity and patient went to a general practitioner. ECG was performed and patient had hypertension, increased pulse, and also had severe pain with NRS 7-9. Patient was taken to the emergency room. There it was evaluated as most likely to be pericarditis. patient developed pericarditis on 05/MAY/2021..<br><br>Company Comment: This case concerns a 26-year-old, female with no relevant medical history reported, who experienced the serious expected AESI event of Pericarditis, serious unexpected events of Hypertension, Pain, Hyperhidrosis, Chest pain and serious unexpected per reported |

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| | | severity events of Nausea, Lymphadenopathy coincided with the non-serious event of Heart rate increased. The events occurred within 1-2 days after the second dose of Spikevax administration. The rechallenge was not applicable since no events were reported after the first dose and no additional dosing was expected. The benefit-risk relationship of mRNA-1273 Moderna vaccine in not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 20-Oct-2021: Translated document received on 22-Oct-2021 - Event verbatim and narrative updated. |
| 4.1(b) | 4.1(b) | This regulatory authority case was reported by a pharmacist and describes the occurrence of MYOCARDITIS (Acute perimyocarditis) in a 25-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) (batch nos. 30036 and 3004215) for COVID-19 immunisation.<br><br>No Medical History information was reported.<br><br>On 03-Aug-2021, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) .5 milliliter.<br>On 10-Sep-2021, received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) dosage was changed to .5 milliliter. On 12-Sep-2021, after starting mRNA-1273 (COVID-19 Vaccine Moderna), the patient experienced MYOCARDITIS (Acute perimyocarditis) (seriousness criteria hospitalization and medically significant). On 16-Sep-2021, MYOCARDITIS (Acute perimyocarditis) had resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 14-Sep-2021, Echocardiogram: normal (normal) Normal echocardiographic findings with an EF of 61% were found in the TTE.. In addition there was no evidence of constrictive physiology or pericardial effusion..<br>On 15-Sep-2021, Angiogram: abnormal (abnormal) Magnetic resonance imaging revealed subepicardial, midventricular inferior and apical anterior late gadolinium enhancement of the lateral wall with myocardial edema. In addition, minimal pericardial effusion and discrete late enhancement of the pericardium were found..<br>On an unknown date, Blood test: abnormal (abnormal) Significantly elevated cardiac enzymes/structural proteins were found by laboratory analysis (troponin T 866 ng/L, reference range < 49 ng/L)..<br>On an unknown date, Electrocardiogram: normal (normal) Accentuated ST segments above V2-V5 were seen electrocardiographically.<br><br>For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered MYOCARDITIS (Acute perimyocarditis) to be possibly related.<br><br>Patient had no other previous known diagnoses or allergies and it was unknown if patient was consuming nicotine or alcohol.<br><br>The patients eGFR (MDRD) lab test was 93.58 mL/min. Based on lab examinations of patient acute peri-myocarditis was diagnosed. |

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| | | Concomitant medication details was reported. The patient was not taking any medications on admission.<br>Patient was treated with analgesic/anti-inflammatory therapy with ibuprofen 3x600 mg for 2 weeks, pantoprazole, and colchicine 0.5 mg/d for at least 3 months for peri-myocarditis.<br><br>The patient had suffered from fever, headache arthralgias and dyspnea from 12-SEP-2021.On14-SEP-2021, hospitalization occurred due to chest pain (difficulty breathing, burning chest, stabbing heartbeat, difficulty inhaling even at rest).On admission, a 25 year old patient who was orientated in all respects, presented in stable general and normal nutritional status. Clinically, the patient was unremarkable and hemodynamically stable. A cardiac checkup was scheduled for 3 months time. The patient was discharged to home on 16-SEP-2021 in good general condition at his own request.<br><br>Company comment: This case concerns a 25 year old male with no reported history who experienced the serious, listed AESI of Myocarditis 3 days after dose 2 of Spikevax. Re-challenge is not applicable for dose 2. Benefit-risk relationship of Spikevax is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 20-Oct-2021: Translation received on 22-OCT-2021 contains: Updated medical history information in narrative, Added comments for lab tests, Dosage text, Event verbatim and Narrative updated.<br>On 08-Nov-2021: Follow up received and contains no new information.<br>On 08-Nov-2021: Translation Received on 11-Nov-21 includes no new information |
| 4.1(b) | 4.1(b) | This case was initially received via Takeda Pharmaceuticals (Reference number: 4.1(b) ) on 15-Oct-2021. The most recent information was received on 19-Oct-2021 and was forwarded to Moderna on 29-Oct-2021. The license partner had received the report from 4.1(b) (Reference number: 4.1(b)<br>This case, initially reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref, 4.1(b)<br><br>On 19-Oct-2021, follow-up information was reported by a physician via a medical representative.<br><br>On 19-Oct-2021, follow-up information, reported by a physician, was received by Takeda via Moderna's adverse reaction reporting site (4.1(b) and reported by a physician via a medical representative.<br><br>On 20-Oct-2021, follow-up information, reported to the 4.1(b) by a physician, was received via 4.1(b) (Ref. 4.1(b)<br><br>On 15-Sep-2021, the patient received the 1st dose of this vaccine.<br><br>On an unknown date, body temperature before the vaccination: 36.7 degrees Celsius. |

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| | | On 13-Oct-2021, at 11:15, the patient received the 2nd dose of this vaccine.<br><br>On 14-Oct-2021, around 02:00, the patient was aware of precordial tightness.<br><br>At 04:00, the patient had pyrexia of 37.7 degrees Celsius and heart pain. After consulting a physician in charge of the vaccination, the patient was recommended to visit another hospital.<br><br>At 16:30, subjective symptoms seemed to be mild, but the patient visited a department of cardiovascular internal medicine due to suspected myocarditis. CPK increased to 2,400. The patient was hospitalized for a definitive diagnosis of myocarditis.<br><br>On 19-Oct-2021, the symptoms were resolving.<br><br>The outcome of myocarditis was reported as resolving.<br><br>No follow-up investigation will be made.<br><br>Follow-up received on 19-OCT-2021<br><br>Updated: Reporter Information, Lab Data, Event Information, Narrative, Reporter Comments<br><br>Follow-up received on 19-OCT-2021<br><br>Updated: Lab Data, Narrative, Reporter Comments<br><br>Company Comment:<br><br>The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.<br>Company Comment: This case concerns an 18-year-old, male patient with no reported relevant medical history, who experienced the expected serious event of myocarditis. The event occurred approximately 1 day after the second dose of Moderna COVID-19 Vaccine. The rechallenge was not applicable as events occurred after second dose and no additional dosing will be administered. The reporter assessed the events as related to the product. The benefit-risk relationship of Moderna COVID-19 Vaccine is not affected by this report.<br><br>The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 19-Oct-2021: Significant follow up received - Lab test data and narrative updated. |
| 4.1(b) | 4.1(b) | This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) ) on 19-Oct-2021 and was forwarded to Moderna on 21-Oct-2021. |

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| | | This case, initially reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref, 4.1(b)<br><br>Myocarditis was assessed as serious by the MAH.<br><br>On 11-Sep-2021, the patient received the 1st dose of this vaccination. There was no problem especially.<br><br>On 09-Oct-2021, the patient received the 2nd dose of this vaccination.<br><br>On 12-Oct-2021, chest pain developed.<br><br>On 13-Oct-2021, the patient had a chest pain.<br><br>On 14-Oct-2021, the patient visited the hospital in the morning. There were no particular findings in echo or electrocardiogram, but troponin increased. The patient was diagnosed with myocarditis.<br><br>On 18-Oct-2021, the recovery of symptom was confirmed.<br><br>The outcome of myocarditis was reported as recovered.<br><br>Follow-up investigation will be made.<br><br>Company Comment:<br><br>The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. |
| 4.1(b) | 4.1(b) | This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 19-Oct-2021 and was forwarded to Moderna on 21-Oct-2021.<br>This case, initially reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref, 4.1(b)<br><br>On an unknown date, the patient received the 1st dose of this vaccine.<br><br>On an unknown date, body temperature before the vaccination: 36.5 degrees Celsius.<br><br>On 05-Oct-2021, at 10:51, the patient received the 2nd dose of this vaccine.<br><br>On 06-Oct-2021, at night, pyrexia of 39 degrees Celsius developed. Antipyretics were taken.<br><br>On 07-Oct-2021, in the early evening, pyrexia went down.<br><br>On 08-Oct-2021, at around 00:00, myocarditis developed, and the patient was aware of chest pain. The patient was raced to a hospital. Electrocardiogram showed no abnormalities, but blood test showed high troponin T (867.7 pg/mL) and CRP (3.57 mg/dL) levels, and the patient was admitted to the hospital for follow-up. At night, the symptoms improved. |

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| | | On 09-Oct-2021, the symptoms resolved, and the patient was discharged from the hospital.<br><br>The outcome of pyrexia and myocarditis was reported as resolved.<br><br>Follow-up investigation will be made.<br><br>Company Comment:<br>The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. |
| 4.1(b) | 4.1(b) | This regulatory authority case was reported by a physician and describes the occurrence of INFLUENZA LIKE ILLNESS (Influenza like illness) and MYOCARDITIS (Myocarditis) in a 26-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) (batch nos. 3002918 and 3004215) for SARS-CoV-2 immunisation.<br><br>No Medical History information was reported.<br><br>On 16-Jun-2021, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form.<br>On 28-Jul-2021, received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) dosage was changed to 1 dosage form. On 29-Jul-2021, after starting mRNA-1273 (COVID-19 Vaccine Moderna), the patient experienced INFLUENZA LIKE ILLNESS (Influenza like illness) (seriousness criterion hospitalization). On 30-Jul-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). On 03-Aug-2021, MYOCARDITIS (Myocarditis) was resolving. In August 2021, INFLUENZA LIKE ILLNESS (Influenza like illness) had resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 31-Jul-2021, Electrocardiogram: normal (normal) Regular and normal sinus rhythm at 81/min, no atrioventricular block with PR interval at 120 msec, narrow QRS at 89 msec, QRS axis at 27°, negative T waves in V1 and V2 and normal (normal) ECG (H1): generally applicable to the first, negative T waves in V1, but normalization of T waves in V2.<br>On 31-Jul-2021, Troponin T: 246 ng/ml (High) 246 ng/ml and 327 ng/ml (High) 327 ng/ml.<br>On 02-Aug-2021, Echocardiogram: normal (normal) Non-dilated, non-hypertrophic left ventricle with good systolic function (left ventricular ejection fraction calculated at 60%), despite very slight basal and mid inferior hypokinesia. Filling pressure considered normal. Left atrium of normal volume. Tricuspid aortic valve, normal opening and no [regurgitation]. Mitral valve normal in appearance, without leakage. Right ventricle not dilated, with overall function intact. No pericardial effusion. Aortic root normal in size. Inferior vena cava not dilated with good respiratory fluctuation. Tricuspid valve normal in appearance, with no detectable [regurgitation]..<br>On 02-Aug-2021, Troponin T: 1458 ng/ml (High) 1458 ng/ml.<br>On 05-Aug-2021, Troponin T: 99 ng/l (High) 99 ng/L. |

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| | | For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter did not provide any causality assessments.<br><br>Concomitant product was not provided by the reporter.<br><br>Patient reported that After receiving 2nd dose he experienced fever like symptoms, asthenia, myalgia, lack of appetite associated with profuse sweating, On 30-jul-2021 he experienced onset of retrosternal pain with progressive worsening, not alleviated by taking Paracetamol and Ibuprofen, it is adiation to the shoulder.<br><br>Patient done with laboratory test On 31-Jul-2021 heart rate 71/min, blood pressure measured at 120/74 mmHg, temperature of 36.4 Celcius, and saturation at 98% in ambient air. Leukocytes at 10 g/L, Hb at 150 g/L, platelets at 160 g/L, CRP at 56.3 mg/L, D-dimers at 346 mcg/L.<br><br>Patient received Ibuprofen, level II analgesia and Paracetamol as a treatment.<br><br>Inappropriate schedule of product administration was also noted in the case.<br><br>Company comment:<br>This case concerns a 26-year-old, male patient with no relevant medical history reported, who experienced the expected serious AESI event of myocarditis and the unexpected serious event of influenza like illness. The event influenza like illness occurred approximately one day after the second dose of Spikevax and the event myocarditis two days after the second dose of Spikevax. The rechallenge was not applicable since the events happened after the second dose and no additional dosing is expected. The benefit-risk relationship of Spikevax is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 20-Oct-2021: Translation received On 25-Oct-2021: Updated dosage text, lab data and case narrative. |
| 4.1(b) | 4.1(b) | This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myopericarditis) in a 39-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination.<br><br>Concurrent medical conditions included Hashimoto's thyroiditis. Concomitant products included LEVOTHYROXINE SODIUM (EUTHYROX) for an unknown indication.<br><br>On 20-Aug-2021, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 100 microgram.<br>On 17-Sep-2021, received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) dosage was changed to 100 microgram. On 19-Sep-2021, after starting mRNA-1273 (COVID-19 Vaccine Moderna), the patient experienced MYOCARDITIS (Myopericarditis) (seriousness criteria hospitalization and medically significant). On 22-Sep-2021, MYOCARDITIS (Myopericarditis) was resolving. |

| Case ID | WW Identifier | Narrative |
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| | | DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 20-Sep-2021, Blood creatine phosphokinase: 281 (High) 281 U/L high.<br>On 20-Sep-2021, C-reactive protein increased: 132 (High) 132 mg/L increased.<br>On 20-Sep-2021, Echocardiogram: normal (normal) Echocardiography revealed normal LVEF (60%) and no structural changes..<br>On 20-Sep-2021, Electrocardiogram: normal (normal) An ECG showed ST depressions in lead III and T-negativity in AVL and AVR;.<br>On 20-Sep-2021, Troponin increased: 442 (High) 442 ng/L elevation.<br><br>For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered MYOCARDITIS (Myopericarditis) to be possibly related.<br><br>On 19-Sep-2021 at 03:00 a.m., the patient developed stabbing chest pain on both sides. Over the course, the pain increased to VAS 8/10. Pain increased with deep inspiration. In addition, the patient suffered from dyspnea on exertion (NYHA III according to the information provided by the reporter).<br>On 20-Sep-2021, the patient presented clinically and was hospitalized.<br>On 22-Sep-2021, due to significant regression of symptoms, inflammation and biomarkers, the patient could be discharged to his home with as-needed pain medication.<br>No treatment medication reported.<br><br>Company comment: This case concerns a 39-year-old, male patient with medical history of Hashimoto's thyroiditis, who experienced the expected event of myocarditis, which required hospitalization. The event occurred approximately 2 days after the second dose of Moderna COVID-19 Vaccine. The patient developed stabbing chest pain on both sides. Pain increased with deep inspiration. In addition, the patient suffered from dyspnea on exertion, presented clinically and was hospitalized. An ECG showed ST depressions in lead III and T-negativity in AVL and AVR, blood creatine phosphokinase was 281 U/L high and troponin was increased: 442 ng/L elevation. The event resolved 3 days later. The rechallenge was not applicable as events occurred after second dose and no further dosing was reported or planned, based on information provided. The reporter assessed the events as related to the product. The benefit-risk relationship of Moderna COVID-19 Vaccine is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 20-Oct-2021: Translated document received on 26-Oct-2021 contains updated lab data and narrative. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 20-Oct-2021 and was forwarded to Moderna on 20-Oct-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myocarditis) in a 29-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination.<br><br>The patient's past medical history included Adenoidectomy. |

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| | | Concurrent medical conditions included Obesity and Penicillin allergy.<br><br>On 01-Oct-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 02-Oct-2021, after starting mRNA-1273 (Spikevax), the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Myocarditis) was resolving.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 03-Oct-2021, C-reactive protein (0-6): 22 (High) High-sensitivity C-reactive protein- 22 milligram per litre.<br>On 03-Oct-2021, N-terminal prohormone brain natriuretic peptide (0-100): 62 (normal) 62 picogram per millilitre.<br>On 03-Oct-2021, Troponin I (0-17.5): 2424 (High) High Sensitive troponin I- 2424 nanogram per litre.<br>On 04-Oct-2021, C-reactive protein (0-6): 18 (High) High-sensitivity C-reactive protein- 18 milligram per litre.<br>On 04-Oct-2021, Troponin I (0-17.5): 1451 nanogram per litre (High) High Sensitive troponin I- 1451 nanogram per litre.<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.<br><br>No concomitant medication information provided by the reporter.<br><br>No treatment medication information was provided.<br><br>Company Comment : This case concerns a 29 year old male patient with medical history of obesity who experienced the expected event of myocarditis. The event occurred approximately 1 day after the second dose of the Moderna COVID-19 vaccine. The rechallenge was unknown. Patient's history of obesity remains a confounder. The benefit-risk relationship of the Moderna COVID-19 vaccine is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 20-Oct-2021: Translated document received on 22 Oct 2021 includes medial history. |
| 4.1(b) | 4.1(b) | This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 11-Oct-2021 and was forwarded to Moderna on 21-Oct-2021.<br>This case, reported by a physician via the Drug Information Center, and reported by a physician, was received by Takeda Pharmaceutical Company Limited via Moderna's adverse reaction reporting site (4.1(b) and reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref, 4.1(b)<br><br>The patient had a history of allergy to inhalation drug which was taken for common cold in childhood. The patient had a drinking habit, and hepatic |

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| | | function disorder was indicated in a medical checkup. The patient had a history of surgery.<br><br>On 03-Sep-2021, the patient received the 1st dose of the vaccine.<br><br>On an unknown date, acute enteritis developed.<br><br>On 13-Sep-2021, the patient started taking an over-the-counter cold medicine for the treatment of acute enteritis.<br><br>On 15-Sep-2021, the patient stopped taking the over-the-counter cold medicine.<br><br>On 01-Oct-2021, at 11:30, the patient received the 2nd dose of the vaccine. Pyrexia developed.<br><br>On 03-Oct-2021, at 21:00, chest pain and queasy developed at night. The patient saw how the condition would be. The patient had not caught a cold in recent days.<br><br>On 04-Oct-2021, on awakening, the symptoms had improved, but the patient had a recurrence and thus visited a hospital. The patient was transferred to the reporting hospital. As wide range of ST elevation was shown in electrocardiogram with increased CPK (CPK = 1,794), the patient was admitted to the hospital with a diagnosis of acute myocarditis. Oedema and enlargement of cardiac muscles were shown by MRI and UCG. Cardiac catheterization of both sides of heart and myocardial biopsy were performed on the day of admission. The findings of nonspecific inflammation were only mild fibrosis and lymphocytic infiltration. No significant stenosis was found in the coronary artery with cardiac function retained, and there were no signs of heart failure. Administration of 2 tablets of 1.25 mg of carvedilol distributed in 2 divided doses (after breakfast and after dinner) was started. Use of ethanol for disinfection was started for skin symptoms. PR: 101/min, BP: 154/91 mmHg, BT: 37.9 degrees Celsius, and SpO2: 97% (RA). No anemia or yellowing of palpebral conjunctiva, no swelling in the cervical lymph nodes, no enlargement of the thyroid, and no distention of the neck veins were found. Respiratory sounds were clear without bilateral differences, and no cardiac murmur was heard. No appreciable problems were found in the abdomen, and no oedema was seen in the lower limbs.<br><br>On 05-Oct-2021, transthoracic echocardiography was performed and showed no problems in the cardiac function.<br><br>On 06-Oct-2021, fever subsided. PR: 56/min, BP: 118/66 mmHg, and SpO2: 95%-98% (RA). Respiratory sounds were clear without bilateral differences, and no cardiac murmur was heard. No oedema was seen in the lower limbs. Cardiac function was retained without pericardial effusions. Although troponin level showed no significant change, CK and CRP showed improving tendencies. The sheath was removed. Biopsy showed no eosinophilic infiltration or giant cells. The result of MRI was consistent with perimyocarditis.<br><br>On 08-Oct-2021, PR: 98/min, BP: 134/92 mmHg, BT: 37.5 degrees Celsius, and SpO2: 97% (RA). Respiratory sounds were clear without |

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| | | bilateral differences, and no cardiac murmur was heard. The patient had low-grade fever. Although slight increases in WBC and CRP were noted, other cardiac enzymes showed improving tendencies.<br><br>On 09-Oct-2021, the symptoms were resolving.<br><br>On 11-Oct-2021, PR: 89/min, BP: 139/92 mmHg, BT: 36.7 degrees Celsius, and SpO2: 97% (RA). In rehabilitation, increased heart rate during exertion was prominent. The result of blood test was smoothly improving.<br><br>The outcome of acute enteritis was unknown. The outcome of acute myocarditis was reported as resolving.<br><br>Follow-up investigation will be made.<br><br>Company Comment:<br><br>The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) on 21-Oct-2021 and was forwarded to Moderna on 21-Oct-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Perimyocarditis) in an 18-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination.<br><br>The patient's past medical history included Depressive episode. Concomitant products included MELATONIN (MELATONIN AGB) from 28-May-2021 to an unknown date for an unknown indication.<br><br>On 05-Oct-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 08-Oct-2021, after starting mRNA-1273 (Spikevax), the patient experienced MYOCARDITIS (Perimyocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Perimyocarditis) was resolving.<br><br>For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.<br><br>Treatment information was not provided.<br><br>Company comment: This case concerns an 18-year-old male with no relevant medical history who experienced the listed, serious AESI event of myocarditis 3 days after receiving the second dose of Spikevax (batch not provided). The patient required hospitalization. The event was resolving at the time of the report. Treatment was not provided. No data for the first dose was provided, so rechallenge is not applicable. The benefit-risk relationship of Spikevax is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes: |

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| | | On 21-Oct-2021: Translation received on 25 Oct 2021,with translated event verbatim. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 21-Oct-2021 and was forwarded to Moderna on 21-Oct-2021.<br>This regulatory authority case was reported by a pharmacist and describes the occurrence of MYOCARDITIS (Myocarditis) and INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (late second dose) in a 26-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 21025 and 3004234) for COVID-19 vaccination.<br><br>The patient's past medical history included Myocarditis.<br>Concurrent medical conditions included Hypertension.<br><br>On 06-Aug-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form.<br>On 20-Sep-2021, received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to 1 dosage form. On 24-Sep-2021, after starting mRNA-1273 (Spikevax), the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). On an unknown date, the patient experienced INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (late second dose) (seriousness criterion medically significant). At the time of the report, MYOCARDITIS (Myocarditis) was resolving and INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (late second dose) had resolved.<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.<br><br>No concomitant medication was given.<br>No treatment medication was given.<br><br>Company Comment: This case concerns a 26-year-old male patient with relevant medical history of Myocarditis and Hypertension who experienced serious expected event of Myocarditis. The event occurred four days following the vaccination with the second dose of the Spikevax. As per SD no rechallenge was done, and therefore, recurrence is not applicable. Very limited information regarding clinical course of the event has been provided at this time. The medical history of Myocarditis and Hypertension remains a confounder. The benefit-risk relationship of Spikevax is not affected by this report. Causality for the event Inappropriate schedule of product administration is assessed as not applicable. |
| 4.1(b) | 4.1(b) | This case was received via Takeda Pharmaceuticals (Reference number: J4.1(b) on 19-Oct-2021 and was forwarded to Moderna on 22-Oct-2021.<br>This case, initially reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref, 4.1(b)<br><br>On an unknown date, the patient received the 1st dose of the vaccine.<br><br>On 09-Oct-2021, the patient received the 2nd dose of the vaccine. |

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| | | From 10-Oct-2021 to 11-Oct-2021, the patient had pyrexia of 38s degrees Celsius.<br><br>On 12-Oct-2021, at 03:00, the patient was aware of pain in the left chest for approximately 10 minutes. As chest discomfort sensation persisted thereafter, the patient visited a hospital. An electrocardiogram showed ST elevations in II, III, and aVF, and the result of blood sampling revealed an inflammatory response and elevated cardiac enzymes. Echocardiography showed enhanced pericardium brightness and accumulation of pericardial fluid. The patient was admitted to the hospital for suspected myopericarditis.<br><br>On an unspecified date, as of the date, any virus that can cause myocarditis had not been detected. Cardiac contrast-enhanced MRI showed findings suggestive of myocarditis. The result of myocardial biopsy showed normal findings of myocardium. After being hospitalized, the patient had no chest pain, cardiac failure, or arrythmia, and the course of the disease was favorable without transformation to fulminant myocarditis. The symptoms had not resolved.<br><br>The outcome of pyrexia and myopericarditis was reported as ongoing and unchanged.<br><br>Follow-up investigation will be made.<br><br>Company Comment:<br><br>The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. |
| 4.1(b) | 4.1(b) | This case was initially received via European Medicines Agency (Reference number: 4.1(b) ) on 21-Oct-2021. The most recent information was received on 21-Oct-2021 and was forwarded to Moderna on 24-Oct-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (MYOCARDITIS) in a 26-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 13-Jun-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form.<br>On 12-Jul-2021, received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. On 05-Sep-2021, the patient experienced MYOCARDITIS (MYOCARDITIS) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (MYOCARDITIS) was resolving.<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.<br><br>No concomitant medications were provided by the reporter.<br>No treatment information was provided by the reporter. |

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| | | Company comment: This case concerns a 26 year-old female patient with no medical history provided, who experienced the expected event of Myocarditis(hospitalization not expected) (seriousness criteria hospitalization and medically significant). This event occurred approximately 2 months after the second dose of Spikevax. The reporter did not provide any causality assessments. The benefit-risk relationship of Spikevax is not affected by this report.<br><br>Company Comment: This case concerns a 26-year-old female patient, with no medical history details provided, who experienced the serious expected AESI of MYOCARDITIS. The event occurred approximately 1 month and 24 days after the receiving the second dose of Spikevax. The rechallenge is not applicable since no additional dose is expected. No clinical records nor lab data were provided. The benefit-risk relation of Spikevax is not affected by this report. Seriousness criterion of hospitalization was provided by Regulatory Authority and was kept as such; however there is no details provided about hospitalization.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 21-Oct-2021: Translated document received on 24-OCT-2021 include translated verbatim |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 21-Oct-2021 and was forwarded to Moderna on 21-Oct-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (MYOCARDITIS) in a 20-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 3005697) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 22-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 25-Sep-2021, the patient experienced MYOCARDITIS (MYOCARDITIS) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (MYOCARDITIS) had not resolved.<br><br>For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.<br><br>No relevant concomitant medications were reported.<br>Treatment information was not provided.<br><br>Company's comment: This case concerns a 20-year old, female subject with no relevant medical history, who experienced the serious expected event of Myocarditis(AESI). The event, which resulted in hospitalization, occurred 3 days after the second dose of Spikevax. Rechallenge is not applicable as no information about the first dose is available. The benefit-risk relationship of Spikevax is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes: |

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| | | On 21-Oct-2021: Translation Document received on 22-OCT-2021 contains translated event verbatim. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) on 21-Oct-2021 and was forwarded to Moderna on 21-Oct-2021.<br><br>This regulatory authority case was reported by a consumer and describes the occurrence of PERICARDITIS (Pericarditis) in a 39-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3003659) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 21-Jul-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 11-Aug-2021, after starting mRNA-1273 (Spikevax), the patient experienced PERICARDITIS (Pericarditis) (seriousness criterion medically significant). On 25-Aug-2021, PERICARDITIS (Pericarditis) had resolved.<br><br>Concomitant medications were not reported.<br><br>Treatment information was not provided.<br><br>Company comment: This case concerns a 39-year-old, male patient with no relevant medical history, who experienced the expected AESI of pericarditis. The event occurred 3 weeks after administration of the second dose of Spikevax. The rechallenge was not applicable as no additional dosing will be given. The patient's gender remains a confounder. The benefit-risk relationship of Spikevax is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 21-Oct-2021: Translation document received on 25-Oct-2021, dosage text and event verbatim translated. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 22-Oct-2021 and was forwarded to Moderna on 22-Oct-2021.<br>This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (Rapid heart rate, increased pulse, fever: diagnosis of heart) in a 30-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 3004233) for Prophylactic vaccination.<br><br>No Medical History information was reported.<br><br>On 14-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 07-Oct-2021, after starting mRNA-1273 (Spikevax), the patient experienced MYOCARDITIS (Rapid heart rate, increased pulse, fever: diagnosis of heart) (seriousness criterion medically significant). At the time of the report, MYOCARDITIS (Rapid heart rate, increased pulse, fever: diagnosis of heart) was resolving. |

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| | | No concomitant medications reported by reporter.<br><br>Fever was lowered, tachycardia was lessened. Continued mild chest pain, fatigue, loss of appetite. Treatment with Ibuflam 600, moxifloxacin for 7 days. Additionally, Colchicine [Ysat] and ivabradine for a total of 4 weeks/at least until the follow-up visit.<br><br>Company Comment<br>This case concerns a 30-year-old, female patient with no relevant medical history, who experienced the expected event of myocarditis. The event myocarditis occurred 23 days after the second dose of mRNA-1273 vaccine administration. The rechallenge was not applicable. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 22-Oct-2021: Translation document received on 25-Oct-2021 included: event verbatim and sender's comments translated.<br>On 05-Nov-2021: Follow-up received on 05-Nov-2021 contain no new information |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 22-Oct-2021 and was forwarded to Moderna on 22-Oct-2021.<br><br>This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (Myocarditis) in a 22-year-old male patient who received mRNA-1273 (Spikevax) for Prophylactic vaccination.<br><br>No Medical History information was reported.<br><br>On 08-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 01-Oct-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization, medically significant and life threatening). At the time of the report, MYOCARDITIS (Myocarditis) outcome was unknown.<br><br>Concomitant medications were not reported.<br>Treatment medications were not reported.<br><br>Additional information included since 01-Oct-2021, patient had general [KH] feeling, fever, chills, chest pain at night. Myocarditis confirmed by cardiac MRI on 07-Oct.<br><br>Completed Company:<br>This case concerns a 22-year-old, male patient with no relevant medical history, who experienced the expected serious (Life-threatening and hospitalization) event of Myocarditis. The event of Myocarditis was also upgraded to serious (Medically Significant) as per Important medical event terms list (MedDRA version 24.0). The event occurred approximately 24 days after the second dose of Spikevax. The rechallenge was not applicable as the AE occurred after the second dose. Since 01-Oct-2021, patient had general feeling, fever, chills, chest pain at night. Myocarditis confirmed by cardiac MRI on 07-Oct. The event is consistent with the current understanding of the mechanism of action of |

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| | | the vaccine. The benefit-risk relationship of Spikevax is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 22-Oct-2021: Translation received on 25-Oct-2021 and sender's comment translated. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 22-Oct-2021 and was forwarded to Moderna on 22-Oct-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myocarditis) in a 17-year-old male patient who received mRNA-1273 (Spikevax) (batch no. FH0161) for COVID-19 vaccination.<br><br>The patient's past medical history included COVID-19 (Had Covid with inpatient care 26-Apr-2021 - 03-May-2021.) from 26-Apr-2021 to 03-May-2021.<br><br>On 05-Oct-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 08-Oct-2021, after starting mRNA-1273 (Spikevax), the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Myocarditis) was resolving.<br><br>For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.<br><br>No concomitant medication details was provided.<br>No treatment medication details was provided.<br><br>Company comment: This case concerns a 17-year-old, male patient with previous relevant medical history of COVID-19 (had COVID with inpatient care 26-Apr-2021 - 03-May-2021), who experienced the expected serious (hospitalization) event of Myocarditis. The event of Myocarditis was also upgraded to serious (Medically Significant) as per Important medical event terms list (MedDRA version 24.0). The event occurred approximately 04 days after the second dose of Spikevax. The rechallenge is not applicable as the AE occurred after the second dose. The medical history of COVID-19 (had COVID with inpatient care 26-Apr-2021 - 03-May-2021) remains a confounder. The event is consistent with the current understanding of the mechanism of action of the vaccine. The benefit-risk relationship of Spikevax is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 22-Oct-2021: Translated document received on 26-OCT-2021 Contains added date of historical condition, added Event verbatim and added dosage text. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number 4.1(b) ) on 25-Oct-2021 and was forwarded to Moderna on 25-Oct-2021. |

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| | | This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myocarditis) in a 34-year-old male patient who received mRNA-1273 (Spikevax) for Prophylactic vaccination.<br><br>No Medical History information was reported.<br><br>On 26-Aug-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 31-Aug-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Myocarditis) had not resolved.<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.<br><br>No concomitant medications reported.<br>No treatment information was provided.<br><br>Course of adverse events and measures: On 31 Aug 2021, sudden chest pain, troponin elevation, monitoring in ICU, cardiac catheterization initially rejected, performed on a supplementary basis during course. Course uncomplicated without cardiac arrhythmia, troponin but clearly increasing during the course, protracted monitoring in ICU. LV function always unremarkable.<br><br>Company comment:<br>This case concerns a 34 year-old, male with no relevant history reported, who experienced the serious expected event of Myocarditis (AESI). The event of Myocarditis was also upgraded to serious (Medically Significant) as per Important medical event terms list. The event occurred approximately 5 days after the second dose of Spikevax. The rechallenge is not applicable since the event occurred after the second dose and another dose will not be administered. The benefit-risk relationship of the vaccine in not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 25-Oct-2021: Translated document received. Reporter's comments provided. |
| 4.1(b) | 4.1(b) | This case was initially received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 20-Oct-2021. The most recent information was received on 26-Oct-2021 and was forwarded to Moderna on 01-Nov-2021.<br>This case, initially reported to the 4.1(b) by a (physician), was received via the 4.1(b) (Ref, 4.1(b)<br><br>On 26-Oct-2021, follow-up information, reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref, 4.1(b)<br><br>On 15-Sep-2021, the patient received the 1st dose of the vaccine. After the vaccination, decreased blood pressure developed. The patient lay in a bed for about 30 minutes and returned home. |

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| | | On 13-Oct-2021, the patient received the 2nd dose of the vaccine. The patient received the vaccine lying on a bed. No poorly feeling had developed throughout the course.<br><br>On 14-Oct-2021, the patient had pyrexia of 38s degrees Celsius without chest pain.<br><br>On 15-Oct-2021, the patient had pyrexia of 38s degrees Celsius without chest pain.<br><br>On 16-Oct-2021, acute myocarditis developed. The patient had a persisting chest pain at the time of awakening and thus visited a nearby physician. As electrocardiogram showed ST elevation in chest leads, and troponin T was positive, the patient was referred to and visited a hospital on the same day. There were mild increases as troponin T was 0.234 ng/mL with CK of 230 and CKMB of 16. The patient was hospitalized with a diagnosis of perimyocarditis on the same day. Treatment with colchicine and loxoprofen sodium hydrate was started.<br><br>On 17-Oct-2021, blood sampling was performed to find increases with CK of 415 and CKMB of 32, and concomitant administration of prednisolone 20 mg was started. Echocardiography showed no abnormalities in cardiac function and no signs of cardiac failure. Subsequently, cardiac enzymes became negative.<br><br>On 25-Oct-2021, the symptoms were confirmed to have resolved.<br><br>On 26-Oct-2021, the patient was going to be discharged from the hospital.<br><br>The outcome of pyrexia and acute myocarditis was reported as resolved.<br><br>Follow-up investigation will be made.<br><br>Follow-up received on 26-OCT-2021<br><br>Updated: Reporter Information, Patient Information, Lab Data, Product Information, Event Information, Narrative, Reporter Comments<br><br>Company Comment:<br><br>The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) on 25-Oct-2021 and was forwarded to Moderna on 25-Oct-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of CHEST PAIN (Thorax pain), DYSPNOEA EXERTIONAL (Exertional dyspnoea), FATIGUE (Fatigue), INFLUENZA LIKE ILLNESS (Flu like symptoms) and PERICARDITIS (Pericarditis) in a 32-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination.<br><br>The patient's past medical history included Gluten intolerance. |

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| | | Concurrent medical conditions included Alcohol use (Reported the use of alcohol rarely in a little amount).<br><br>On 20-Jun-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 100 microgram. On 01-Jul-2021, the patient experienced CHEST PAIN (Thorax pain) (seriousness criterion medically significant), DYSPNOEA EXERTIONAL (Exertional dyspnoea) (seriousness criterion medically significant), FATIGUE (Fatigue) (seriousness criterion medically significant), INFLUENZA LIKE ILLNESS (Flu like symptoms) (seriousness criterion medically significant) and PERICARDITIS (Pericarditis) (seriousness criterion medically significant). At the time of the report, CHEST PAIN (Thorax pain), DYSPNOEA EXERTIONAL (Exertional dyspnoea), FATIGUE (Fatigue), INFLUENZA LIKE ILLNESS (Flu like symptoms) and PERICARDITIS (Pericarditis) had not resolved.<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.<br><br>Concomitant product use included pantoprazole 20 mg as 1-0-0.<br><br>From 07 Jul 2021 to 20 Jul 2021 the patient had consumed Ibuprofen 600mg as 3x1. No further treatment information was provided.<br><br>Following transient flu-like infection symptoms for a few days, sharp chest pain, fatigue, and exertional dyspnea NYHA II-III had occurred later. The patient had excellent resilience during competitive sports like rowing. She experienced pericarditis after SARS-CoV-2 immunization which was a mild peri myocarditis that cannot be identified by echocardiography but may be possible by paraclinical investigation. Cardiac MRI was not performed due to a lack of therapeutic consequence.<br><br>Company comment:<br>This is a regulatory case concerning a 32-year-old, female patient with medical history of gluten intolerance , who experienced the serious unexpected events of CHEST PAIN, DYSPNOEA EXERTIONAL, FATIGUE, INFLUENZA LIKE ILLNESS and the serious expected and AESI event of PERICARDITIS 12 days after receiving the second dose of spikevax. Time to onset for the first dose is unknown. The benefit-risk relationship of Spikevax is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 25-Oct-2021: Translation received on 26 Oct 2021. Added patients medical history and dose number. Narrative was also updated. |
| 4.1(b) | 4.1(b) | This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) ) on 20-Oct-2021 and was forwarded to Moderna on 26-Oct-2021.<br>This case, initially reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref, 4.1(b)<br><br>On an unknown date, the patient received the 1st dose of this vaccine. |

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| | | On 26-Jul-2021, the patient received the 2nd dose of this vaccination. Pyrexia developed.<br><br>On 28-Jul-2021, the patient visited another hospital with chest pain.<br><br>On 29-Jul-2021, at 04:00, myocarditis developed. The patient visited an emergency department of the reporting hospital and was admitted. ECG showed ST elevation in 2, 3, aVF, and V2-6. Elevated CK and troponin were noted. There was no stenosis in the emergency catheterization, and autoimmune myocarditis or the like was negative in the myocadiac biopsy.<br><br>On an unknown date, after that, the patient rested, and no cardiac failure or fatal arrhythmia occurred with NSAIDs, and chest pain also improved.<br><br>On 02-Aug-2021, the patient was discharged from the hospital.<br><br>On 10-AUg-2021, the symptoms were resolving.<br><br>The outcome of pyrexia and myocarditis was reported as resolving.<br><br>Follow-up investigation will be made.<br><br>Company Comment:<br><br>The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. |
| 4.1(b) | 4.1(b) | This regulatory authority case was reported by a physician and describes the occurrence of CHEST PAIN (sudden, respiro-dependent, diffuse chest pain between the scapulae radiating to the right arm), HYPERHIDROSIS (episodes of sweating after injection) and MYOCARDITIS (Myocarditis) in a 20-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 immunisation.<br><br>No Medical History information was reported.<br><br>On 11-Oct-2021, the patient received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) dosage was changed to 1 dosage form.<br>On an unknown date, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form. On 11-Oct-2021, after starting mRNA-1273 (COVID-19 Vaccine Moderna), the patient experienced HYPERHIDROSIS (episodes of sweating after injection) (seriousness criteria hospitalization and medically significant). On 13-Oct-2021, the patient experienced CHEST PAIN (sudden, respiro-dependent, diffuse chest pain between the scapulae radiating to the right arm) (seriousness criteria hospitalization and medically significant). On 14-Oct-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, CHEST PAIN (sudden, respiro-dependent, diffuse chest pain between the scapulae radiating to the right arm) and MYOCARDITIS (Myocarditis) had not resolved and HYPERHIDROSIS (episodes of sweating after injection) outcome was unknown. |

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| | | DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 14-Oct-2021, Blood creatine phosphokinase (47-222 international unit per litre): 514 international unit per litre (High) 514 iU/L and 909 international unit per litre (High) 909 iU/L.<br>On 14-Oct-2021, C-reactive protein (0-10 milligram per litre): 55 milligram per litre (High) high.<br>On 14-Oct-2021, Chest X-ray: normal (normal) Normal.<br>On 14-Oct-2021, Electrocardiogram: abnormal (abnormal) Elevation in DII-III-aVF, V4-6 with descending PR interval DII-III-avF.<br>On 14-Oct-2021, SARS-CoV-2 test: negative (Negative) Negative.<br>On 14-Oct-2021, Troponin (Unknown-14 ng/L): 838 ng/L (High) 838 ng/L and 1096 ng/L (High) 1096 ng/L.<br>On 14-Oct-2021, White blood cell count (4-11): 13 (High) high.<br><br>For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered CHEST PAIN (sudden, respiro-dependent, diffuse chest pain between the scapulae radiating to the right arm), HYPERHIDROSIS (episodes of sweating after injection) and MYOCARDITIS (Myocarditis) to be possibly related.<br><br>No concomitant medications were reported.<br><br>Patient was presented to Emergency during the night of 13-Oct to 14-Oct for respirodependent, diffuse chest pain, especially between the scapulae and radiating to the right arm, and whose sudden onset awakened him. Patient had family history of history of myocarditis following a viral disease.<br>Lab data also included of, LDH 285 U/L, AST 101 U/L, remainder of liver and kidney function panel aligned.<br>Analgesic therapy with Paracetamol was started, and a cardiac MRI was planned.<br><br>Company Comment:<br>This case concerns a 20-year-old male patient with no relevant medical history, who experienced the serious unexpected events of Chest pain and Hyperhidrosis and the serious expected event of Myocarditis. The event of Hyperhidrosis occurred on the same day after the second dose of mRNA-1273, the event of Chest pain occurred 2 days after the second dose of mRNA-1273 and the event of Myocarditis occurred 3 days after the second dose of mRNA-1273. The lab investigation of high Creatine kinase, C- reactive protein, Troponin and an abnormal ECG support the diagnosis of Myocarditis. The rechallenge information is not applicable as the events occurred after the second dose. The benefit-risk relationship of the mRNA-1273 is not affected by this report. Event seriousness assessed as per Regulatory Authority reporting and retained for consistency with the RA report. However, there is a discrepancy with the date for the event of chest pain in the structured field was it was reported 13- Nov-2021 but in the narrative it occurred on the 13-Oct- 2021.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 25-Oct-2021: Translation document received on 27-Oct-2021: Lab data, event verbatim, narrative and senders comment updated. |

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| 4.1(b) | 4.1(b) | This case was received via 4.1(b) (Reference number: 4.1(b) ) on 24-Oct-2021 and was forwarded to Moderna on 24-Oct-2021.<br>This regulatory authority case was reported by a consumer and describes the occurrence of PERICARDITIS (Pericarditis) and MEDICATION ERROR (Medication error) in a 40-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for Ill-defined disorder.<br><br>No Medical History information was reported.<br><br>On 30-Jun-2021, the patient received first dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (Parenteral) 1 dosage form.<br>On 06-Sep-2021, received second dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (Parenteral) dosage was changed to 1 dosage form. On 14-Sep-2021, after starting mRNA-1273 (Moderna CoviD-19 Vaccine), the patient experienced PERICARDITIS (Pericarditis) (seriousness criterion medically significant). On an unknown date, the patient experienced MEDICATION ERROR (Medication error) (seriousness criterion medically significant). On 30-Sep-2021, PERICARDITIS (Pericarditis) had resolved with sequelae. At the time of the report, MEDICATION ERROR (Medication error) outcome was unknown.<br><br>mRNA-1273 (Moderna CoviD-19 Vaccine) (Parenteral) dosing remained unchanged.<br><br>No concomitant medications were reported. Treatment information was not provided.<br>The patients past medical history included Beal's syndrome and was reported that it was recently confirmed.<br><br>Patient lab data included Troponin high" , MRI result: confirmed pericarditis.<br><br>The details reported included strong chest pain, palpitations, high troponin, and pericarditis that got confirmed from MRI. The patient was administered with Moderna vaccine for COVID 19.<br>Based on the guidelines action was there to avoid aspiration due to increased pain in new born and toddlers but the one reported was related to adult.<br>patient got every reason to believe that the vaccine itself is safe however the intramuscular administration must be performed with aspiration to avoid inadvertent intravenous administration."<br><br>Company comment:<br>This case concerns a 40-year-old, male patient with medical history of Beal's syndrome, who experienced the expected, serious and AESI event of pericarditis. Medication error is also reported. The event occurred approximately 8 days after second dose of Spikevax. The rechallenge is unknown, as the outcome of the event is recovered and no additional dosing information was disclosed. The medical history of Beal's syndrome, remains as a confounder. The benefit-risk relationship of Spikevax vaccine is not affected by this report. |

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| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 25-Oct-2021 and was forwarded to Moderna on 25-Oct-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of WHITE BLOOD CELL COUNT INCREASED (Leukocyte count increased), EJECTION FRACTION DECREASED (mildly impaired EF), TROPONIN INCREASED (Troponin increased), C-REACTIVE PROTEIN INCREASED (C-reactive protein increased), PYREXIA (Fever) and MYOCARDITIS (Myocarditis) in a 37-year-old male patient who received mRNA-1273 (Spikevax) for Prophylactic vaccination.<br><br>The patient's past medical history included Attention deficit/hyperactivity disorder and Obesity.<br>Concurrent medical conditions included Gout and Asthma bronchial.<br>Concomitant products included BECLOMETASONE DIPROPIONATE, FORMOTEROL FUMARATE (FOSTER [BECLOMETASONE DIPROPIONATE;FORMOTEROL FUMARATE]) for Asthma bronchial, METHYLPHENIDATE HYDROCHLORIDE (MEDIKINET) for Attention deficit/hyperactivity disorder, REPEVAX from 23-Jul-2021 to an unknown date for Booster, ALLOPURINOL for Gout, PNEUMOCOCCAL VACCINE POLYSACCH 23V (PNEUMOVAX 23) for an unknown indication.<br><br>On 24-Jun-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 23-Jul-2021, the patient experienced WHITE BLOOD CELL COUNT INCREASED (Leukocyte count increased) (seriousness criteria hospitalization and medically significant), EJECTION FRACTION DECREASED (mildly impaired EF) (seriousness criteria hospitalization and medically significant), TROPONIN INCREASED (Troponin increased) (seriousness criteria hospitalization and medically significant), C-REACTIVE PROTEIN INCREASED (C-reactive protein increased) (seriousness criteria hospitalization and medically significant), PYREXIA (Fever) (seriousness criteria hospitalization and medically significant) and MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, WHITE BLOOD CELL COUNT INCREASED (Leukocyte count increased), EJECTION FRACTION DECREASED (mildly impaired EF), TROPONIN INCREASED (Troponin increased), C-REACTIVE PROTEIN INCREASED (C-reactive protein increased), PYREXIA (Fever) and MYOCARDITIS (Myocarditis) outcome was unknown.<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.<br><br>Patient was treated with ASA 100 mg (temporarily limited according to myocardial biopsy) and Ramipril 2 x 2.5 mg.<br><br>Company comment<br>This case concerns a 37-year-old male patient with concurrent medical history of Obesity, Gout and bronchial asthma who experienced the expected event of myocarditis and unexpected events of pyrexia, white blood cell count increased, ejection fraction decreased, troponin increased and c-reactive protein increased. The events occurred |

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| | | approximately 1 month after second dose of mRNA-1273 (Spikevax). The rechallenge was not applicable as event occurred after second dose and no information provided about first dose. Though Myocarditis is consistent with the current understanding of the mechanism of action of the vaccine; however, this patient history of Obesity remains a confounder . The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes: On 25-Oct-2021: Translation Received on 28-OCT-2021. Updated medical history, event verbatim, dose details, action taken, inarrative and reporter's comments. |
| 4.1(b) | 4.1(b) | This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 14-Oct-2021 and was forwarded to Moderna on 27-Oct-2021.<br><br>This case, reported by a pharmacist, was received by Takeda via Moderna's adverse reaction reporting site 4.1(b) and reported to the 4.1(b) by a pharmacist, was received via the 4.1(b) (Ref, 4.1(b)<br><br>The patient had coronary risk factors such as smoking and abnormal lipids.<br><br>On 07-Sep-2021, the patient received the 1st dose of the vaccine.<br><br>On 05-Oct-2021, at 12:40, the patient received the 2nd dose of the vaccine. At night, the patient experienced pyrexia, which persisted thereafter.<br><br>On 06-Oct-2021, around 03:00, acute myocarditis developed. The patient had chest pain. The degree of pain fluctuated and persisted.<br><br>On 07-Oct-2021, at 23:30, the patient was aware of taste disorder. Chest pain persisted. An emergency call was made, and the patient was transported and admitted to the reporting hospital.<br><br>On 08-Oct-2021, before dawn, elevated cardiac enzymes were noted. As the patient had coronary risk factors, coronary angiography (CAG) was performed, showing no abnormalities. Echocardiography showed no abnormal left ventricular contraction. Inpatient conservative treatments were continued.<br><br>On 14-Oct-2021, the patient was discharged from the hospital as the symptoms were resolving.<br><br>The outcome of pyrexia, acute myocarditis, and taste disorder was reported as resolving.<br><br>Follow-up was not possible due to lack of cooperation from the reporter.<br><br>Company Comment:<br><br>The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. |

| Case ID | WW Identifier | Narrative |
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| 4.1(b) | 4.1(b) | This case was received via 4.1(b) (Reference number: 4.1(b) on 26-Oct-2021 and was forwarded to Moderna on 26-Oct-2021.<br>This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCARDITIS (Myocarditis), PERICARDITIS (Pericarditis) and CHEST PAIN (Chest pain) in a 32-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 03-Oct-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 07-Oct-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant), PERICARDITIS (Pericarditis) (seriousness criteria hospitalization and medically significant) and CHEST PAIN (Chest pain) (seriousness criterion hospitalization). The patient was hospitalized from 07-Oct-2021 to 09-Oct-2021 due to CHEST PAIN, MYOCARDITIS and PERICARDITIS. The patient was treated with IBUPROFEN (MOTRIN [IBUPROFEN]) for Myopericarditis, at an unspecified dose and frequency and COLCHICINE for Pericarditis, at an unspecified dose and frequency. At the time of the report, MYOCARDITIS (Myocarditis), PERICARDITIS (Pericarditis) and CHEST PAIN (Chest pain) had resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 07-Oct-2021, Cardiac imaging procedure: abnormal (abnormal) Cardiac MRI showed LGE indicative of myocarditis.<br>On 07-Oct-2021, Catheterisation cardiac: normal (normal) normal.<br>On 07-Oct-2021, Echocardiogram: abnormal (abnormal) focal WMA.<br>On 07-Oct-2021, Electrocardiogram: abnormal (abnormal) abnormal.<br>On 07-Oct-2021, Troponin: 1.31 (High) increased.<br>On 07-Oct-2021, Wall motion score index: abnormal (abnormal) abnormal.<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments.<br><br>Concomitant medications was not reported.<br><br>Company Comment : This case concerns a 32-year old, male subject with no relevant medical history, who experienced the serious expected events of Myocarditis(AESI) and Pericarditis(AESI) and the serious unexpected event of Chest pain. The events, which resulted in hospitalization, occurred 4 days after the second dose of Moderna COVID-19 vaccine. The patient's age and gender, which are risk factors for Myocarditis and Pericarditis remain as confounders. The benefit-risk relationship of Spikevax is not affected by this report. The dose number is captured per Lab Data text and differ from the structured field of the Regulatory Authority reporting (unknown Dosage text). |

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| 4.1(b) | 4.1(b) | This case was received via 4.1(b) (Reference number: 4.1(b) on 26-Oct-2021 and was forwarded to Moderna on 26-Oct-2021.<br>This regulatory authority case was reported by an other health care professional and describes the occurrence of CHEST PAIN (Chest pain) and MYOCARDITIS (Myocarditis) in a 25-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 076C21A) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 10-Oct-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 13-Oct-2021, the patient experienced CHEST PAIN (Chest pain) (seriousness criterion hospitalization) and MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, CHEST PAIN (Chest pain) and MYOCARDITIS (Myocarditis) outcome was unknown.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 13-Oct-2021, Troponin: increased (High) High.<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments.<br><br>No concomitant medications were reported<br><br>No treatment information was provided.<br><br>Company comment: This case concerns a 25-year old, male subject with no relevant medical history, who experienced the serious expected event of Myocarditis(AESI) and the serious unexpected event of Chest pain. The events, which resulted in hospitalization, occurred 3 days after the second dose of Moderna COVID-19 vaccine. Rechallenge is not applicable as no information about adverse events following the first dose is available. The patient's age and gender, which are associated with a higher incidence of Myocarditis, remain as confounders. The benefit-risk relationship of Moderna COVID-19 vaccine is not affected by this report. |
| 4.1(b) | 4.1(b) | This case was received via 4.1(b) (Reference number: 4.1(b) on 26-Oct-2021 and was forwarded to Moderna on 26-Oct-2021.<br>This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCARDITIS (Myocarditis) in a 36-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 047c21a) for COVID-19 vaccination.<br><br>No medical history was provided by the reporter.<br>Concomitant products included FUROSEMIDE, METOPROLOL TARTRATE and CALCITRIOL for an unknown indication. |

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| | | On 26-Sep-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 30-Sep-2021, after starting mRNA-1273 (Moderna COVID-19 Vaccine), the patient experienced MYOCARDITIS (Myocarditis) (seriousness criterion medically significant). At the time of the report, MYOCARDITIS (Myocarditis) outcome was unknown.<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments.<br><br>Treatment medications were not provided.<br><br>Company comment:<br>This case concerns a 36 year-old, male with no relevant history reported, who experienced the serious expected event of Myocarditis (AESI). The event of Myocarditis was also upgraded to serious (Medically Significant) as per Important medical event terms list (MedDRA version 24.0). The event occurred 4 days after the second dose of the administration of Moderna COVID-19 Vaccine. At the time of the report, the outcome of the event is unknown. The rechallenge is not applicable since the event occurred after the second dose and another dose will not be administered. The benefit-risk relationship of the vaccine in not affected by this report. |
| 4.1(b) | 4.1(b) | This case was received via 4.1(b) (Reference number: 4.1(b) on 26-Oct-2021 and was forwarded to Moderna on 26-Oct-2021.<br>This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCARDITIS (Myocarditis) in a 23-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 027A21A) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 04-Mar-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 06-Mar-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). The patient was hospitalized for 2 days due to MYOCARDITIS. The patient was treated with ASPIRIN [ACETYLSALICYLIC ACID] for Adverse event, at an unspecified dose and frequency. At the time of the report, MYOCARDITIS (Myocarditis) had resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 07-Mar-2021, Blood test: abnormal (abnormal) Abnormal.<br>On 07-Mar-2021, Catheterisation cardiac: diagnosed as myocarditis (abnormal) Officially diagnosed as myocarditis.<br>On 07-Mar-2021, Chest X-ray: normal (normal) The chest x-ray came back fine..<br>On 07-Mar-2021, Echocardiogram: diagnosed as myocarditis (abnormal) Officially diagnosed as myocarditis. |

| Case ID | WW Identifier | Narrative |
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| | | On 07-Mar-2021, Electrocardiogram: abnormal (abnormal) Slight abnormality.<br>On 07-Mar-2021, Troponin: elevated (High) Elevated.<br>In April 2021, Echocardiogram: 100 percent good to go (normal) 100 percent good to go.<br>In April 2021, Electrocardiogram: 100 percent good to go (normal) 100 percent good to go.<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments.<br><br>On 06-Mar-2021, at around 12:30, patient felt slight pain in sternum (middle of chest), that lasted less than a second and it felt similar to heartburn and patient felt it again and at approx. 07:30 pm that day patient had the same symptoms and also at 11:30 pm that night patient again had the same symptoms.<br>On 07-Mar-2021, at the same location patient had the same feeling except time increased to a second and a half, a pinching sensation in the middle of the sternum. Patient reported to a clinic and was sent to hospital and had performed tests.<br>The patient had EKG, chest x-ray and blood tests. They noted very slight abnormality on the EKG and the chest x-ray came back fine and patient had elevated Troponin. At that point, the patient was admitted to a local larger hospital. The patient had another EKG, echocardiogram and a cath exam with a camera and was officially diagnosed as myocarditis. It was in the apex of heart-the very bottom tip. The patient was admitted for an overnight evaluation (two nights).<br>Treatment included Ace inhibitor, beta blocker and normal aspirin for 30 days.<br>After 30 days, patient went to Heart hospital doctor and patient had a follow up EKG and echo-cardiogram and was said it was 100 percent good to go, like nothing ever happened.<br><br>Company comment: This case concerns a 23-year-old male patient with relevant medical history who experienced serious expected event of myocarditis. The event occurred approximately 2 days after the second dose of Spikevax. Reportedly, the patient experienced slight pain in the sternum, the middle of the chest that lasted less than a second and felt like heartburn. The patient had this feeling later in the day again and at night. One day later, the patient had the same feeling again however, the duration was longer and there was a pinching sensation in the middle of sternum. The patient was sent to the hospital where he had EKG, chest X ray and blood tests performed. |
| 4.1(b) | 4.1(b) | This case was received via 4.1(b) (Reference number: 4.1(b) on 26-Oct-2021 and was forwarded to Moderna on 26-Oct-2021.<br>This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCARDITIS (Myocarditis) in a 34-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 001C21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below.<br><br>No Medical History information was reported. |

| Case ID | WW Identifier | Narrative |
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| | | On 26-Apr-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 26-Apr-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criterion medically significant) and CHEST PAIN (Excessive chest pain for 2 days and then chest pain off). At the time of the report, MYOCARDITIS (Myocarditis) and CHEST PAIN (Excessive chest pain for 2 days and then chest pain off) had resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 26-Apr-2021, Chest X-ray: normal (normal) Normal.<br>On 26-Apr-2021, Echocardiogram: normal (normal) Normal.<br>On 26-Apr-2021, Magnetic resonance imaging: abnormal (abnormal) Cardiac MRI showing myocarditis.<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments.<br><br>Concomitant product use was not provided by the reporter.<br><br>No treatment information was provided.<br><br>Company comment: This regulatory report from 4.1(b) concerns a previously healthy 34 years old female who experienced the listed serious AESI event of Myocarditis. The start date of the event is reported as the day of second dose administration of Moderna COVID-19 vaccine: 26-Apr-2021 (Batch not provided). The patient experienced severe intermittent chest pain during 4 month, and the cardiac magnetic resonance was abnormal. At the time of the report (26-Oct-2021) the outcome of the event is reported as recovered/resolved.<br>The patient had no medical current conditions and was not taking medications.<br>The date of first dose was not provided. Accordingly, the schedule of product administration is not assessable.<br>The rechallenge is unknown.<br>The benefit-risk relationship of Moderna COVID-19 vaccine is not affected by this report |
| 4.1(b) | 4.1(b) | This case was received via 4.1(b) (Reference number: 4.1(b) on 26-Oct-2021 and was forwarded to Moderna on 26-Oct-2021.<br>This regulatory authority retrospective pregnancy case was reported by an other health care professional and describes the occurrence of DYSPNOEA (Dyspnoea), INDUCED LABOUR (Induced labour), PREMATURE DELIVERY (Premature delivery), PERICARDITIS (Acute pericarditis) and MATERNAL EXPOSURE DURING PREGNANCY (Maternal exposure during pregnancy) in a 28-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 011D21A) for COVID-19 vaccination.<br><br>Concurrent medical conditions included Allergy to antibiotic (Moxifloxacin). |

| Case ID | WW Identifier | Narrative |
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| | | On 24-Sep-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. Last menstrual period and estimated date of delivery were not provided. On 24-Sep-2021, the patient experienced MATERNAL EXPOSURE DURING PREGNANCY (Maternal exposure during pregnancy) (seriousness criterion hospitalization prolonged). On 25-Sep-2021, the patient experienced DYSPNOEA (Dyspnoea) (seriousness criterion hospitalization) and PERICARDITIS (Acute pericarditis) (seriousness criteria hospitalization prolonged and medically significant). On 01-Oct-2021, the patient experienced INDUCED LABOUR (Induced labour) (seriousness criterion hospitalization prolonged) and PREMATURE DELIVERY (Premature delivery) (seriousness criterion hospitalization prolonged). The delivery occurred on 01-Oct-2021, which was reported as Premature.<br>For neonate 1, The outcome was reported as Pre-Term Birth w Complications. On 24-Sep-2021, MATERNAL EXPOSURE DURING PREGNANCY (Maternal exposure during pregnancy) had resolved. At the time of the report, DYSPNOEA (Dyspnoea), INDUCED LABOUR (Induced labour), PREMATURE DELIVERY (Premature delivery) and PERICARDITIS (Acute pericarditis) had not resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 25-Sep-2021, Blood test: abnormal (abnormal) abnormal confirmed acute pericarditis.<br>On 25-Sep-2021, Echocardiogram: abnormal (abnormal) abnormal confirmed acute pericarditis.<br>On 25-Sep-2021, Hepatic enzyme: high (High) High, Liver enzymes with 100+ (AST/ALT).<br>On 25-Sep-2021, Inflammatory marker test: high (High) High.<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments.<br><br>Was induced and gave birth on 10/1 to a baby 34 weeks and 5 days old.<br>Company comment: This is a case of Maternal Exposure during Pregnancy concerning a 28-year-old, female patient with no relevant medical history, who experienced the unexpected events of Dyspnea, Pericarditis, Induced Labor and Premature Delivery. The patient received the second dose of vaccine at an unknown age of gestation. Induced Labor and Premature Delivery occurred approximately 8 days after the second dose of mRNA-1273 (Moderna COVID-19 Vaccine). The events of Dyspnea and Pericarditis occurred approximately 1-2 days after receiving the second dose of mRNA-1273 (Moderna COVID-19 Vaccine) all with outcome of hospitalization. The benefit-risk relationship of mRNA-1273 (Moderna COVID-19 Vaccine) is not affected by this report. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) on 27-Oct-2021 and was forwarded to Moderna on 27-Oct-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myocarditis) in a 20-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3005835) for COVID-19 vaccination. |

| Case ID | WW Identifier | Narrative |
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| | | No Medical History information was reported.<br><br>On 23-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 03-Oct-2021, after starting mRNA-1273 (Spikevax), the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Myocarditis) outcome was unknown.<br><br>For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.<br><br>Concomitant medication was not reported.<br>Treatment information was not reported.<br><br>Local Evaluator Comment English Spanish Japanese French German Swiss Assessment<br><br>Company Comment: This case concerns a 20 year-old male patient with no reported medical history, who experienced the expected serious event of Myocarditis. The event occurred 11 days after the second dose of mRNA-1273 vaccine. Details of clinical presentation, diagnostic criteria, and clinical course were not provided. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 27-Oct-2021: Translation Document received on 29-OCT-202, includes translated dosage and relevant information. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 27-Oct-2021 and was forwarded to Moderna on 27-Oct-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Acute myocarditis) in a 22-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 3005790 and 3005695) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 06-Sep-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form.<br>On 04-Oct-2021, received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. On 06-Oct-2021, the patient experienced MYOCARDITIS (Acute myocarditis) (seriousness criteria hospitalization and medically significant). On 14-Oct-2021, MYOCARDITIS (Acute myocarditis) had resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 07-Oct-2021, C-reactive protein (0-10): 123.7 (High) CRP - 123.7 mg/l. |

| Case ID | WW Identifier | Narrative |
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| | | On 07-Oct-2021, Echocardiogram: abnormal (abnormal) Conclusions - Non dilated left ventricle with slightly depressed subjective systolic function (LVEF 45 percent) and BSA to lateral level..<br>On 07-Oct-2021, Fibrin D dimer: 815 (abnormal) D DIMER - 815 ng/ml.<br>On 07-Oct-2021, Magnetic resonance imaging heart: normal (normal) CONCLUSION - Normal left and right ventricle. There is no edema, or areas of delayed enhancement..<br>On 07-Oct-2021, Troponin I (0.01-0.02): 2.3 (High) 2.3 ng/mL.<br>On 09-Oct-2021, SARS-CoV-2 test: negative (Negative) Negative.<br><br>mRNA-1273 (Spikevax) (Unknown) was withdrawn on 06-Sep-2021.<br><br>For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.<br><br>No concomitant medications reported by reporter.<br><br>No treatment medications provided by the reporter.<br><br>Company Comment:<br>This case concerns a 22-year-old male patient with no relevant medical history, who experienced the serious expected (AESI) of Myocarditis. The event occurred approximately 2 day after the second dose of the mRNA-1273. The lab investigations of increase levels of CRP (123.7mg/L), D-dimer (815ng/ml), Troponin (2.3ng/ml) and an abnormal echocardiogram were provided to support the diagnosis of Myocarditis. The rechallenge was not applicable since the event occurred after the second dose. The benefit-risk relationship of the mRNA-1273 is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 27-Oct-2021: Translated received on 29-Oct-2021 as patient laboratory data notes and translated event verbatim updated. |
| 4.1(b) | 4.1(b) | This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 16-Oct-2021 and was forwarded to Moderna on 28-Oct-2021.<br>This case, initially reported to the 4.1(b) by a (pharmacist), was received via the 4.1(b) (Ref, 4.1(b)<br><br>On an unknown date, the patient received the 1st dose of this vaccine.<br><br>On an unknown date, body temperature before the vaccination: 36.3 degrees Celsius.<br><br>On 08-Oct-2021, the patient received the 2nd dose of this vaccine.<br><br>On 10-Oct-2021, at 02:00, myocarditis developed, and chest pain developed. The patient took over-the-counter loxoprofen sodium hydrate and went to bed. However, at the time of awakening, the patient had chest pain and visited a hospital. There were no major changes on the electrocardiogram. No increase in cardiac enzymes was observed, and the patient was hospitalized with consideration of the possibility of developing into serious myocarditis. |

| Case ID | WW Identifier | Narrative |
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| | | On 11-Oct-2021, the patient had chest pain and discomfort, and loxoprofen sodium hydrate as needed was prescribed<br><br>On 12-Oct-2021, there were no major changes on the electrocardiogram and cardiac enzyme data. Chest pain improved, but the patient complained of a touch of discomfort.<br><br>On 13-Oct-2021, the patient did not complain of chest symptoms and did not have any problems in hospital life.<br><br>On 14-Oct-2021, the patient was discharged from the hospital.<br><br>On 15-Oct-2021, recovery of the symptoms was confirmed.<br><br>The outcome of myocarditis was reported as resolved.<br><br>Follow-up investigation will be made.<br><br>Company Comment:<br><br>The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. |
| 4.1(b) | 4.1(b) | This case was initially received via Takeda Pharmaceuticals (Reference number: 4.1(b) ) on 20-Oct-2021. The most recent information was received on 27-Oct-2021 and was forwarded to Moderna on 04-Nov-2021.<br>This case, initially reported to the 4.1(b) ) by a pharmacist, was received via the 4.1(b) (Ref, 4.1(b)<br><br>On 27-Oct-2021, follow-up information, initially reported to the 4.1(b) by a pharmacist, was received via the 4.1(b) (Ref, 4.1(b)<br><br>Myocarditis was assessed as serious by the MAH.<br><br>On 26-Aug-2021, the patient received the 1st dose of this vaccine.<br><br>On 30-Sep-2021, the patient received the 2nd dose of this vaccine.<br><br>On 01-Oct-2021, pyrexia and chills developed.<br><br>On 02-Oct-2021, around noon, feeling of tightness in the neck and upper arm from the left shoulder developed and was resolving in about 1 hour. There was no queasy or cold feeling.<br><br>On 03-Oct-2021, chest pain developed. The symptom was resolving in about 1 hour, but chest pain recurred. There was slight chest pain before going to bed. The patient visited a medical institution. Electrocardiogram showed normal sinus rhythm with no significant ST-T changes. Echocardiography showed good left ventricular ejection fraction (EF), but ejection fraction of the base of the heart was slightly weaker than that of the apex without wall motion abnormality. CRP: 1.42 mg/mL, troponin I: 2,428 pg/mL, CK-MB: 21 U/L, and CK: 309 U/L. The patient was diagnosed with myocarditis. |

| Case ID | WW Identifier | Narrative |
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| | | On 04-Oct-2021, no chest pain was noted at rest. The patient walked for about 10 minutes to see a physician and became aware of chest discomfort. Echocardiography showed EF of 63% and slight mitral regurgitation (MR). CRP: 0.77 mg/mL, troponin I: 1,904.5 pg/mL, CK-MB: 14 U/L, and CK: 246 U/L.<br><br>On 05-Oct-2021, chest pain subsided. Recovery of the symptoms was confirmed.<br><br>On 08-Oct-2021, echocardiography showed EF of 69% and slight MR. CRP: less than 0.24 mg/mL, troponin I: 76.7 pg/mL, CK-MB :6 U/L, and CK: 74 U/L.<br><br>The outcome of pyrexia, chills, myocarditis, feeling of tightness in the neck and upper arm from the left shoulder was reported as resolved.<br><br>No follow-up investigation will be made.<br><br>Follow-up received on 27-OCT-2021<br><br>Updated: Product Information, Narrative<br><br>Company Comment:<br><br>The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.<br><br>Company comment-<br>This case concerns a 31-year-old male patient with no medical history, who experienced serious expected event of Myocarditis. The event occurred the 3 days after the second dose of Moderna COVID-19 vaccine. The lab information of creatine phosphokinase, creatine phosphokinase MB, C-reactive protein, Echocardiogram, Troponin I, support the diagnosis of Myocarditis. The rechallenge information is not applicable as the event occurred after the second dose. The benefit-risk relationship of Moderna COVID-19 vaccine is not affected by this report. |
| 4.1(b) | 4.1(b) | This case was initially received via European Medicines Agency (Reference number: 4.1(b) ) on 27-Oct-2021. The most recent information was received on 08-Nov-2021 and was forwarded to Moderna on 08-Nov-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of HEART RATE INCREASED (Pulse increased), CHEST PAIN (CHEST PAINS), MYALGIA (MUSCLE PAIN), SWELLING (FEELING THAT THE THROAT IS SWOLLEN), VACCINATION SITE PAIN (PAIN IN THE ARM AT THE INJECTION SITE), PYREXIA (FEVER), HEADACHE (HEADACHE) and MYOCARDITIS (SUPECTED MYOCARDITIS) in a 30-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 3005697) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 23-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 23-Sep-2021, the patient |

| Case ID | WW Identifier | Narrative |
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| | | experienced HEART RATE INCREASED (Pulse increased) (seriousness criteria hospitalization and medically significant), CHEST PAIN (CHEST PAINS) (seriousness criteria hospitalization and medically significant), MYALGIA (MUSCLE PAIN) (seriousness criteria hospitalization and medically significant), SWELLING (FEELING THAT THE THROAT IS SWOLLEN) (seriousness criteria hospitalization and medically significant), VACCINATION SITE PAIN (PAIN IN THE ARM AT THE INJECTION SITE) (seriousness criteria hospitalization and medically significant), PYREXIA (FEVER) (seriousness criteria hospitalization and medically significant), HEADACHE (HEADACHE) (seriousness criteria hospitalization and medically significant) and MYOCARDITIS (SUPECTED MYOCARDITIS) (seriousness criteria hospitalization and medically significant). On 25-Sep-2021, PYREXIA (FEVER) had resolved. At the time of the report, HEART RATE INCREASED (Pulse increased), CHEST PAIN (CHEST PAINS) and MYOCARDITIS (SUPECTED MYOCARDITIS) had not resolved and MYALGIA (MUSCLE PAIN), SWELLING (FEELING THAT THE THROAT IS SWOLLEN), VACCINATION SITE PAIN (PAIN IN THE ARM AT THE INJECTION SITE) and HEADACHE (HEADACHE) was resolving.<br><br>For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.<br><br>No Concomitant medications was reported.<br><br>No Treatment details was reported.<br><br>Company comment: This case concerns a 30-year-old female patient, with no relevant medical history, who experienced serious expected event of myocarditis (AESI) and serious unexpected events of heart rate increased, chest pain, swelling, pyrexia, myalgia and vaccination site pain. The events occurred on the same day after the second dose of Moderna COVID-19 vaccine. The rechallenge was not applicable since AEs occurred after the second dose. The benefit-risk relationship of Moderna COVID-19 vaccine is not affected by this report.<br><br>This case was linked to 4.1(b) (E2B Linked Report).<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 27-Oct-2021: Translation document received on 29-OCT-2021 contains added Event verbatim.<br>On 08-Nov-2021: Seriousness (Hospitalization) was updated. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b)) on 27-Oct-2021 and was forwarded to Moderna on 27-Oct-2021.<br>This regulatory authority case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of MYOCARDITIS (Myocarditis) in a 27-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3004235) for Prophylactic vaccination.<br><br>No Medical History information was reported. |

| Case ID | WW Identifier | Narrative |
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| | | On 29-Aug-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 01-Sep-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Myocarditis) was resolving.<br><br>No concomitant medication were reported. No treatment information was provided by the reporter.<br><br>Hospitalization, ultrasound examinations, MRI, cardiac catheterization. Tablet intake since 01-Sep-2021.<br><br>Company comment -This case concerns a 27-year-old, male patient with no relevant medical history reported, who experienced the unexpected event of Myocarditis. The event occurred approximately 3 days after the second dose of mRNA-1273. The rechallenge was not applicable since the event happened after the second dose. T The benefit-risk relationship of mRNA-1273 is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 27-Oct-2021: Translated document received on 29 Oct 2021 contains translated event terms. |
| 4.1(b) | 4.1(b) | This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 15-Oct-2021 and was forwarded to Moderna on 28-Oct-2021.<br>This case, initially reported to the 4.1(b) by a pharmacist, was received via the 4.1(b) (Ref, 4.1(b)<br><br>The patient had a history of allergy to antibiotics and a history of urticaria due to faropenem sodium hydrate.<br><br>On an unknown date, the patient received the 1st dose of the vaccine.<br><br>On an unknown date, body temperature before the vaccination: 36.5 degrees Celsius.<br><br>On 08-Oct-2021, at 11:00, the patient received the 2nd dose of the vaccine.<br><br>On 09-Oct-2021, at 21:00, myocarditis developed. The patient visited a hospital for chest pain, queasy, and pyrexia. Changes on the electrocardiogram included early repolarization waveforms. Heart rate was 120/min. Blood test showed troponin of 0.011 with CK of 68 and no elevation in cardiac enzymes. Drip infusion of acetaminophen 1000 mg was given for chest pain. The patient was hospitalized because follow-up was needed for changes on the electrocardiogram and chest symptoms.<br><br>On 10-Oct-2021, blood collection was performed to show elevated troponin of 0.055 with CK of 57. Electrocardiogram showed high T waves in the V2 lead to V6 lead. Heart rate was 90/min. There were no subjective symptoms. |

| Case ID | WW Identifier | Narrative |
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| | | On 11-Oct-2021, CK decreased to 35 and troponin to 0.011. There were no subjective symptoms. There were no changes on the electrocardiogram. The patient had no problems with a stay at the hospital.<br><br>On 14-Oct-2021, the symptoms improved. Resolution was confirmed, and the patient was discharged from the hospital.<br><br>The outcome of myocarditis was reported as resolved.<br><br>Follow-up investigation will be made.<br><br>Company Comment:<br><br>The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 27-Oct-2021 and was forwarded to Moderna on 27-Oct-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (MYOCARDITIS) in a 28-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 23-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 26-Sep-2021, the patient experienced MYOCARDITIS (MYOCARDITIS) (seriousness criteria hospitalization, medically significant and life threatening). At the time of the report, MYOCARDITIS (MYOCARDITIS) was resolving.<br><br>For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.<br><br>No concomitant medication was given.<br>No treatment medication was given.<br><br>This is a regulatory authority case concerning a 28-year-old, male patient with unknown medical history, who experienced the unexpected serious (hospitalization, medically significant and life threatening and AESI) event of Myocarditis. The event occurred approximately 4 days after the second dose of Moderna COVID 19 vaccine (lot # unk). Information regarding the first dose or other details about the event were not disclosed. The rechallenge is not applicable. The benefit-risk relationship of Spikevax is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 27-Oct-2021: Translated document attached on 29-Oct-2021 contains verbatim of event updated to English. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 28-Oct-2021 and was forwarded to Moderna on 28-Oct-2021. |

| Case ID | WW Identifier | Narrative |
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| | | This regulatory authority case was reported by a physician and describes the occurrence of PERICARDITIS (PERICARDITIS) in a 24-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3003604) for Vaccination.<br><br>No Medical History information was reported.<br><br>On 06-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 16-Oct-2021, the patient experienced PERICARDITIS (PERICARDITIS) (seriousness criterion medically significant). At the time of the report, PERICARDITIS (PERICARDITIS) had not resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 16-Oct-2021, C-reactive protein: elevated (High) Elevated.<br>On 16-Oct-2021, Echocardiogram: normal (normal) Normal findings.<br>On 16-Oct-2021, Electrocardiogram: abnormal (abnormal) Abnormal.<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered PERICARDITIS (PERICARDITIS) to be possibly related.<br><br>No concomitant medications were provided.<br><br>No treatment information was provided.<br><br>Company comment: This case concerns a 24 year old male patient with no relevant medical history, who experienced the expected event of pericarditis. The event pericarditis occurred approximately 40 days after the second dose of the Moderna COVID-19 vaccine. The rechallenge was unknown. The benefit-risk relationship of the Moderna COVID-19 vaccine is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 28-Oct-2021: Translation received on 29-Oct-2021. Translated event verbatim and sender's comment updated. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 28-Oct-2021 and was forwarded to Moderna on 28-Oct-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Perimyocarditis: Patient was admitted to the hospital with symptoms of fever and chest pain, myocardial infarction and pulmonary embolism were excluded. After further examinations, perimyocarditis was confirmed.) in a 27-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3004493) for COVID-19 immunisation. The occurrence of additional non-serious events is detailed below.<br><br>No Medical History information was reported.<br><br>On 01-Jul-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. |

| Case ID | WW Identifier | Narrative |
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| | | On 15-Sep-2021, received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. On 03-Oct-2021, the patient experienced MYOCARDITIS (Perimyocarditis: Patient was admitted to the hospital with symptoms of fever and chest pain, myocardial infarction and pulmonary embolism were excluded. After further examinations, perimyocarditis was confirmed.) (seriousness criteria hospitalization, disability and medically significant) and PYREXIA (Fever: 38 to 40.5 degrees Celsius). At the time of the report, MYOCARDITIS (Perimyocarditis: Patient was admitted to the hospital with symptoms of fever and chest pain, myocardial infarction and pulmonary embolism were excluded. After further examinations, perimyocarditis was confirmed.) and PYREXIA (Fever: 38 to 40.5 degrees Celsius) was resolving.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 07-Oct-2021, Pyrexia: high (High) 38 tot 40.5 Degrees Celcius.<br><br>For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.<br><br>No concomitant medication details were provided.<br><br>No treatment medication details were provided.<br><br>Company comment: This case concerns a 27-year-old male subject, with no relevant medical history, who experienced the expected, serious, and AESI event of Myocarditis. The event occurred 17 days after the second dose of Moderna COVID-19 vaccine. The rechallenge is not applicable, as no additional dosing will be given. The benefit-risk relationship of Moderna COVID-19 vaccine is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 28-Oct-2021: Translation received on 01-Nov-2021. Translated event verbatim updated. |
| 4.1(b) | 4.1(b) | This case was initially received via European Medicines Agency (Reference number: 4.1(b) ) on 28-Oct-2021. The most recent information was received on 29-Nov-2021 and was forwarded to Moderna on 29-Nov-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of the first episode of TROPONIN INCREASED (Troponin increased), CHEST PAIN (Precordial pain), PYREXIA (Fever), INFLAMMATION (Diffuse inflammation), the second episode of TROPONIN INCREASED (Troponin increased), CHEST PAIN (Chest pain) and MYOCARDITIS (Myocarditis) in a 14-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 prophylaxis.<br><br>Concurrent medical conditions included Myocarditis.<br><br>On 08-Oct-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form.<br>On an unknown date, the patient received dose of mRNA-1273 (Spikevax) (unknown route) at an unspecified dose. On 11-Oct-2021, the patient experienced the first episode of TROPONIN INCREASED |

| Case ID | WW Identifier | Narrative |
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| | | (Troponin increased) (seriousness criteria hospitalization and medically significant), CHEST PAIN (Precordial pain) (seriousness criteria hospitalization and medically significant) and MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). On an unknown date, the patient experienced PYREXIA (Fever) (seriousness criteria hospitalization and medically significant), INFLAMMATION (Diffuse inflammation) (seriousness criteria hospitalization and medically significant), the second episode of TROPONIN INCREASED (Troponin increased) (seriousness criteria hospitalization and medically significant) and CHEST PAIN (Chest pain) (seriousness criteria hospitalization and medically significant). On 17-Oct-2021, CHEST PAIN (Precordial pain) and MYOCARDITIS (Myocarditis) had resolved. At the time of the report, PYREXIA (Fever), INFLAMMATION (Diffuse inflammation), the last episode of TROPONIN INCREASED (Troponin increased) and CHEST PAIN (Chest pain) outcome was unknown.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 11-Oct-2021, Troponin: 4000 (High) 4000 and 14000 (High) 14000.<br>On 12-Oct-2021, Troponin: 16000 (High) 16000.<br>On 16-Oct-2021, C-reactive protein: 2 (High) 2.<br>On an unknown date, Magnetic resonance imaging heart: abnormal (abnormal) It confirmed the diagnosis of the myocarditis..<br>On an unknown date, Troponin: 14000 (High) 14000.<br><br>For mRNA-1273 (Spikevax) (Unknown), the reporter considered TROPONIN INCREASED (Troponin increased), CHEST PAIN (Precordial pain), PYREXIA (Fever), INFLAMMATION (Diffuse inflammation), TROPONIN INCREASED (Troponin increased), CHEST PAIN (Chest pain) and MYOCARDITIS (Myocarditis) to be probably related.<br><br>No concomitant details were reported. No treatment information was provided. Lab data: On 16-OCT-2021, C-reactive protein was 2.<br><br>Company Comment:<br>This case concerns a 14 year-old male patient with no relevant medical history who experienced the unexpected serious events of Chest pain, Troponin increased, Inflammation, Pyrexia and the expected serious AESI event of Myocarditis. The event occurred approximately 6 days after the second dose of mRNA-1273 vaccine which resulted in Hospitalization. Lab tests done showed an increase in troponin values and C-reactive protein, while MRI confirmed the diagnosis of Myocarditis. At the time of report the outcome of the event Myocarditis was - Recovered/Resolved. The rechallenge was not applicable as no additional dosing will be administered. The benefit-risk relationship of mRNA-1273 is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 29-Nov-2021: Significant follow up received contains updated event outcome and relatedness of drug to reaction(s)/event(s), probable. |
| 4.1(b) | 4.1(b) | This case was initially received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 20-Oct-2021. The most recent information |

| Case ID | WW Identifier | Narrative |
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| | | was received on 19-Nov-2021 and was forwarded to Moderna on 25-Nov-2021.<br>This case was reported by a physician via a medical representative.<br><br>On 12-Nov-2021, follow-up information was received by a physician via a medical representative.<br><br>On 19-Nov-2021, follow-up information, reported to Takeda by a physician, was received via Moderna's adverse reaction reporting site 4.1(b)<br><br>On 19-Nov-2021, follow-up information was received by a physician via a medical representative.<br><br>On 20-Nov-2021, follow-up information, reported to the 4.1(b) by a physician, was received via 4.1(b) (Ref 4.1(b)<br><br>On an unknown date, the patient received the 1st dose of this vaccine.<br><br>On 15-Oct-2021, the patient received the 2nd dose of this vaccine.<br><br>On 16-Oct-2021, at 16:00, the patient experienced respiratory chest pain as a chest symptom.<br><br>On 17-Oct-2021, the patient visited a clinic. Twelve-lead electrocardiogram showed ST segment elevation in all leads, and the patient was referred to the reporting hospital. The patient was diagnosed with myocarditis due to positive troponin T. Echocardiography showed diffuse hypokinesis of the wall. There were no signs of heart failure.<br><br>On an unknown date, the patient was hospitalized. The severity of myocarditis was moderate. The electrocardiogram improved on the next day. There was no increase in CK-MB. The patient was resolving spontaneously without specific treatment, and then the patient was discharged from the hospital after several days without complications.<br><br>On 01-Nov-2021, cardiac MRI was performed two weeks after the onset. LGE positive was revealed in the middle layer of the lateral wall region and was considered to be a finding after inflammation in the same region.<br><br>On 08-Nov-2021, the recovery of the symptoms was recognized.<br><br>The outcome of myocarditis was reported as resolved.<br><br>No Follow-up investigation will be made.<br><br>Follow-up received on 12-NOV-2021<br><br>Updated: Patient Information, Other Relevant History, Lab Data, Product Information, Event Information, Narrative, Reporter Comments<br><br>Follow-up received on 19-NOV-2021 |

| Case ID | WW Identifier | Narrative |
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| | | Updated: Reporter Information, Patient Information, Lab Data, Event Information, Narrative, Reporter Comments<br><br>Company Comment:<br>The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. |
| 4.1(b) | 4.1(b) | This regulatory authority case was reported by a pharmacist and describes the occurrence of MYOCARDITIS (Perimyocarditis), ARTHRALGIA (Arthralgia), PYREXIA (Fever) and HEADACHE (Headache) in a 19-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 14-Sep-2021, the patient received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form. On 15-Sep-2021, the patient experienced ARTHRALGIA (Arthralgia) (seriousness criteria hospitalization and medically significant), PYREXIA (Fever) (seriousness criteria hospitalization and medically significant) and HEADACHE (Headache) (seriousness criteria hospitalization and medically significant). On 19-Sep-2021, the patient experienced MYOCARDITIS (Perimyocarditis) (seriousness criteria hospitalization and medically significant). On 16-Sep-2021, ARTHRALGIA (Arthralgia), PYREXIA (Fever) and HEADACHE (Headache) had resolved. On 22-Sep-2021, MYOCARDITIS (Perimyocarditis) had resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 20-Sep-2021, Echocardiogram: normal (normal) Good pumping function without wall motion disorder, [mi]...<br>On 20-Sep-2021, Electrocardiogram: abnormal (abnormal) T-wave inversions in II, III, avF and V3 to V5.<br><br>For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered ARTHRALGIA (Arthralgia), PYREXIA (Fever) and HEADACHE (Headache) to be probably related and MYOCARDITIS (Perimyocarditis) to be possibly related.<br><br>No relevant concomitant and treatment medications were reported<br><br>Patient experienced Intermittent left chest pain with pain in the left arm, increased when lying down,improvement while sitting. Due to severe pain, the patient is no longer able to fall asleep and presented to the emergency ward during the night on 20-Sep-2021.<br>On admission, the patient presented in good general condition -afebrile and with stable cardiopulmonary status<br>Patient's Troponin T dynamics up to a maximum value of 136 ng/L<br>The patient was asymptomatic over the further course and had stable vital signs.<br><br>Company comment: This case concerns a 19 year old male patient, with no medical history reported, who experienced serious expected AESI of myocarditis after second dose of mRNA-1273. The event occurred 6 days |

| Case ID | WW Identifier | Narrative |
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| | | after second dose. The re-challenge is unknown since event occurred after second dose and outcome was recovered. The benefit-risk relationship of Moderna COVID-19 vaccine is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 28-Oct-2021: Translation received on 02-Nov-2021-case narrative, dosage text and lab data results updated. |
| 4.1(b) | 4.1(b) | This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) ) on 23-Oct-2021 and was forwarded to Moderna on 29-Oct-2021.<br>This case, initially reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref, 4.1(b)<br><br>On 02-Sep-2021, the patient received the 1st dose of this vaccine.<br><br>On 01-Oct-2021, the patient received the 2nd dose of this vaccine.<br><br>On 04-Oct-2021, at 02:00, myocarditis developed. Precordial pain was noted. Blood test showed elevated cardiac enzymes, and electrocardiogram showed diffuse ST elevation. The patient was hospitalized.<br><br>On 13-Oct-2021, the symptoms resolved, and the patient was discharged from the hospital.<br><br>The outcome of myocarditis was reported as resolved.<br><br>Follow-up investigation will be made.<br><br>Company Comment:<br><br>The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. |
| 4.1(b) | 4.1(b) | This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 25-Oct-2021 and was forwarded to Moderna on 29-Oct-2021.<br>This case was reported by a physician via the companys medical representative.<br><br>On an unknown date, the patient received the 1st dose of this vaccination.<br><br>On 24-Oct-2021, the patient received the 2nd dose of this vaccination.<br><br>On 25-Oct-2021, the patient complained of pyrexia and tiredness. The patient visited a medical institution, and the symptoms turned out to be a myocarditis when electrocardiogram was taken, and the patient was urgently transported. The patient was hospitalized.<br><br>The outcome of pyrexia and myocarditis was reported as unknown.<br><br>Follow-up investigation will be made.<br><br>Company Comment: |

| Case ID | WW Identifier | Narrative |
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| | | The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. |
| 4.1(b) | 4.1(b) | This case was initially received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 22-Oct-2021. The most recent information was received on 24-Dec-2021 and was forwarded to Moderna on 29-Dec-2021.<br><br>This case, initially reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref, 4.1(b)<br><br>On 24-Dec-2021, follow-up information was received from a physician.<br><br>On an unknown date, the patient received the 1st dose of this vaccine.<br><br>On 12-Oct-2021, the patient received the 2nd dose of this vaccine. There were no symptoms.<br><br>On 16-Oct-2021, at 17:00, acute myocarditis developed. The patient was aware of sudden onset of squeezing chest pain and left shoulder pain.<br><br>On 17-Oct-2021, at 00:00, the patient visited the previous physician, and electrocardiogram showed ST elevation in all leads except aVR and V1. At 05:00, the patient was transferred to the reporting hospital. The patient was examined, and there were ST elevation in all chest leads and extremity leads other than aVR, mild apical wall hypokinesis on echocardiography, and elevations of troponin I (11 ng/mL), BNP (51 pg/mL), CK-MB (59 IU/L), and CRP (7.45 mg/dL) in blood tests. At 05:40, emergency coronary angiography was performed to show no significant stenosis and only mild hypokinesis around the apex was shown by left ventriculography. After testing, CK peaked out at 859. Diltiazem hydrochloride 200 mg in two divided doses, aspirin, and rabeprazole sodium were prescribed. Chest pain and left shoulder pain disappeared. On an unknown date, the patient was hospitalized.<br><br>On 18-Oct-2021, contrast-enhanced MRI showed LGE in the epicardial myocardium, which was consistent with myocarditis. Echocardiography showed no cardiac contractile problems. Symptoms disappeared. On 19-Oct-2021, electrocardiogram showed a negative T wave in V4-V6.<br><br>On 25-Oct-2021, echocardiogram showed no significant changes, and the patient was discharged from the hospital because the symptoms were resolving. The outcome of acute myocarditis was reported as resolving.<br><br>No follow-up investigation will be made.<br><br>Reporter comments continuation: Considering myocarditis for a patient of young age, viral antibody titer and other tests were performed to find the cause of the disease, but no abnormalities of pathological significance were found. Follow-up received on 24-DEC-2021 Updated: Patient Information, Lab Data, Narrative, Reporter Comments<br><br>Company Comment: The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. |

| Case ID | WW Identifier | Narrative |
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| 4.1(b) | 4.1(b) | This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) ) on 23-Oct-2021 and was forwarded to Moderna on 29-Oct-2021.<br>This case, initially reported to the 4.1(b) by a pharmacist, was received via the 4.1(b) (Ref, 4.1(b)<br><br>On 19-Sep-2021, at 10:00, the patient received the 1st dose of this vaccine.<br><br>On 17-Oct-2021, at 10:00, the patient received the 2nd dose of this vaccine.<br><br>On 18-Oct-2021, at 01:00, pyrexia of 38 degrees Celsius or higher developed.<br><br>At 13:00, myocarditis developed. The patient had chest discomfort.<br><br>On 20-Oct-2021, at 02:00, the patient visited a nearby hospital because of severe chest symptoms. The patient was referred to our hospital due to suspected myocarditis after vaccination with this vaccine because of ST elevation and troponin T positive. The patient was then hospitalized. After the patient was hospitalized, oral administration of A (330) containing aspirin, aluminum glycinate, and magnesium carbonate was started for 3 times of 6 tablets.<br><br>The outcome of pyrexia, myocarditis was unknown.<br><br>Follow-up investigation will be made.<br><br>Company Comment:<br><br>The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. |
| 4.1(b) | 4.1(b) | This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 22-Oct-2021 and was forwarded to Moderna on 29-Oct-2021.<br><br>This case, reported by a physician, was received by Takeda via Moderna's adverse reaction reporting site 4.1(b) and reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref 4.1(b)<br><br>Acute myocarditis was assessed as serious by the MAH.<br><br>On 24-Sep-2021, at 17:00, the patient received the 1st dose of this vaccine.<br><br>On 17-Oct-2021, at 13:00, the patient received the 2nd dose of this vaccine.<br><br>On 18-Oct-2021, pyrexia of 39 degrees Celsius developed. |

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| | | On 19-Oct-2021, around 13:15, acute myocarditis developed with chest pain at rest. Improvement was poor, and the patient made an emergency visit at the reporting hospital. ECG showed ST segment elevation in leads 1, 2, aVF, and V3 -6, and ST segment depression in leads V1 and aVR. Echocardiography showed decreased wall motion localized to the apex. Increased cardiac enzymes were noted with CK 263 U/L, CK-MB 20.1 ng/mL, and troponin I 2,234 pg/mL.<br><br>On 22-Oct-2021, resolving of the symptoms was confirmed.<br><br>The outcome of acute myocarditis was reported as resolving.<br><br>Follow-up investigation will be made.<br><br>Company Comment:<br>The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) on 29-Oct-2021 and was forwarded to Moderna on 29-Oct-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of DYSPNOEA (Dyspnea), CHEST PAIN (Chest pain) and MYOCARDITIS (Myocarditis) in an 18-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3005835) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 23-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 16-Oct-2021, the patient experienced DYSPNOEA (Dyspnea) (seriousness criteria hospitalization, disability and life threatening), CHEST PAIN (Chest pain) (seriousness criteria hospitalization, disability and life threatening) and MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization, disability, medically significant and life threatening). At the time of the report, DYSPNOEA (Dyspnea), CHEST PAIN (Chest pain) and MYOCARDITIS (Myocarditis) had not resolved.<br><br>For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.<br><br>Concomitant medications were not provided.<br>Treatment information was not provided.<br><br>Company comment: This case concerns a 18-year-old male patient with no relevant medical history reported, who experienced the serious (medically significant, life threatening, hospitalization and disability) unexpected events of chest pain and dyspnoea, and expected event myocarditis. The events occurred approximately 24 days after the second dose of mRNA-1273. The rechallenge was not applicable since no further doses are scheduled. The concurrent diagnosis of myocarditis is a confounder for dyspnoea and chest pain. Seriousness assessments has been retained as per Regulatory Authority reporting, however there was no information in the source document supporting that the events resulted |

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| | | in a persistent or permanent incapacity. The benefit-risk relationship of mRNA-1273 is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 29-Oct-2021: Translation Document received on 01-NOV-2021 contains Event verbatim updated to English..<br>On 19-Nov-2021: Follow up received on 19-NOV-2021 contained non significant information. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) on 29-Oct-2021 and was forwarded to Moderna on 29-Oct-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myopericarditis) in a 24-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3006273) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 05-Oct-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 05-Oct-2021, after starting mRNA-1273 (Spikevax), the patient experienced MYOCARDITIS (Myopericarditis) (seriousness criterion medically significant). At the time of the report, MYOCARDITIS (Myopericarditis) was resolving.<br><br>For mRNA-1273 (Spikevax) (Unknown), the reporter considered MYOCARDITIS (Myopericarditis) to be possibly related.<br><br>Concomitant product use was not provided by the reporter.<br>Treatment information was not provided.<br><br>Company Comment : This case concerns a 24-year-old, male patient with no relevant medical history, who experienced the expected AESI of myocarditis. The event occurred on the same day after administration of the second dose of the Moderna COVID-19 Vaccine. The rechallenge was not applicable as no additional dosing will be given. The patient's gender remains a confounder. The benefit-risk relationship of the Moderna COVID-19 Vaccine is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 29-Oct-2021: Translation received on 02-NOV-2021, verbatim translated. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 29-Oct-2021 and was forwarded to Moderna on 29-Oct-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of PERICARDITIS (Acute pericarditis) in a 31-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 3005834 and 214017) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 09-Sep-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. |

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| | | On 07-Oct-2021, received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to 1 dosage form. On 09-Oct-2021, after starting mRNA-1273 (Spikevax), the patient experienced PERICARDITIS (Acute pericarditis) (seriousness criterion medically significant). At the time of the report, PERICARDITIS (Acute pericarditis) was resolving.<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.<br><br>No concomitant medication details were reported.<br>No treatment medication details were reported.<br><br>Company comment: This case concerns a 31-year-old male patient with no relevant medical history who experienced serious expected event of Pericarditis. The event occurred approximately two days after the second dose of Moderna COVID-19 vaccine. Very limited information regarding clinical course of the event has been provided at this time. The rechallenge was not applicable as the event occurred following the second dose of the vaccine. The event was classified as non-serious by RA, however, as per IME list was upgraded to serious and retained as such based on medical judgment. The benefit-risk relationship of Moderna COVID-19 vaccine is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 29-Oct-2021: Follow-up received contains translated information of 1st dose in medical history |
| 4.1(b) | 4.1(b) | This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 23-Oct-2021 and was forwarded to Moderna on 29-Oct-2021.<br>This case, initially reported to the 4.1(b) by a physician, was received via 4.1(b) (Ref 4.1(b)<br><br>On an unknown date, the patient received the 1st dose of this vaccine.<br><br>On an unknown date, body temperature before the vaccination: 36.2 degrees Celsius.<br><br>On 08-Oct-2021, at 16:30, the patient received the 2nd dose of this vaccine.<br><br>Onn 09-Oct-2021, around 22:00, precordial pain developed.<br><br>On 10-Oct-2021, around 05:00, chest pain was exacerbated. An emergency call was made, and the patient visited the reporting emergency outpatient department. The patient was hospitalized for epicarditis.<br><br>On 15-Oct-2021, the symptoms were resolving, and the patient was discharged from the hospital.<br><br>The outcome of chest pain and epicarditis was reported as resolving. |

| Case ID | WW Identifier | Narrative |
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| | | Follow-up investigation will be made.<br><br>Company Comment:<br><br>The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. |
| 4.1(b) | 4.1(b) | This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 23-Oct-2021 and was forwarded to Moderna on 29-Oct-2021.<br>This case, initially reported to the 4.1(b) by a (nurse), was received via the 4.1(b) (Ref, 4.1(b)<br><br>On an unknown date, the patient received the 1st dose of this vaccine.<br><br>On 28-Sep-2021, the patient received the 2nd dose of this vaccine.<br><br>On 29-Sep-2021, pyrexia of 39 degrees Celsius developed.<br><br>On 30-Sep-2021, pyrexia went down, and the patient went to work and did exercise after returning home. Thereafter, chest pain, disordered breathing, and pyrexia of 39 degrees Celsius developed again.<br><br>On 01-Oct-2021, the patient visited a hospital and was referred to the reporting hospital due to suspected myocarditis. At the visit, troponin I: 1,864.8, BPN: 25.5, CRP: 5.41, heart rate: 56 times/min, and increased ST-T in 12-lead electrocardiogram. The patient was hospitalized.<br><br>On 03-Oct-2021, CPK peaked out.<br><br>On 04-Oct-2021, cardiac MRI showed no problem, and acute myocarditis was diagnosed.<br><br>On 06-Oct-2021, the patient was discharged from the hospital.<br><br>On 11-Oct-2021, recovery of the symptoms was confirmed.<br><br>The outcome of pyrexia, chest pain, and acute myocarditis was reported as resolved.<br><br>Follow-up investigation will be made.<br><br>Company Comment:<br><br>The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. |
| 4.1(b) | 4.1(b) | This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) ) on 25-Oct-2021 and was forwarded to Moderna on 01-Nov-2021.<br>This case, initially reported to the 4.1(b) by a medical safety officer, was received via the 4.1(b) (Ref 4.1(b)<br><br>Suspected myocarditis was assessed as serious by the MAH. |

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| | | On an unknown date, the patient received the 1st dose of this vaccine.<br>On 15-Oct-2021, the patient received the 2nd dose of this vaccine. After the vaccination, vaccination site pain, pyrexia of high 39 degrees Celsius range developed. The symptoms were controlled by internal use of loxoprofen sodium hydrate.<br>On 19-Oct-2021, in the morning, the patient was suddenly aware of lower sternal pain. NRS: 4-5/10. Thereafter, pain disappeared temporarily.<br>On 20-Oct-2021, the patient experienced pain similar to that of the previous day and visited a medical institution. The patient said that the pain was aggravated by bending forward or deep breathing. Blood test, electrocardiogram, chest X-ray, and echocardiography were performed for suspected myocarditis. Blood test showed a high level of troponin of 1.170, but ultrasonography and electrocardiogram showed no abnormalities.<br>On 22-Oct-2021, at the time of returning to the medical institution, blood test was normal with troponin of 0.149, and there were no symptoms, so the examination was finished. The symptoms were resolving.<br><br>The outcome of vaccination site pain, pyrexia, lower sternal pain, suspected myocarditis, and high troponin level was reported as resolving.<br><br>Follow-up investigation will be made.<br><br>Company Comment:<br>The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. |
| 4.1(b) | 4.1(b) | This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 26-Oct-2021 and was forwarded to Moderna on 01-Nov-2021.<br>This case, initially reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref, 4.1(b)<br><br>Pericarditis was assessed as serious by the MAH.<br><br>On an unknown date, the patient received the 1st dose of this vaccine.<br><br>On 15-Oct-2021, the patient received the 2nd dose of this vaccine.<br><br>On 16-Oct-2021, in the morning, pericarditis developed. A dull pain in the midline of the chest developed and persisted on the Numerical Rating Scale (NRS) of approximately 2/10. The patient was followed up without using analgesics.<br><br>On 17-Oct-2021, the patient visited our emergency department because of exacerbation to NRS 5/10. BT 36.9 degrees Celsius, BP 151/73 mmHg, HR 86, RR 19, SpO2 100% (room air), and deep breathing exacerbated chest pain. Electrocardiogram showed mild ST elevation in V2 -4, normal CK-MB and troponin I, and echo showed no pericardial effusion. CRP 4.09, WBC 8,100. There was no history of heart disease or family history. Pericarditis after vaccination was diagnosed, and the patient was prescribed loxoprofen sodium hydrate 60 mg 3 tablets/day.<br><br>On 19-Oct-2021, the symptoms gradually improved and disappeared. |

| Case ID | WW Identifier | Narrative |
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| | | The outcome of pericarditis, chest pain was reported as resolving.<br><br>Follow-up investigation will be made.<br><br>Company Comment:<br>The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. |
| 4.1(b) | 4.1(b) | This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) ) on 26-Oct-2021 and was forwarded to Moderna on 01-Nov-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of PERICARDITIS (Pericarditis) and MYOCARDITIS (Myocarditis) in a 14-year-old male patient who received mRNA-1273 (COVID 19 Vaccine Moderna) (batch no. 3005700) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 16-Oct-2021, the patient received second dose of mRNA-1273 (COVID 19 Vaccine Moderna) (Intramuscular) dosage was changed to 1 dosage form.<br>On an unknown date, the patient received first dose of mRNA-1273 (COVID 19 Vaccine Moderna) (Intramuscular) 1 dosage form. On 17-Oct-2021, after starting mRNA-1273 (COVID 19 Vaccine Moderna), the patient experienced PERICARDITIS (Pericarditis) (seriousness criteria hospitalization and medically significant). On 19-Oct-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, PERICARDITIS (Pericarditis) and MYOCARDITIS (Myocarditis) was resolving.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 17-Oct-2021, Electrocardiogram: abnormal (abnormal) Abnormal..<br>On 19-Oct-2021, Troponin I: abnormal (abnormal) Increase..<br>On an unknown date, Troponin I: abnormal (abnormal) Peak-out..<br><br>For mRNA-1273 (COVID 19 Vaccine Moderna) (Intramuscular), the reporter considered PERICARDITIS (Pericarditis) and MYOCARDITIS (Myocarditis) to be possibly related.<br><br>Company comment: This case concerns a 14-year-old male patient with no medical history provided, who experienced serious unexpected events of Myocarditis and Pericarditis (adverse events of special interest). The patient initially developed pyrexia and chest pain, and pericarditis was diagnosed one day after the administration of the second dose of COVID-19 Vaccine Moderna. In addition, as troponin I increased, the diagnosis of Myocarditis was established three days after the second dose of the vaccine, and the patient was hospitalized. At the time of the report, the patient was discharged from the hospital and the events were resolving. The rechallenge is not applicable as the events occurred after the second dose of the vaccine. The event was considered related to the product per the reporter's assessment. The benefit-risk relationship of COVID-19 Vaccine Moderna is not affected by this report. |

| Case ID | WW Identifier | Narrative |
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| 4.1(b) | 4.1(b) | This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) ) on 26-Oct-2021 and was forwarded to Moderna on 01-Nov-2021.<br>This case, initially reported to the 4.1(b) by a physician, was received via 4.1(b) (Ref 4.1(b)<br><br>On an unknown date, the patient received the 1st dose of this vaccine.<br><br>On 03-Oct-2021, the patient received the 2nd dose of this vaccine.<br><br>On 04-Oct-2021, pyrexia developed. At night, the patient was aware of chest pain.<br><br>On 05-Oct-2021, in the afternoon, the patient visited a nearby hospital. Myocarditis was suspected from electrocardiographic and echocardiographic findings, and the patient was referred to the reporting hospital on the same day. Electrocardiogram showed ST elevation, decreased cardiac contractility with EF of 40%, and increased CK up to 1,600. The patient was hospitalized.<br><br>On an unknown date, after follow-up in an intensive care unit, blood test results and cardiac function improved.<br><br>On 13-Oct-2021, the symptoms were resolving, and the patient was discharged from the hospital.<br><br>The outcome of pyrexia and myocarditis was reported as resolving.<br><br>Follow-up investigation will be made.<br><br>Company Comment:<br><br>The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. |
| 4.1(b) | 4.1(b) | This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) ) on 27-Oct-2021 and was forwarded to Moderna on 01-Nov-2021.<br>This case, initially reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref, 4.1(b)<br><br>Myocarditis was assessed as serious by the MAH.<br><br>On an unknown date, the patient received the 1st dose of this vaccination.<br>On an unknown date, body temperature before the vaccination 36.9 degrees Celsius.<br>On 23-Oct-2021, at 17:25, the patient received the 2nd dose of this vaccination.<br>On 26-Oct-2021, at 06:00, the patient had chest pain. At 08:00, the patient visited the hospital. ECG showed ST elevation and increased troponin I was observed. The patient was diagnosed with myocarditis.<br><br>The outcome of chest pain and myocarditis was reported as unknown. |

| Case ID | WW Identifier | Narrative |
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| | | Follow-up investigation will be made.<br><br>Company Comment:<br>The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.<br><br>This is a regulatory case concerning a 14-year-old, male patient with no relevant medical history reported , who experienced the serious expected and AESI event of myocarditis 3 days after receiving the second dose of Moderna COVID-19 vaccine. Time to onset for the first dose is unknown. ECG showed ST elevation and increased troponin I was observed. The benefit-risk relationship of Moderna COVID-19 vaccine is not affected by this report. Events seriousness assessed as per regulatory authority reporting. |
| 4.1(b) | 4.1(b) | This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) ) on 22-Oct-2021 and was forwarded to Moderna on 01-Nov-2021.<br>This case, reported to the 4.1(b) (4.1(b) by a physician, was received via the 4.1(b) (Ref, 4.1(b) and reported by a physician, was received by Takeda via Moderna's adverse reaction reporting site (4.1(b)<br><br>Pericarditis was assessed as serious by the MAH.<br><br>On an unknown date, the patient received the 1st dose of this vaccine.<br><br>On an unknown date, body temperature before the vaccination: 36.4 degrees Celsius.<br><br>On 15-Oct-2021, at 10:30, the patient received the 2nd dose of this vaccine.<br><br>On 18-Oct-2021, chest pain and respiratory discomfort developed. The patient visited a nearby department of cardiovascular internal medicine. Electrocardiogram and chest XP were performed. The patient was followed up for suspected myocarditis or pericarditis.<br><br>On 21-Oct-2021, the patient experienced chest pain when climbing up the stairs to the 3rd floor. There was no respiratory discomfort. The patient visited the cardiovascular department again. Heart sounds were heard. The patient was diagnosed with pericarditis or pain from surrounding joints and muscles based on the examination and symptoms that were local and not accompanied by respiratory discomfort. Follow-up was continued. The patient had no symptoms at rest.<br><br>On 22-Oct-2021, the symptoms were ongoing and unchanged.<br><br>The outcome of pericarditis and pain from surrounding joints and muscles was reported as ongoing and unchanged.<br><br>Follow-up investigation was impossible due to the reporters non-cooperation. |

| Case ID | WW Identifier | Narrative |
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| | | Company Comment: The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. |
| 4.1(b) | 4.1(b) | This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) ) on 27-Oct-2021 and was forwarded to Moderna on 01-Nov-2021.<br>This case, initially reported to the 4.1(b) by a pharmacist, was received via the 4.1(b) (Ref, 4.1(b)<br><br>The patient had a history of allergic symptoms due to an over-the-counter headache drug.<br><br>On an unknown date, the patient received the 1st dose of this vaccine. Pyrexia of 37.8 degrees Celsius and arm pain developed overnight.<br><br>On 15-Oct-2021, the patient received the 2nd dose of this vaccine. At night, left axillary pain developed.<br><br>On 16-Oct-2021, around 02:00, the patient was awakened by pain. Throbbing pain developed. The patient also had pain when turning over in bed. At 08:00, after the patient woke up, left precordial pain and pyrexia gradually developed, and the patient visited an emergency outpatient department of the reporting hospital. The patient had pyrexia of 38.1 degrees Celsius at visit. Pain increased during inspiration. Heart rate was sinus rhythm. There was no abnormal electrocardiogram, skin eruption, or respiratory symptom. The patient was hospitalized for follow-up due to suspected pericarditis after the vaccination with this vaccine.<br><br>On 17-Oct-2021, chest pain persisted. Repeated electrocardiogram was performed. ST-T in V2-6 decreased from the previous day, and CRP increased to 1.13. Myocardial troponin I was not elevated.<br><br>On 22-Oct-2021, electrocardiogram was normalized, and chest pain tended to improve. The symptoms resolved, and the patient was discharged from the hospital.<br><br>The outcome of pyrexia and chest pain after the 1st vaccination was unknown.<br><br>The outcome of left axillary pain, left precordial pain, pyrexia, increased CRP, and suspected pericarditis after the 2nd vaccination was reported as resolved.<br><br>Follow-up investigation will be made.<br><br>Reporter comments continuation:<br><br>The patient complained of chest pain even when breathing cold air during hospitalization. There were press reports that myocarditis developed after the vaccination with this vaccine; thus, the patient may have been concerned about the vaccination.<br><br>Company Comment: |

| Case ID | WW Identifier | Narrative |
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| | | The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. |
| 4.1(b) | 4.1(b) | This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) ) on 28-Oct-2021 and was forwarded to Moderna on 01-Nov-2021.<br>This case, initially reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref, 4.1(b)<br><br>On an unknown date, the patient received the 1st dose of this vaccine.<br>On 07-Sep-2021, the patient received the 2nd dose of this vaccine.<br>On 09-Sep-2021, around 21:00, myocarditis developed. The patient became aware of respiratory discomfort just before bedtime. Thereafter, the patient slept.<br>On 10-Sep-2021, at 00:00, the patient awoke with chest pains. The patient visited a medical institution. At the time of examination, blood pressure was 132/90, Sp02 100%, and other vital signs were normal. There was no special note of blood counts on the blood collection. Biochemical test showed high-sensitivity troponin I 2,579.8, CK-MB 16.4, CRP 6.01, no abnormality in other electrolyte or hepatobiliary enzyme, no hepatic function abnormalities or lipid abnormalities. Electrocardiography showed ST elevation except for V1, aVR, aVL, and 3. Echocardiography showed no obvious morphological abnormalities or no abnormal contractions. The patient was diagnosed as having myocarditis based on the above and was admitted to hospital for treatment. Tests for coxsackie virus, cytomegalovirus, and echovirus did not reveal any evidence suggestive of infection. The patient had peaked out at CK 597 on a blood sample taken 10 hours after admission, and symptoms had disappeared. On an unknown date, after that, the progress was also stable.<br>On 14-Sep-2021, the patient was discharged with recovery of symptoms. On an unknown date, outpatient examinations for coxsackievirus, cytomegalovirus, and echovirus showed no evidence suggestive of infection. The patient was diagnosed with myocarditis related to this vaccine.<br><br>The outcome of myocarditis was reported as recovered.<br><br>Follow-up investigation will be made.<br><br><br>Company Comment:<br>The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.<br><br>This is a regulatory case concerning a 19 years old, male patient with no clinical who experienced the expected serious events of MIOCARDITIS. The event occurred three days after the second dose of Moderna Covid 19 vaccine<br>The rechallenge is not applicable" as the events occurred after the second dose and no details were provided about the first dose<br>The benefit-risk relationship of Moderna Covid 19 vaccine is not affected by this report. |
| 4.1(b) | 4.1(b) | This case was initially received via 4.1(b) (Reference number: 4.1(b) ) on 01-Nov-2021. The most recent |

| Case ID | WW Identifier | Narrative |
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| | 4.1(b) [redacted] | information was received on 02-Nov-2021 and was forwarded to Moderna on 02-Nov-2021.<br>This regulatory authority case was reported by an other health care professional and describes the occurrence of CHEST PAIN (Chest Pain), DYSPNOEA (Dyspnoea) and MYOCARDITIS (Myocarditis) in a 29-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 05-Oct-2021, the patient received second dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 09-Oct-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). On an unknown date, the patient experienced CHEST PAIN (Chest Pain) (seriousness criterion hospitalization) and DYSPNOEA (Dyspnoea) (seriousness criterion hospitalization). At the time of the report, CHEST PAIN (Chest Pain) and DYSPNOEA (Dyspnoea) outcome was unknown and MYOCARDITIS (Myocarditis) was resolving.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 09-Oct-2021, Electrocardiogram: abnormal (abnormal) ST elevation inferior leads..<br>On 09-Oct-2021, Troponin: 686 ng/l (High) Troponin- 686 ng/l.<br>On an unknown date, SARS-CoV-2 test: negative (Negative) Negative.<br>On an unknown date, Troponin: 689 (High) 689 and 383 (High) 383.<br><br>For mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown), the reporter did not provide any causality assessments.<br><br>The patient's relevant investigations or tests conducted included blood tests, echo cardiogram done on 10-Oct-2021, result ST elevation inferior lead, Troponin was measured on 10-Oct-2021, were high with peak value 686ng/L(normal range-normal less than 15 for males) troponin serial values were 686/689/ 383. The patient was admitted to hospital 09-Oct-2021 with chest pain, diagnosed myocarditis, awaited outpatient MRI. He was admitted to hospital on 09-Oct-2021 with chest pain for 3 days. Treatment information included NSAID's.<br><br>Company comment:<br>This is a regulatory case concerns a 29-year old, male subject with no relevant medical history, who experienced the serious expected event of Myocarditis(AESI) and the serious unexpected events of Chest pain and Dyspnoea. The event Myocarditis occurred 4 days after the second dose of Moderna COVID-19 vaccine while events Chest pain and Dyspnoea occurred unknown number of days after the second dose of Moderna COVID-19 vaccine. Rechallenge is not applicable (no more doses are expected) relevant lab data: troponin values: 686 ng/ml (9 Oct) and 689, 383 (unk dates). The benefit-risk relationship of Moderna COVID-19 vaccine is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes: |

| Case ID | WW Identifier | Narrative |
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| | | On 02-Nov-2021: Lab data added. Action taken updated as not applicable. |
| 4.1(b) | | This case was initially received via Takeda Pharmaceuticals (Reference number: 4.1(b) ) on 29-Oct-2021. The most recent information was received on 26-Nov-2021 and was forwarded to Moderna on 06-Dec-2021.<br>This case, initially reported to the 4.1(b) by a pharmacist, was received via the 4.1(b) (Ref, 4.1(b)<br><br>On 26-Nov-2021, follow-up information, reported to the 4.1(b) by a physician, was received via 4.1(b) (Ref, 4.1(b)<br><br>On 01-Sep-2021, the patient received the 1st dose of this vaccine.<br><br>On an unknown date, body temperature before the vaccination: 36.5 degrees Celsius.<br><br>On 30-Sep-2021, at 16:57, the patient received the 2nd dose of this vaccine.<br><br>On 01-Oct-2021, pyrexia of 40 degrees Celsius developed.<br><br>On 02-Oct-2021, pyrexia went down. During the night, the patient had stabbing chest pain and vomited.<br><br>On 03-Oct-2021, around 02:00, the patient was aware of epigastric pain and chest tightness. At 03:00, acute myocarditis developed. An ambulance was called and the patient was transported to the hospital. At the visit, pyrexia of high 37 degrees Celsius was noted. Electrocardiographic findings at the visit showed ST elevation in leads 1, 2, aVL, and V2-6, and elevated cardiac enzymes. Diffuse hypokinesis of the wall was noted on echocardiography. Acute myocarditis due to this vaccine was suspected based on electrocardiogram and echocardiography. Emergency cardiac catheterization was performed, and detailed examinations were performed. Coronary angiography showed no significant stenosis in the left or right coronary arteries. Right heart catheterization showed Forrester type 1 equivalent and stable hemodynamics. The patient was hospitalized for follow-up.<br><br>On an unknown date, acetated ringer's solution, heparin sodium, and acetaminophen were administered, and the symptoms improved.<br><br>On 09-Oct-2021, the patient was discharged from the hospital without any sequelae.<br><br>On 14-Oct-2021, it was confirmed that there was no particular health hazard at the medical consultation with an industrial physician.<br><br>The outcome of acute myocarditis and pyrexia was reported as recovering.<br><br>No follow-up investigation will be made. |

| Case ID | WW Identifier | Narrative |
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| | | Follow-up received on 26-NOV-2021<br><br>Updated: Reporter Information, Lab Data, Product Information, Event Information, Narrative, Reporter Comments<br><br>Company Comment:<br>The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 02-Nov-2021 and was forwarded to Moderna on 02-Nov-2021.<br><br>This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (suspected myocarditis) in a 33-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 214008) for Prophylactic vaccination.<br><br>No Medical History information was reported.<br><br>On 13-Aug-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 14-Aug-2021, the patient experienced MYOCARDITIS (suspected myocarditis) (seriousness criteria hospitalization, medically significant and life threatening). At the time of the report, MYOCARDITIS (suspected myocarditis) had not resolved.<br><br>Concomitant medications were not reported .<br>Treatment information was not provided.<br><br>The patient had the 1st dose of Spikevax on 02/07/2021 (3003609). Laboratory data include ECG, laboratory, transthoracic echocardiography, cardiac catheter DD excluded: STEMI.<br><br>Company Comment:<br>This case concerns a 33-year-old, female patient with no relevant medical history, who experienced the expected AESI of myocarditis. The event, which was life-threatening and resulted in hospitalization, occurred 1 day after administration of the second dose of the Moderna COVID-19 Vaccine. The rechallenge was not applicable as no additional dosing will be given. The benefit-risk relationship of the Moderna COVID-19 Vaccine is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 02-Nov-2021: Translation document received on 04-Nov-2021. Reaction/event as reported by primary source is updated. Sender's comments are updated. |
| 4.1(b) | 4.1(b) | This case was received via 4.1(b) (Reference number: 4.1(b) on 02-Nov-2021 and was forwarded to Moderna on 02-Nov-2021.<br>This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCARDITIS (Myocarditis), PRESYNCOPE (Presyncope), DYSPEPSIA (Dyspepsia) and CHEST PAIN (Chest pain) in an 18-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. O25BZ1A and 006BZ1A) for COVID-19 vaccination. |

| Case ID | WW Identifier | Narrative |
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| | | No Medical History information was reported.<br><br>On 30-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form.<br>On 30-Mar-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 04-Oct-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria medically significant and life threatening), PRESYNCOPE (Presyncope) (seriousness criterion life threatening), DYSPEPSIA (Dyspepsia) (seriousness criterion life threatening) and CHEST PAIN (Chest pain) (seriousness criterion life threatening). At the time of the report, MYOCARDITIS (Myocarditis), PRESYNCOPE (Presyncope), DYSPEPSIA (Dyspepsia) and CHEST PAIN (Chest pain) outcome was unknown.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 04-Oct-2021, SARS-CoV-2 test: negative (Negative) Negative.<br>On 08-Oct-2021, SARS-CoV-2 test: negative (Negative) results came back NEGATIVE on 10-OCT-2021..<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments.<br><br>Lab data included on 04-OCT-2021 and 08-OCT-2021 EKG test was performed but results were not provided.<br>No concomitant medication details were reported.<br>No treatment medication details was reported.<br>The patient was in excellent health, was a firefighter recruit. On 10/04/21 – the patient felt like his chest was burning. The patient said he had heartburn. On 10/08/21, While in the middle of EMT class, the patient almost passed out. Senior firefighters drove him directly to local Medical center for treatment after they checked his heart rate and blood pressure. The patient was diagnosed with MYOCARDITIS, given a series of oral steroids and an inhaler.<br>Company Comment : This case concerns an 18-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) with no relevant medical history who experienced the serious expected event (AESI) of myocarditis 6 months 5 days after the second dose of the vaccine. Rechallenge is not applicable, since no further dosing is expected. The benefit-risk relationship is not affected by this report |
| 4.1(b) | 4.1(b) | This case was received via 4.1(b) (Reference number: 4.1(b) on 02-Nov-2021 and was forwarded to Moderna on 02-Nov-2021.<br>This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCARDITIS (Myocarditis) and PERICARDITIS (Pericarditis) in a 29-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 011A21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below.<br><br>Concurrent medical conditions included Drug allergy (4.1(b) ).<br>Concomitant products included LEVOTHYROXINE for an unknown indication. |

| Case ID | WW Identifier | Narrative |
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| | | On 26-Feb-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 30-Mar-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criterion medically significant), PERICARDITIS (Pericarditis) (seriousness criterion medically significant), CHEST PAIN (Chest pain) and PALPITATIONS (Palpitations). At the time of the report, MYOCARDITIS (Myocarditis), PERICARDITIS (Pericarditis), CHEST PAIN (Chest pain) and PALPITATIONS (Palpitations) had not resolved.<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments.<br><br>Concomitant medication Birth control medication were provided<br><br>On Mar-2021, Patient visited emergency room for chest pain and heart palpitations.<br><br>Multiple tests ran plus x-rays which results were not provided and steroids from primary care doctor to treat.<br><br>Company Comment: This case concerns a 29 year-old, female with no relevant history reported in this case, who experienced the serious AESI expected events of Myocarditis and Pericarditis. The events of Myocarditis and Pericarditis were also upgraded to serious (Medically Significant) as per Important medical event terms list (MedDRA version 24.0). The events occurred approximately after 30 days after the administration of the second dose of Moderna COVID-19 vaccine. At the time of the report, the outcome of the events were Not Recovered/Not Resolved. The rechallenge is not applicable since the event occurred after the second dose and another dose will not be administered. The benefit-risk relationship of the vaccine is not affected by this report. |
| 4.1(b) | 4.1(b) | This case was received via 4.1(b) (Reference number: 4.1(b) on 02-Nov-2021 and was forwarded to Moderna on 02-Nov-2021.<br>This regulatory authority case was reported by an other health care professional and describes the occurrence of PERICARDITIS (Pericarditis) in a 20-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 019F21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below.<br><br>The patient's past medical history included Aspergillosis.<br>Concurrent medical conditions included Allergy to antibiotic (Red cell antibody allergy), Hypertension and Lupus nephritis.<br>Concomitant products included LISINOPRIL for Product used for unknown indication, MYCOPHENOLATE MOFETIL (CELLCEPT [MYCOPHENOLATE MOFETIL]), HYDROXYCHLOROQUINE PHOSPHATE (PLAQUENIL [HYDROXYCHLOROQUINE PHOSPHATE]), AMLODIPINE, CARVEDILOL, HYDRALAZINE and ISAVUCONAZONIUM SULFATE (CRESEMBA) for an unknown indication. |

| Case ID | WW Identifier | Narrative |
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| | | On 30-Sep-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 01-Oct-2021, the patient experienced PERICARDITIS (Pericarditis) (seriousness criterion medically significant), CHEST PAIN (Chest pain) and PLEURITIC PAIN (Pleuritic pain). At the time of the report, PERICARDITIS (Pericarditis), CHEST PAIN (Chest pain) and PLEURITIC PAIN (Pleuritic pain) had not resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 15-Oct-2021, Magnetic resonance imaging heart: abnormal (abnormal) There was circumferential late gadolinium enhancement of the pericardium consistent with active inflammation (pericarditis).<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments.<br><br>The patient had symptoms of pericarditis with pleuritic chest pain and chest pain when lying flat occurring a couple days after administration of covid-19 vaccine. Patient was undergoing treatment for pericarditis. Company Comment : This case concerns a 20-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) with relevant medical history of HTN and Lupus nephritis who experienced the serious expected event of pericarditis one day after the second dose of the vaccine. Medical history of HTN and lupus nephritis are confounding factors. Rechallenge is not applicable, since no further dosing is expected. The benefit-risk relationship is not affected by this report |
| 4.1(b) | 4.1(b) | This case was received via 4.1(b) (Reference number: 4.1(b) on 02-Nov-2021 and was forwarded to Moderna on 02-Nov-2021.<br>This regulatory authority case was reported by an other health care professional and describes the occurrence of PERICARDITIS (Pericarditis) in a 23-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below.<br><br>The patient's past medical history included Anxiety.<br>Concurrent medical conditions included Allergy to antibiotic (Neomycin).<br><br>On 18-Apr-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 24-Sep-2021, the patient experienced PERICARDITIS (Pericarditis) (seriousness criterion medically significant), COVID-19 (COVID-19) and CHEST PAIN (Chest pain). In October 2021, PERICARDITIS (Pericarditis), COVID-19 (COVID-19) and CHEST PAIN (Chest pain) had resolved.<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments.<br><br>Patient reported that Chest pain due to pericarditis as a result of COVID-19 infection. Resolved after every 8 hours for 3 weeks. |

| Case ID | WW Identifier | Narrative |
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| | | Concomitant products were not provided.<br>Treatment medication were not reported.<br>Company comment: This case concerns a 23-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) with relevant recent of Covid 19 infection who experienced the serious expected event (AESI) of pericarditis 5 months and 7 days after the second dose of the vaccine. Recent history of Covid 19 infection is a confounding factor. Rechallenge is not applicable, since no further dosing is expected. The benefit-risk relationship is not affected by this report |
| 4.1(b) | 4.1(b) | This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) ) on 29-Oct-2021 and was forwarded to Moderna on 04-Nov-2021.<br>This case, initially reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref, 4.1(b)<br><br>On an unknown date, the patient received the 1st dose of the vaccine.<br><br>On 20-Oct-2021, the patient received the 2nd dose of the vaccine.<br><br>On 23-Oct-2021, at 02:30, chest pain developed, and the patient visited an emergency outpatient department of the reporting hospital. The patient was diagnosed with acute myocarditis and was hospitalized. Improvement was achieved by fluid replacement and pain control.<br><br>On 28-Oct-2021, the symptom improved, and the patient was discharged from the hospital.<br><br>The outcome of acute myocarditis was reported as recovered.<br><br>Follow-up investigation will be made.<br><br>Company Comment:<br><br>The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. |
| 4.1(b) | 4.1(b) | This case was initially received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 30-Oct-2021. The most recent information was received on 08-Nov-2021 and was forwarded to Moderna on 15-Nov-2021.<br>This case was reported by a physician via a medical representative.<br><br>On 08-Nov-2021, follow-up information was received by a physician via a medical representative.<br><br>Myocarditis was assessed as serious by the MAH.<br><br>On an unknown date, the patient received the 1st dose of this vaccine.<br><br>On 24-Oct-2021, the patient received the 2nd dose of this vaccine.<br><br>On 28-Oct-2021, the patient noticed anterior chest pain several times, which disappeared soon. |

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| | | On 29-Oct-2021, at 15:00, the anterior chest pain was intensified, and the patient had a pain even by breathing. The pain was not alleviated, and thus the patient visited the internal medicine department complaining of chest pain in the early evening. KT: 36.6 degrees Celsius, BP: 122/67, P: 92, and SpO2: 98%. The patient had no pyrexia or cold symptoms. There was no pneumothorax-like symptom in both lungs. Chest XP (frontal and lateral), electrocardiogram, and blood test were performed. Electrocardiogram showed HR of 77 bpm, PR of 0.146 s, QRS of 0.095 s, QTc of 0.401, and no changes in ST-T. In the results of blood test, CRP was 0.1 ng/dL with WBC of 6,800/mcL. No abnormalities were found in chest XP, electrocardiogram, and blood sampling. After examination and tests, the patient was diagnosed with myocarditis. The condition was mild. The patient was placed on recuperation at home with administration of NSAID. The patient was prescribed three tablets of loxoprofen sodium hydrate 60 mg divided into 3 doses after each meal for four days, three tablets of rebamipide 100 mg divided into 3 doses after each meal for four days, granular extract of arrowroot tea 7.5 g divided into 3 doses between each meal for four days, and ketoprofen tape 40 mg (10 cm x 14 cm) as needed basis.<br><br>On 05-Nov-2021, the symptom was confirmed to have resolved over the phone. The patient did not use ketoprofen tape in practice.<br><br>The outcome of myocarditis was reported as resolved.<br><br>Follow-up investigation will be made.<br><br>Follow-up received on 08-NOV-2021<br><br>Updated: Reporter Information, Patient Information, Lab Data, Event Information, Narrative, Reporter Comments<br><br>Company Comment:<br>The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. |
| 4.1(b) | 4.1(b) | This case was received via an unknown source (no reference has been entered for a health authority or license partner) on 03-Nov-2021 and was forwarded to Moderna on 03-Nov-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myocarditis) in an 18-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for SARS-CoV-2 immunisation.<br><br>No Medical History information was reported.<br><br>In 2021, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form.<br>On 21-Oct-2021, received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) dosage was changed to 1 dosage form. On 24-Oct-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Myocarditis) had not resolved. |

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| | | DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 24-Oct-2021, Blood creatine phosphokinase (47-222): 374 (High) 374.<br>On 24-Oct-2021, C-reactive protein (0-10): 13 (High) mg/L.<br>On 24-Oct-2021, Electrocardiogram: abnormal (abnormal) ST ascendant v3-v4-v5.<br>On 24-Oct-2021, Troponin (Unknown-90 nanogram per litre): 494 nanogram per litre High.<br><br>For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered MYOCARDITIS (Myocarditis) to be possibly related.<br><br>No concomitant medications were provided.<br><br>On 24 Oct 2021, he went to the Emergency Room for sudden-onset left-sided chest pain, that woke him up, reproducible on palpation and radiating into the left shoulder plus back, assessed at 7/10. An electrocardiogram showed ST elevation in v3-v4-v5. The laboratory tests show CRP of 13 mg/L, CK at a max of 374 U/L and still increasing troponins, currently at 494 ng/L. Transthoracic echocardiography shows a preserved left ventricular ejection fraction, with a mild pericardial effusion over the right ventricle. The Covid swab result is negative. The diagnosis of myocarditis was retained, and the patient was hospitalized for heart-rate monitoring with analgesic treatment with paracetamol + tramadol. In terms of etiological investigation, HIV, HCV, B19, CMV,<br>EBV and HHV6 serological tests still need to be performed, and a cardiac MRI is pending.<br>Company Comment : This case concerns an 18-year-old male patient with no medical history, who experienced the serious expected (AESI) of Myocarditis. The event occurred three days after the second dose of Moderna COVID-19 vaccine. Lab data of high blood creatine phosphokinase, high C-reactive protein, high troponin and an abnormal Electrocardiogram all support the diagnosis. The rechallenge was not applicable, as the event occurred after the second dose. The benefit-risk relationship of Moderna COVID-19 vaccine is not affected by this report. Event seriousness assessed as per Regulatory Authority reporting and retained for consistency with the RA report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 03-Nov-2021: Translation received on 5-Nov-2021.Case narrative were translated treatment drugs were added. No new information |
| 4.1(b) | 4.1(b) | This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Suspected myopericarditis), CHEST PAIN (Progressive-onset stabbing retrosternal pain radiating into the back), MYALGIA (Myalgia) and FEELING OF BODY TEMPERATURE CHANGE (Sensation of warmth/cold) in a 29-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for SARS-CoV-2 immunization.<br><br>The patient's past medical history included Cocaine abuse, episodic use on 21-Oct-2021.<br>Concurrent medical conditions included Alcohol abuse, unspecified drinking behavior and Smoker (15 UPA). |

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| | | In 2021, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form.<br>On 23-Oct-2021, received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) dosage was changed to 1 dosage form. In October 2021, the patient experienced MYALGIA (Myalgia) (seriousness criterion hospitalization) and FEELING OF BODY TEMPERATURE CHANGE (Sensation of warmth/cold) (seriousness criterion hospitalization). On 25-Oct-2021, after starting mRNA-1273 (COVID-19 Vaccine Moderna), the patient experienced MYOCARDITIS (Suspected myopericarditis) (seriousness criteria hospitalization and medically significant) and CHEST PAIN (Progressive-onset stabbing retrosternal pain radiating into the back) (seriousness criterion hospitalization). At the time of the report, MYOCARDITIS (Suspected myopericarditis) and CHEST PAIN (Progressive-onset stabbing retrosternal pain radiating into the back) had not resolved and MYALGIA (Myalgia) and FEELING OF BODY TEMPERATURE CHANGE (Sensation of warmth/cold) had resolved.<br><br>For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered MYALGIA (Myalgia) and FEELING OF BODY TEMPERATURE CHANGE (Sensation of warmth/cold) to be probably related and MYOCARDITIS (Suspected myopericarditis) and CHEST PAIN (Progressive-onset stabbing retrosternal pain radiating into the back) to be possibly related.<br><br>An electrocardiogram of patient showed depression of the PR segment in II, III and V3-V6, and a submillimeter ST segment depression in the same leads. The laboratory workup of patient on 26-OCT-2021 showed troponins of up to 298 ng/l, creatinine kinases of up to 290 U/l and an inflammatory syndrome with no leukocytosis. A cardiac ultrasound and cardiac magnetic resonance imaging tests were pending.<br><br>Concomitant medication and treatment medication were not reported.<br><br>Patient was in usual good health, Habits of patient included High-risk alcohol consumption and Active smoking habit at 15 pack-years occasional cocaine consumption. Patient had received 2 injections of the Spikevax. The second injection was administered on 23-OCT-2021, after which the patient was presented with myalgia and a sensation of warmth/cold which spontaneously resolved in 24 hours. During the evening of 25-OCT-2021, patient presented at the Emergency Department with progressive-onset stabbing retrosternal pain radiating into the back. The patient was currently in hospital within a context of suspected myo-pericarditis for cardiac rhythm monitoring.<br><br>This case concerns a 29 year-old male patient with a history of alcohol and cocaine abuse and tobacco smoker who experienced the unexpected serious events of myocarditis, an AESI, myalgia, and chest pain. The event of myalgia and sensation of warmth and cold occurred during the first day after the second dose of Moderna COVID-19 Vaccine. The event myocarditis occurred approximately 2 days after the second dose of Moderna COVID-19 Vaccine. The date of the first dose of the vaccine was not provided. The rechallenge was not applicable as no additional dosing will be administered. The medical history of alcohol and cocaine |

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| | | abuse and tobacco smoking remain confounders for myocarditis and chest pain. The benefit-risk relationship of Moderna COVID-19 Vaccine is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 03-Nov-2021: Translation document received on 05-NOV-2021 contains: Dosage text updated, event verbatim updated and senders comments which contains lab details and event information added in narrative. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 02-Nov-2021 and was forwarded to Moderna on 02-Nov-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (MYOCARDITIS) in an 18-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 05-Oct-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 06-Oct-2021, after starting mRNA-1273 (Spikevax), the patient experienced MYOCARDITIS (MYOCARDITIS) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (MYOCARDITIS) had not resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On an unknown date, SARS-CoV-2 test: negative (Negative) Negative.<br><br>For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.<br><br>Concomitant product use was not provided by the reporter.<br>No treatment information was provided.<br><br>Company Comment: This case concerns a 18-year-old, male patient with no relevant medical history, who experienced the unexpected event of myocarditis. The event myocarditis occurred 1 day after the second dose of Moderna Covid-19 vaccine administration. The rechallenge was not applicable. The patient's age and gender remain confounders. The benefit-risk relationship of Moderna Covid-19 vaccine is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 02-Nov-2021: Translation document received on 04-NOV-2021 as live follow up contained non-significant information that include event of Description as Reported updated. |
| 4.1(b) | 4.1(b) | This case was initially received via 4.1(b) (Reference number: 4.1(b) ) on 02-Nov-2021. The most recent information was received on 16-Dec-2021 and was forwarded to Moderna on 16-Dec-2021. |

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| | | This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (Myocarditis), SYNCOPE (Fainting), ARRHYTHMIA (Heart palpitations), PALPITATIONS (Heart palpitations), DYSPNOEA (Shortness of breath), FATIGUE (Fatigue/unusual tiredness), CHEST PAIN (Chest pain), PYREXIA (Fever), DIZZINESS (dizziness), TACHYCARDIA (Racing heart (tachycardia)) and SYNCOPE (Heart palpitations) in a 32-year-old female patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for COVID-19 vaccination.<br><br>The patient's past medical history included Asthma (very mild) and Concussion in June 2021.<br>Concomitant products included ELASOMERAN (COVID-19 VACCINE MODERNA) for an unknown indication.<br><br>On 20-Jul-2021, the patient received second dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 23-Jul-2021, after starting mRNA-1273 (Moderna CoviD-19 Vaccine), the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria disability and medically significant). On 27-Jul-2021, the patient experienced ARRHYTHMIA (Heart palpitations) (seriousness criteria disability and medically significant), PALPITATIONS (Heart palpitations) (seriousness criteria disability and medically significant), DYSPNOEA (Shortness of breath) (seriousness criteria disability and medically significant) and SYNCOPE (Heart palpitations) (seriousness criteria disability and medically significant). On an unknown date, the patient experienced SYNCOPE (Fainting) (seriousness criteria disability and medically significant), FATIGUE (Fatigue/unusual tiredness) (seriousness criteria disability and medically significant), CHEST PAIN (Chest pain) (seriousness criteria disability and medically significant), PYREXIA (Fever) (seriousness criteria disability and medically significant), DIZZINESS (dizziness) (seriousness criteria disability and medically significant) and TACHYCARDIA (Racing heart (tachycardia)) (seriousness criteria disability and medically significant). At the time of the report, MYOCARDITIS (Myocarditis) had not resolved and SYNCOPE (Fainting), ARRHYTHMIA (Heart palpitations), PALPITATIONS (Heart palpitations), DYSPNOEA (Shortness of breath), FATIGUE (Fatigue/unusual tiredness), CHEST PAIN (Chest pain), PYREXIA (Fever), DIZZINESS (dizziness), TACHYCARDIA (Racing heart (tachycardia)) and SYNCOPE (Heart palpitations) outcome was unknown.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On an unknown date, Blood test: normal (normal) normal.<br>On an unknown date, Electrocardiogram: normal (normal) normal.<br>On an unknown date, SARS-CoV-2 test: negative (Negative) Negative COVID-19 test.<br>On an unknown date, X-ray: normal (normal) normal.<br><br>No treatment medication were provided by the reporter.<br>Patient had not received any treatment and not recovered<br>She had lingering problems with physical exertion. |

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| | | Patient last menstrual period date was 01-JAN-2014.<br>Unsure if patient has had symptoms associated with COVID-19 Patient is not pregnant,Patient is not currently breastfeeding<br>Patient has not tested positive for COVID-19 since having the vaccine.<br><br>Patient is not enrolled in clinical trial.<br>This report relate to possible inflammation of the heart myocarditis or pericarditis.<br>It was reported that, the symptoms lead to a hospital stay for few hours.<br><br>A few days after having the second dose of the vaccine she started to feel short of breath and heart pounding without doing any strenuous activity. This got worse and after about a week she was experiencing a constant aching pain in her chest, dizziness and trouble breathing even while resting. Patient took 3 weeks off work in which time the symptoms improved but they seem to get come and go periodically even 3 months later. She was still unable to do strenuous exercise or drink caffeinated drinks or chocolate.<br><br>Company comment<br>This is a regulatory case concerning a 32-year-old female patient with medical history of asthma and concussion, who experienced the serious expected, according CCDS, (AESI) of myocarditis, serious unexpected events of SYNCOPE, ARRHYTHMIA, PALPITATIONS, DYSPNOEA, FATIGUE, CHEST PAIN, PYREXIA, DIZZINESS, TACHYCARDIA and SYNCOPE. The event myocarditis occurred approximately 3 days after the second dose of mRNA-1273 vaccine. ARRHYTHMIA, PALPITATIONS, DYSPNOEA and SYNCOPE occurred approximately 7 days after the second dose of mRNA-1273 vaccine. The events SYNCOPE, FATIGUE, CHEST PAIN, PYREXIA, DIZZINESS, TACHYCARDIA occurred on an unknown date after the second dose. Rechallenge is unknown according to SD. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 16-Dec-2021: significant follow-up appended. Relevant medical history asthma and concussion. Lab-test X-Ray and results of lab-data were updated. Concomitant drug Covid-19 vaccine was updated. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 02-Nov-2021 and was forwarded to Moderna on 02-Nov-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (MYOCARDITIS) in a 19-year-old male patient who received mRNA-1273 (Spikevax) (batch no. DOSE 2: 3004670) for COVID-19 vaccination.<br><br>Concurrent medical conditions included ADHD (now without treatment). Concomitant products included METHYLPHENIDATE HYDROCHLORIDE (CONCERTA) for an unknown indication.<br><br>On 24-Aug-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 02-Oct-2021, the patient experienced MYOCARDITIS (MYOCARDITIS) (seriousness criterion |

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| | | medically significant). At the time of the report, MYOCARDITIS (MYOCARDITIS) had not resolved.<br><br>For mRNA-1273 (Spikevax) (Unknown), the reporter considered MYOCARDITIS (MYOCARDITIS) to be possibly related.<br><br>The treatment history was not provided.<br><br>Company Comment: This case concerns a 19-year-old, male patient with no relevant medical history, who experienced the expected AESI of myocarditis. The event occurred approximately 1 month after administration of the second dose of the Moderna COVID-19 Vaccine. The rechallenge was not applicable as no additional dosing will be given. The patient's gender remains a confounder. The benefit-risk relationship of the Moderna COVID-19 Vaccine is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes: On 02-Nov-2021: Translated document received on 04-NOV-2021 contains significant information. Text for relevant history comments dosage text and event description were translated. |
| 4.1(b) | 4.1(b) | This case was initially received via 4.1(b) (Reference number: 4.1(b) ) on 02-Nov-2021. The most recent information was received on 10-Nov-2021 and was forwarded to Moderna on 10-Nov-2021.<br>This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCARDITIS (Myocarditis), TACHYCARDIA (Tachycardia), PALPITATIONS (Palpitations), DYSPNOEA (Dyspnoea), CHEST PAIN (Chest Pain), PAIN (Pain) and FATIGUE (Fatigue) in a 30-year-old female patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) (batch no. 3004674) for COVID-19 vaccination.<br><br>Concurrent medical conditions included Migraine.<br>Concomitant products included AMITRIPTYLINE for Migraine, TOZINAMERAN (COVID-19 MRNA VACCINE BNT162B2) for an unknown indication.<br><br>On 28-Oct-2021, the patient received third dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 01-Nov-2021, after starting mRNA-1273 (Moderna CoviD-19 Vaccine), the patient experienced MYOCARDITIS (Myocarditis) (seriousness criterion medically significant). On an unknown date, the patient experienced TACHYCARDIA (Tachycardia) (seriousness criterion medically significant), PALPITATIONS (Palpitations) (seriousness criterion medically significant), DYSPNOEA (Dyspnoea) (seriousness criterion medically significant), CHEST PAIN (Chest Pain) (seriousness criterion medically significant), PAIN (Pain) (seriousness criterion medically significant) and FATIGUE (Fatigue) (seriousness criterion medically significant). At the time of the report, MYOCARDITIS (Myocarditis) had not resolved and TACHYCARDIA (Tachycardia), PALPITATIONS (Palpitations), DYSPNOEA (Dyspnoea), CHEST PAIN (Chest Pain), PAIN (Pain) and FATIGUE (Fatigue) outcome was unknown. |

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| | | DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 01-Nov-2021, Chest X-ray: normal (normal) Normal Clear.<br>On 01-Nov-2021, Electrocardiogram: abnormal (abnormal) Abnormal.<br><br>The action taken with mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown) was unknown.<br><br>For mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown), the reporter did not provide any causality assessments.<br><br>Lab test included Troponin on 1-Nov-2021 with value 3.<br><br>Patient has not tested positive for COVID-19 since having the vaccine. Patient is not enrolled in clinical trial. Patient experienced pericarditis.It was reported that 4 days after the vaccination the symptoms occurred. The patient was diagnosed with heart inflammation and she had a abnormal ECG. she reported that she still had pain and she was taking strong anti inflammatory, pain killer. Due to pain she woke up in the sleep.<br><br>Treatment medications prescribed as anti inflammatories and pain relief.<br><br>Company Comment:<br>This case concerns a 30-year-old, female with relevant medical history of previous vaccination with COVID-19 mRNA vaccine BIONTECH, who experienced the serious unexpected events of Tachycardia, Palpitations, Chest pain, Dyspnoea and Fatigue and the serious expected (AESI) of Myocarditis. The event Myocarditis occurred approximately 4 days after the 3rd dose of mRNA-1273, the events of Tachycardia, Palpitations, Chest pain, Dyspnoea and Fatigue occurred on an unknown date after the 3rd dose of mRNA-1273. The benefit-risk relationship of mRNA-1273 is not affected by this report. Event seriousness assessed as per Regulatory Authority reporting and retained for consistency with the RA report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 04-Nov-2021: Follow up received as lab data results are added.<br>On 10-Nov-2021: Follow up document received contains, medical history were added. Event (chest pain) outcome, action taken and I narrative were updated. |
| 4.1(b) | 4.1(b) | This spontaneous case was reported by a physician and describes the occurrence of MYOCARDITIS (Acute myocarditis) in a 21-year-old male patient who received mRNA-1273 (COVID 19 Vaccine Moderna) for COVID-19 vaccination.<br><br>Concurrent medical conditions included Food allergy (Allergy to buckwheat).<br><br>On 22-Oct-2021, the patient received second dose of mRNA-1273 (COVID 19 Vaccine Moderna) (Intramuscular) dosage was changed to 1 dosage form.<br>On an unknown date, the patient received first dose of mRNA-1273 (COVID 19 Vaccine Moderna) (Intramuscular) 1 dosage form. On 23-Oct-2021, after starting mRNA-1273 (COVID 19 Vaccine Moderna), the |

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| | | patient experienced MYOCARDITIS (Acute myocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Acute myocarditis) was resolving.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 23-Oct-2021, Body temperature: 37.2 (normal) 37.2 degree Celsius, 39.0 (High) 39.0 degree Celsius and 39.0 (High) 39.0 degree Celsius.<br>On 24-Oct-2021, Aspartate aminotransferase (8-38): 28 (normal) 28 international unit per litre.<br>On 24-Oct-2021, Blood creatine phosphokinase (56-244): 146 (normal) 146 international unit per litre.<br>On 24-Oct-2021, Blood creatine phosphokinase MB (Unknown-5): 4.8 (normal) 4.8 nanogram per millliiter.<br>On 24-Oct-2021, Blood lactate dehydrogenase (124-222): 145 (normal) 145 international unit per litre.<br>On 24-Oct-2021, C-reactive protein (Unknown-0.3): 3 (High) 3 milligram per decilitre.<br>On 24-Oct-2021, Computerised tomogram coronary artery: normal (normal) No findings such as pleural effusion retention, coronary artery calcification, and aortic dissection were noted..<br>On 24-Oct-2021, Echocardiogram: abnormal (abnormal) Abnormal Wall hypokinesis in the left ventricular apex.<br>On 24-Oct-2021, Electrocardiogram: abnormal (abnormal) V3, V4: acute anterior infarction. III, aVF: Suspected acute inferior infarction..<br>On 24-Oct-2021, Troponin T: positive (Positive) Test Result:+ and 0.155 (High) 0.155 nanogram per millliiter.<br>On 24-Oct-2021, White blood cell count (3300-9000): 6850 (normal) 6850 per microlitre.<br>On 25-Oct-2021, Aspartate aminotransferase (8-38): 46 (High) 46 international unit per litre.<br>On 25-Oct-2021, Blood creatine phosphokinase (56-244): 345 (High) 345 international unit per litre.<br>On 25-Oct-2021, Blood creatine phosphokinase MB (Unknown-5): 16 (High) 16 nanogram per millliiter.<br>On 25-Oct-2021, Blood lactate dehydrogenase (124-222): 163 (normal) 163 international unit per litre.<br>On 25-Oct-2021, C-reactive protein (Unknown-0.3): 2.4 (High) 2.4 milligram per decilitre.<br>On 25-Oct-2021, Echocardiogram: abnormal (abnormal) LV:diffuse mild hypokinesis (appear especially weak in the venticular apex). EF: 46.8% (BDS method). LA: Enlargement (-) MR: trivial. Right heart system: Enlargment (-). TR: trivial. TR-PG: 2.8 mmHg. IVC: Respiratory fluctuation was 14.3 mm..<br>On 25-Oct-2021, Electrocardiogram: abnormal (abnormal) V4: Suspected acute anterior infarction. V5: Suspected acute lateral wall infarction..<br>On 25-Oct-2021, Magnetic resonance imaging: abnormal (abnormal) An inflammation in the ventricular apex..<br>On 25-Oct-2021, Myocardial necrosis marker: increased (High) Increased.<br>On 25-Oct-2021, Troponin T: positive (Positive) Test Result:+ and 0.399 (High) 0.399 nanogram per millliiter.<br>On 25-Oct-2021, White blood cell count (3300-9000): 8800 (normal) 8800 per microlitre. |

| Case ID | WW Identifier | Narrative |
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| | | On 26-Oct-2021, Blood creatine phosphokinase (56-244): 452 (High) 452 international unit per litre.<br>On 26-Oct-2021, Blood creatine phosphokinase MB (Unknown-5): 19.1 (High) 19.1 nanogram per millliiter.<br>On 26-Oct-2021, C-reactive protein (Unknown-0.3): 1.8 (High) 1.8 milligram per decilitre.<br>On 26-Oct-2021, N-terminal prohormone brain natriuretic peptide (Unknown-125): 112 (normal) 112 picogram per millilitre.<br>On 27-Oct-2021, Blood creatine phosphokinase (56-244): 215 (normal) 215 international unit per litre.<br>On 27-Oct-2021, Blood creatine phosphokinase MB (Unknown-5): 5 (normal) 5 nanogram per millliiter.<br>On 27-Oct-2021, C-reactive protein (Unknown-0.3): 0.8 (High) 0.8 milligram per decilitre.<br>On 27-Oct-2021, Electrocardiogram: normal (normal) Normalized.<br>On 27-Oct-2021, Myocardial necrosis marker: normal (normal) Normal.<br>On 27-Oct-2021, N-terminal prohormone brain natriuretic peptide (Unknown-125): 54 (normal) 54 picogram per millilitre.<br>On 27-Oct-2021, White blood cell count (3300-9000): 5800 (normal) 5800 per microlitre.<br>On 28-Oct-2021, Echocardiogram: abnormal (abnormal) LV wall motion: asynergy (-). EF: the motion of 60% was improved. LA: Enlargement (-) MR: trivial. Right heart system: Enlargement (-). TR: trial. IVC: Respiratory fluctuation was 11.8 mm..<br>On 28-Oct-2021, Ejection fraction: 59 (normal) 59 %.<br>On 02-Nov-2021, Electrocardiogram: normal (normal) Normalized.<br><br>For mRNA-1273 (COVID 19 Vaccine Moderna) (Intramuscular), the reporter considered MYOCARDITIS (Acute myocarditis) to be possibly related.<br><br>Company comment:This is a spontaneous case concerning a 21 year-old male patient with no relevant medical history provided, who experienced the serious expected event of Myocarditis. This event occurred one day after the patient received their second dose of mRNA-1273.The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 24-Dec-2021: Followup received included patient demographics (initials, date of birth, height, weight), laboratory details (Aspartate aminotransferase, CPK , CK-MB, LDH (IFCC), Coronary artery CT , CRP, Troponin T quantification and WBC) |
| 4.1(b) | 4.1(b) | This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myopericarditis) in a 35-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination.<br><br>The patient's past medical history included Viral myocarditis in 2020. Concurrent medical conditions included Smoker (10 pack-years) and Alcohol allergy (Alcohol occasional).<br><br>On 20-Sep-2021, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form. |

| Case ID | WW Identifier | Narrative |
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| | | On 19-Oct-2021, received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) dosage was changed to 1 dosage form. On 22-Oct-2021, after starting mRNA-1273 (COVID-19 Vaccine Moderna), the patient experienced MYOCARDITIS (Myopericarditis) (seriousness criterion hospitalization). At the time of the report, MYOCARDITIS (Myopericarditis) was resolving.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 24-Oct-2021, Echocardiogram: reduced by 46% (abnormal) Abnormal.<br>On 24-Oct-2021, Electrocardiogram: normal (normal) Normal Test was on 23-OCT-2021.<br>On an unknown date, Electrocardiogram: abnormal (abnormal) Abnormal Test was on 25-OCT-2021.<br><br>For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered MYOCARDITIS (Myopericarditis) to be probably related.<br><br>No concomitant medication reported.<br><br>No Treatment Medication reported.<br>Based on Medical Review, the event of inappropriate schedule of vaccine administered is applicable as dose 1 and dose 2 are 20 days apart.<br><br>A little while after the vaccination, patient presented symptoms of myalgia, arthralgia and self-limiting chills. On 22 Oct 2021 he experienced respiration-dependent retrosternal pain, which worsened when he moved, leading him to consult a physician on 23 Oct 2021. Vital signs on admission showed heart rate (HR) of 85 bpm, blood pressure (BP) of 113/80 mmHg, 100% saturation in ambient air, and a temperature of 35.9°C. The laboratory test done on 24 Oct 2021 showed troponin T at 498 ng/L, CK at 186 U/L (spike at 312 U/L) as well as NT proBNP at 361 ng/L. A search for FAN and myositis DOT came back negative. The pain decreased with acetylsalicylic acid (Aspegic®). Due to the LVEF reduction, treatment with lisinopril was introduced. The patient could go home on 25 Oct 2021.<br><br>On 24 Oct 2021 Troponin T, Creatine kinase and NT-proBNP were performed with unknown results.<br><br>Company comment: This case concerns a 35 year-old male patient with a history of viral myocarditis in 2020, tobacco smoking, overweight and allergy to alcohol who experienced the unexpected event of myocarditis. The event occurred approximately 3 days after the second dose of Moderna COVID-19 Vaccine. The rechallenge was not applicable as no additional dosing will be administered. The medical history of viral myocarditis in 2020, and tobacco smoking remain confounders. The benefit-risk relationship of Moderna COVID-19 Vaccine is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes: |

| Case ID | WW Identifier | Narrative |
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| | | On 04-Nov-2021: Translation document received on 05 Nov 2021 contains Translated text for relevant Medical history, Test results, Case Narrative updated and Events verbatim updated. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 05-Nov-2021 and was forwarded to Moderna on 05-Nov-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Perimyocarditis) in a 15-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 27-Aug-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 29-Aug-2021, after starting mRNA-1273 (Spikevax), the patient experienced MYOCARDITIS (Perimyocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Perimyocarditis) had resolved.<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered MYOCARDITIS (Perimyocarditis) to be probably related.<br><br>The concomitant medication was not reported.<br>The Treatment history was not reported.<br><br>Company Comment: This case concerns a 15-year-old, male patient with no relevant medical history, who experienced the expected AESI of myocarditis. The event, which resulted in hospitalization, occurred 2 days after administration of the second dose of the Moderna COVID-19 Vaccine. The rechallenge was not applicable as no additional dosing will be given. The patient's gender remains a confounder. The benefit-risk relationship of the Moderna COVID-19 Vaccine is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 05-Nov-2021: Translation received on 07-Nov-2021, which contains dosage text information and event verbatim in English language were updated. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 05-Nov-2021 and was forwarded to Moderna on 05-Nov-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of PERICARDITIS (Pericarditis) in a 26-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3004671) for Prophylactic vaccination.<br><br>Previously administered products included for Product used for unknown indication: COVID-19 Vaccine Moderna dispersion for injectionCOVID-19 mRNA Vaccine (nucleoside modified)SpykeVax on 21-Jul-2021.<br>Past adverse reactions to the above products included No adverse event with COVID-19 Vaccine Moderna dispersion for injectionCOVID-19 mRNA Vaccine (nucleoside modified)SpykeVax. |

| Case ID | WW Identifier | Narrative |
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| | | On 25-Aug-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 08-Sep-2021, after starting mRNA-1273 (Spikevax), the patient experienced PERICARDITIS (Pericarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, PERICARDITIS (Pericarditis) had not resolved.<br><br>For mRNA-1273 (Spikevax) (Unknown), the reporter considered PERICARDITIS (Pericarditis) to be possibly related.<br><br>No concomitant medications were provided.<br>No treatment medications were provided.<br><br>Company comment:<br>This case concerns a 26-year-old, male patient with no relevant medical history, who experienced the expected AESI of pericarditis. The event, which resulted in hospitalization, occurred 2 weeks after administration of the second dose of the Moderna COVID-19 Vaccine. The rechallenge was not applicable as no additional dosing will be given. The patient's gender remains a confounder. The benefit-risk relationship of the Moderna COVID-19 Vaccine is not affected by this report. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) on 05-Nov-2021 and was forwarded to Moderna on 05-Nov-2021.<br>This regulatory authority case was reported by a pharmacist and describes the occurrence of DISEASE RECURRENCE (disease recurrence) and MYOCARDITIS (myocarditis) in an 18-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination.<br><br>The patient's past medical history included Myopericarditis.<br><br>On 11-Sep-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form.<br>On 02-Oct-2021, received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to 1 dosage form. On 05-Oct-2021, the patient experienced DISEASE RECURRENCE (disease recurrence) (seriousness criterion hospitalization) and MYOCARDITIS (myocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, DISEASE RECURRENCE (disease recurrence) and MYOCARDITIS (myocarditis) had resolved.<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.<br><br>Concomitant product use was not provided by the reporter.<br><br>Treatment information was not provided.<br><br>Company comment: This case concerns a 18-year-old, male patient with previous relevant medical history of Myopericarditis, who experienced the unexpected serious event of disease recurrence and the expected serious AESI event of myocarditis. The events occurred 3 days after the second |

| Case ID | WW Identifier | Narrative |
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| | | dose of mRNA-1273 Moderna vaccine. The rechallenge was not applicable as no additional dose is expected. The medical history of Myopericarditis could be confounder. The benefit-risk relationship of mRNA-1273 Moderna vaccine is not affected by this report. Events term, onset date, outcome and seriousness captured per source document from Regulatory Authority reporting.<br><br>Most recent FOLLOW-UP information incorporated above includes: On 05-Nov-2021: Translation document received on 08-Nov-2021 included event verbatim updated. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 05-Nov-2021 and was forwarded to Moderna on 05-Nov-2021.<br><br>This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (Perimyocarditis) in a 19-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3004671) for Prophylactic vaccination.<br><br>No Medical History information was reported.<br><br>On 08-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 11-Sep-2021, the patient experienced MYOCARDITIS (Perimyocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Perimyocarditis) had resolved.<br><br>Patient had medical history of posttraumatic stress disorder and drug allergy of quetiapine 25 mg. Gastrointestinal infection several weeks ago has been reported.<br><br>Labs reported as Trop 3,000 pg/mL, proBNP 637 ng/L, D-dimer 0.333 mg/L. Cardiovascular: 12- lead ECG, echocardiograph initially showed normal pumping function with echo-rich pericardium. Ultrasound cardiograph showed mildly impaired pump function with global hypokinesis. Chemistry tests showed a significantly decreasing trend of cardiac integrity markers. On 13-Sep-2021 echocardiography showed non-hypertrophic LV with mildly impaired systolic LV pump function (EF: 47% biplane, acc. to Simpson) with global hypokinesis. Right atrium: narrow. Mitral valve: morphologically and functionally unremarkable. Aortic valve: aortic valve morphologically and functionally unremarkable. Tricuspid valve: VCI collapses completely. Ascending aorta but the examination had to be discontinued due to claustrophobia of the patient. Patient was hospitalized from 11-Sep-2021 to 14-Sep-2021, due to thoracic pressure since yesterday evening. Patient was diagnosed with peri myocarditis with ST elevations in I, II, III, aVF, V2-V6. Treatment medication was mentioned as intensive monitoring Infusion ASA 300 mg IV , Heparin 5,000 I.U., 600 mg ibuprofen. Taking quetiapine DD with status post viral infection; ibuprofen therapy was initiated.<br>This case concerns a 19 year-old male patient with a history of post-traumatic stress disorder on quetiapine who experienced the expected, serious adverse event of special interest of myocarditis. The event occurred approximately 4 after the second dose of mRNA-1273. The rechallenge was not applicable as no additional dosing will be administered. The use of concomitant medication quetiapine remains a |

| Case ID | WW Identifier | Narrative |
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| | | confounder. The benefit-risk relationship of mRNA-1273 is not affected by this report. The case's Regulatory Authority narrative reports the patient as having received Biontech vaccine and mRNA-1273.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 05-Nov-2021: Translation received on 7 Nov 2021 and it contains significant information of patient history, lab data and treatment medication along with hospitalization start date and stop date. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number:4.1(b) on 05-Nov-2021 and was forwarded to Moderna on 05-Nov-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myocarditis) in an 18-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 07-Sep-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form.<br>On 05-Oct-2021, received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. On 07-Oct-2021, after starting mRNA-1273 (Spikevax), the patient experienced MYOCARDITIS (Myocarditis) (seriousness criterion medically significant). At the time of the report, MYOCARDITIS (Myocarditis) had not resolved.<br><br>For mRNA-1273 (Spikevax) (Unknown), the reporter considered MYOCARDITIS (Myocarditis) to be possibly related.<br><br>Concomitant product use was not provided by the reporter.<br><br>Treatment information was not provided.<br><br>Company Comment:<br>This case concerns an 18-year-old, male patient with no relevant medical history, who experienced the expected AESI of myocarditis. The event occurred 2 days after administration of the second dose of the Moderna COVID-19 Vaccine. The rechallenge was not applicable as no additional dosing will be given. The patient's gender remains a confounder. The benefit-risk relationship of the Moderna COVID-19 Vaccine is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 05-Nov-2021: Translation received on 08-Nov-2021, contains no new information.<br>On 08-Nov-2021: Secondary reporter details were added.<br>On 24-Nov-2021: non-significant follow up appended |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 05-Nov-2021 and was forwarded to Moderna on 05-Nov-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of PERICARDITIS (SUSPECTED PERICARDITIS) in an 18-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 3005242 and 3004218) for COVID-19 vaccination. |

| Case ID | WW Identifier | Narrative |
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| | | No Medical History information was reported.<br><br>On 10-Aug-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form.<br>On 14-Sep-2021, received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. On 30-Sep-2021, after starting mRNA-1273 (Spikevax), the patient experienced PERICARDITIS (SUSPECTED PERICARDITIS) (seriousness criteria hospitalization and medically significant). At the time of the report, PERICARDITIS (SUSPECTED PERICARDITIS) was resolving.<br><br>For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.<br><br>No concomitant medications were mentioned.<br><br>No treatment details were reported.<br><br>This is a regulatory case concerning a 18 year-old male patient with no relevant medical history reported, who experienced the serious expected and AESI event of PERICARDITIS 17 days after receiving the second dose of proper vaccination schedule with mRNA-1273 .The benefit-risk relationship of mRNA-1273 is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 05-Nov-2021: Translation document received on 08-Nov-2021 included suspect product dosage form and event as reported by primary source updated.<br>On 08-Nov-2021: Significant follow-up document were received on 08-Nov-2021, Dose 1 details and batch number for both doses were Updated.<br>On 08-Nov-2021: Translation received on 09-Nov-2021 dosage text updated. |
| 4.1(b) | 4.1(b) | This case was initially received via European Medicines Agency (Reference number: 4.1(b) ) on 05-Nov-2021. The most recent information was received on 10-Dec-2021 and was forwarded to Moderna on 10-Dec-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (4.1(b) in a 22-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3005238) for an unknown indication.<br><br>The patient's past medical history included Pericarditis in 2016.<br><br>On 02-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 05-Sep-2021, the patient experienced MYOCARDITIS (4.1(b) (seriousness criterion hospitalization). At the time of the report, MYOCARDITIS (4.1(b) had resolved.<br><br>For mRNA-1273 (Spikevax) (Unknown), the reporter considered MYOCARDITIS (4.1(b) to be possibly related. |

| Case ID | WW Identifier | Narrative |
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| | | No concomitant medications were reported.<br>No treatment medications were reported.<br><br>Company Comment :<br>This case concerns a 22-year-old, male patient with a relevant medical history of Pericarditis, who experienced the serious expected AESI of Myocarditis. The event occurred 3 days after the second dose of mRNA-1273 vaccine. The medical history of pericarditis is a confounder. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 05-Nov-2021: Translation doc received on 08-Nov-2021 and narrative were updated<br>On 10-Dec-2021: Follow Up information was received on 10-Dec-2021 and Added medical history. |
| 4.1(b) | 4.1(b) | This case was initially received via European Medicines Agency (Reference number: 4.1(b) ) on 05-Nov-2021. The most recent information was received on 13-Dec-2021 and was forwarded to Moderna on 13-Dec-2021.<br>This regulatory authority case was reported by a consumer and describes the occurrence of MUSCULOSKELETAL PAIN (Pain in the left shoulder blade), DYSPNOEA (Respiratory distress), CHEST PAIN (Sharp pain on the left side around the heart), HEART RATE INCREASED (High pulse), MYOCARDITIS (Symptoms of heart muscle inflammation) and PERICARDITIS (Symptoms of cardiac inflammation) in a 20-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 3005835 and 3004493) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 13-Aug-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form.<br>On 01-Oct-2021, received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. On 02-Oct-2021, the patient experienced MUSCULOSKELETAL PAIN (Pain in the left shoulder blade) (seriousness criterion disability), DYSPNOEA (Respiratory distress) (seriousness criterion disability), CHEST PAIN (Sharp pain on the left side around the heart) (seriousness criterion disability), HEART RATE INCREASED (High pulse) (seriousness criterion disability), MYOCARDITIS (Symptoms of heart muscle inflammation) (seriousness criteria disability and medically significant) and PERICARDITIS (Symptoms of cardiac inflammation) (seriousness criteria disability and medically significant). At the time of the report, MUSCULOSKELETAL PAIN (Pain in the left shoulder blade), DYSPNOEA (Respiratory distress), CHEST PAIN (Sharp pain on the left side around the heart), HEART RATE INCREASED (High pulse), MYOCARDITIS (Symptoms of heart muscle inflammation) and PERICARDITIS (Symptoms of cardiac inflammation) had not resolved.<br><br>Concomitant medication was not reported.<br>Treatment information was not reported. |

| Case ID | WW Identifier | Narrative |
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| | | Company comment:Company comment: This case concerns a 20 year-old male patient with no reported medical history who experienced the expected serious adverse events of special interest of myocarditis and pericarditis, as well as the unexpected serious events of musculoskeletal pain, dyspnea, chest pain and increased heart rate. The events occurred approximately 1 day after the second dose of mRNA-1273. The rechallenge was not applicable as no additional dosing will be administered. The benefit-risk relationship of mRNA-1273 is not affected by this report. Event seriousness assessed as per Regulatory Authority reporting, however there was no information in the source document supporting that the events resulted in a persistent or permanent incapacity.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 05-Nov-2021: Translation received on 08-Nov-2021, which contains updated event verbatim.<br>On 13-Dec-2021: Follow up information received on 13-Dec-2021,, Dosage text, start date and batch lot number added. narrative updated. |
| 4.1(b) [redacted] | 4.1(b) [redacted] | This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 05-Nov-2021 and was forwarded to Moderna on 05-Nov-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of PERICARDITIS (Pericarditis) in a 40-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3004498) for Vaccination. The occurrence of additional non-serious events is detailed below.<br><br>Previously administered products included for Vaccination: COMIRNATY. Past adverse reactions to the above products included No adverse event with COMIRNATY.<br><br>On 10-Sep-2021 at 12:00 PM, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 10-Sep-2021, the patient experienced COVID-19 IMMUNISATION (REVACCINATION WITH DIFFERENT COVID-19 VACCINE). On 15-Oct-2021, the patient experienced PERICARDITIS (Pericarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, PERICARDITIS (Pericarditis) outcome was unknown and COVID-19 IMMUNISATION (REVACCINATION WITH DIFFERENT COVID-19 VACCINE) had resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 15-Oct-2021, Echocardiogram: abnormal (abnormal) Pericarditis.<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered PERICARDITIS (Pericarditis) and COVID-19 IMMUNISATION (REVACCINATION WITH DIFFERENT COVID-19 VACCINE) to be possibly related.<br><br>Concomitant product was not provided by the reporter<br>Treatment product was not provided by the reporter. |

| Case ID | WW Identifier | Narrative |
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| | | Company comment: This case concerns a 40 year-old male patient with a history of vaccination with a different COVID-19 vaccine tozinameran who experienced the expected serious adverse events of special interest of pericarditis. The event occurred approximately 1 month, 6 days after vaccination with mRNA-1273 vaccine. The rechallenge was unknown as only one dose of mRNA-1273 was administered. The medical history of vaccination with COVID-19 vaccine tozinameran remain a confounder for pericarditis. The benefit-risk relationship of mRNA-1273 is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 05-Nov-2021: Translation received on 08 Nov 2021 with verbatim was translated and senders comment updated |
| 4.1(b) | 4.1(b) | This case was initially received via European Medicines Agency (Reference number: 4.1(b) on 08-Nov-2021. The most recent information was received on 11-Dec-2021 and was forwarded to Moderna on 11-Dec-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Chest pain and shortness of pain with myopericarditic symptomatology arose 24 hours after Moderna covid19 vaccine), DYSPNOEA (Chest pain and shortness of pain with myopericarditic symptomatology arose 24 hours after Moderna covid19 vaccine) and CHEST PAIN (Chest pain and shortness of pain with myopericarditic symptomatology arose 24 hours after Moderna covid19 vaccine) in a 25-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3005884) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 17-Oct-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form in total. On 18-Oct-2021, the patient experienced MYOCARDITIS (Chest pain and shortness of pain with myopericarditic symptomatology arose 24 hours after Moderna covid19 vaccine) (seriousness criteria hospitalization and medically significant), DYSPNOEA (Chest pain and shortness of pain with myopericarditic symptomatology arose 24 hours after Moderna covid19 vaccine) (seriousness criterion hospitalization) and CHEST PAIN (Chest pain and shortness of pain with myopericarditic symptomatology arose 24 hours after Moderna covid19 vaccine) (seriousness criterion hospitalization). At the time of the report, MYOCARDITIS (Chest pain and shortness of pain with myopericarditic symptomatology arose 24 hours after Moderna covid19 vaccine), DYSPNOEA (Chest pain and shortness of pain with myopericarditic symptomatology arose 24 hours after Moderna covid19 vaccine) and CHEST PAIN (Chest pain and shortness of pain with myopericarditic symptomatology arose 24 hours after Moderna covid19 vaccine) was resolving.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 20-Oct-2021, C-reactive protein: positive (Positive) C-reactive protein positive.<br>On 20-Oct-2021, Troponin T: negative (Negative) Negative. |

| Case ID | WW Identifier | Narrative |
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| | | For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.<br><br>No concomitant medication was reported.<br><br>Patient was hospitalized in the cardiology department due to symptoms of myopericarditis, which started 24 hours after the second dose of the vaccine, hospitalization 48 hours after, hospitalized for 3 days with improvement of symptoms.<br><br>Treatment medication was not provided by the reporter.<br>Company comment-<br>This case concerns a 25-year-old male patient with no medical history, who experienced the serious expected AESI of Myocarditis and the serious unexpected event of Dyspnoea and Chest pain. The events occurred 1 day after the second dose of mRNA- 1273 vaccine. The labs of C reactive protein (positive) and T Troponin was done. The benefit-risk relationship of mRNA- 1273 vaccine is not affected by this report. Event seriousness assessed as per Regulatory Authority reporting and retained for consistency with the RA report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 08-Nov-2021: Translation received on 09-Nov-2021 includes translated verbatim and Reporter comments. Narrative updated accordingly<br>On 17-Nov-2021: Follow up received contains No New Information.<br>On 17-Nov-2021: Translation received on 18-NOV-2021 contains no new information.<br>On 11-Dec-2021: Follow-up received on 11-Dec-2021: Laboratory test results were updated for Troponin T and event verbatim was updated. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 08-Nov-2021 and was forwarded to Moderna on 08-Nov-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of HEAD DISCOMFORT (Decreased general condition, asthenia, strange sensation in the body, reduced appetite, unwell after physical activity. Palpitations/sensation of pressure in the chest), PALPITATIONS (Decreased general condition, asthenia, strange sensation in the body, reduced appetite, unwell after physical activity. Palpitations/sensation of pressure in the chest), DIZZINESS (Decreased general condition, asthenia, strange sensation in the body, reduced appetite, unwell after physical activity. Palpitations/sensation of pressure in the chest), CHEST DISCOMFORT (Decreased general condition, asthenia, strange sensation in the body, reduced appetite, unwell after physical activity. Palpitations/sensation of pressure in the chest), GENERAL PHYSICAL HEALTH DETERIORATION (Decreased general condition, asthenia, strange sensation in the body, reduced appetite, unwell after physical activity. Palpitations/sensation of pressure in the chest), MALAISE (Decreased general condition, asthenia, strange sensation in the body, reduced appetite, unwell after physical activity. Palpitations/sensation of pressure in the chest), DISCOMFORT (Decreased general condition, asthenia, strange sensation in the body, reduced appetite, unwell after physical activity. Palpitations/sensation of pressure in the chest), DECREASED APPETITE (Decreased general condition, asthenia, strange sensation in the body, reduced appetite, |

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| | | unwell after physical activity. Palpitations/sensation of pressure in the chest), COLD SWEAT (Decreased general condition, asthenia, strange sensation in the body, reduced appetite, unwell after physical activity. Palpitations/sensation of pressure in the chest), ASTHENIA (Decreased general condition, asthenia, strange sensation in the body, reduced appetite, unwell after physical activity. Palpitations/sensation of pressure in the chest), DYSPNOEA (Decreased general condition, asthenia, strange sensation in the body, reduced appetite, unwell after physical activity. Palpitations/sensation of pressure in the chest), MUSCULOSKELETAL STIFFNESS (Decreased general condition, asthenia, strange sensation in the body, reduced appetite, unwell after physical activity. Palpitations/sensation of pressure in the chest), CHEST PAIN (Decreased general condition, asthenia, strange sensation in the body, reduced appetite, unwell after physical activity. Palpitations/sensation of pressure in the chest) and MYOCARDITIS (Decreased general condition, asthenia, strange sensation in the body, reduced appetite, unwell after physical activity. Palpitations/sensation of pressure in the chest) in a 27-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3004498) for Vaccination.<br><br>The patient's past medical history included Overweight.<br><br><br>On 10-Sep-2021 at 12:00 PM, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 13-Sep-2021, the patient experienced HEAD DISCOMFORT (Decreased general condition, asthenia, strange sensation in the body, reduced appetite, unwell after physical activity. Palpitations/sensation of pressure in the chest) (seriousness criterion hospitalization), DIZZINESS (Decreased general condition, asthenia, strange sensation in the body, reduced appetite, unwell after physical activity. Palpitations/sensation of pressure in the chest) (seriousness criterion hospitalization), GENERAL PHYSICAL HEALTH DETERIORATION (Decreased general condition, asthenia, strange sensation in the body, reduced appetite, unwell after physical activity. Palpitations/sensation of pressure in the chest) (seriousness criterion hospitalization), MALAISE (Decreased general condition, asthenia, strange sensation in the body, reduced appetite, unwell after physical activity. Palpitations/sensation of pressure in the chest) (seriousness criterion hospitalization), DISCOMFORT (Decreased general condition, asthenia, strange sensation in the body, reduced appetite, unwell after physical activity. Palpitations/sensation of pressure in the chest) (seriousness criterion hospitalization), DECREASED APPETITE (Decreased general condition, asthenia, strange sensation in the body, reduced appetite, unwell after physical activity. Palpitations/sensation of pressure in the chest) (seriousness criterion hospitalization), ASTHENIA (Decreased general condition, asthenia, strange sensation in the body, reduced appetite, unwell after physical activity. Palpitations/sensation of pressure in the chest) (seriousness criterion hospitalization), DYSPNOEA (Decreased general condition, asthenia, strange sensation in the body, reduced appetite, unwell after physical activity. Palpitations/sensation of pressure in the chest) (seriousness criterion hospitalization), MUSCULOSKELETAL STIFFNESS (Decreased general condition, asthenia, strange sensation in the body, reduced appetite, unwell after physical activity. Palpitations/sensation of pressure in the chest) (seriousness criterion |

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| | | hospitalization) and MYOCARDITIS (Decreased general condition, asthenia, strange sensation in the body, reduced appetite, unwell after physical activity. Palpitations/sensation of pressure in the chest) (seriousness criteria hospitalization and medically significant). On 12-Oct-2021, the patient experienced PALPITATIONS (Decreased general condition, asthenia, strange sensation in the body, reduced appetite, unwell after physical activity. Palpitations/sensation of pressure in the chest) (seriousness criterion hospitalization), CHEST DISCOMFORT (Decreased general condition, asthenia, strange sensation in the body, reduced appetite, unwell after physical activity. Palpitations/sensation of pressure in the chest) (seriousness criterion hospitalization), COLD SWEAT (Decreased general condition, asthenia, strange sensation in the body, reduced appetite, unwell after physical activity. Palpitations/sensation of pressure in the chest) (seriousness criterion hospitalization) and CHEST PAIN (Decreased general condition, asthenia, strange sensation in the body, reduced appetite, unwell after physical activity. Palpitations/sensation of pressure in the chest) (seriousness criterion hospitalization). At the time of the report, HEAD DISCOMFORT (Decreased general condition, asthenia, strange sensation in the body, reduced appetite, unwell after physical activity. Palpitations/sensation of pressure in the chest), PALPITATIONS (Decreased general condition, asthenia, strange sensation in the body, reduced appetite, unwell after physical activity. Palpitations/sensation of pressure in the chest), DIZZINESS (Decreased general condition, asthenia, strange sensation in the body, reduced appetite, unwell after physical activity. Palpitations/sensation of pressure in the chest), CHEST DISCOMFORT (Decreased general condition, asthenia, strange sensation in the body, reduced appetite, unwell after physical activity. Palpitations/sensation of pressure in the chest), GENERAL PHYSICAL HEALTH DETERIORATION (Decreased general condition, asthenia, strange sensation in the body, reduced appetite, unwell after physical activity. Palpitations/sensation of pressure in the chest), MALAISE (Decreased general condition, asthenia, strange sensation in the body, reduced appetite, unwell after physical activity. Palpitations/sensation of pressure in the chest), DISCOMFORT (Decreased general condition, asthenia, strange sensation in the body, reduced appetite, unwell after physical activity. Palpitations/sensation of pressure in the chest), DECREASED APPETITE (Decreased general condition, asthenia, strange sensation in the body, reduced appetite, unwell after physical activity. Palpitations/sensation of pressure in the chest), COLD SWEAT (Decreased general condition, asthenia, strange sensation in the body, reduced appetite, unwell after physical activity. Palpitations/sensation of pressure in the chest), ASTHENIA (Decreased general condition, asthenia, strange sensation in |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 08-Nov-2021 and was forwarded to Moderna on 08-Nov-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (4.1(b) ) in a 17-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 3005835 and 3004670) for COVID-19 vaccination.<br><br>No Medical History information was reported. |

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| | | On 12-Aug-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form.<br>On 23-Sep-2021, received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. On 10-Oct-2021, after starting mRNA-1273 (Spikevax), the patient experienced MYOCARDITIS (4.1(b) ) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (4.1(b) ) was resolving.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 12-Oct-2021, SARS-CoV-2 antibody test: positive (Positive) Positive.<br><br>For mRNA-1273 (Spikevax) (Unknown), the reporter considered MYOCARDITIS (4.1(b) ) to be possibly related.<br><br>No concomitant medications were reported<br>No treatment medications were reported.<br><br>Company Comment:<br>This case concerns a 17-year-old, male patient with no relevant medical history, who experienced the expected AESI of myocarditis. The event, which resulted in hospitalization, occurred 17 days after administration of the second dose of the Moderna COVID-19 Vaccine. The rechallenge was not applicable as no additional dosing will be given. The patient's gender remains a confounder. The benefit-risk relationship of the Moderna COVID-19 Vaccine is not affected by this report. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 08-Nov-2021 and was forwarded to Moderna on 08-Nov-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of PERICARDITIS (Pericarditis) in a 25-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 3003604) for COVID-19 vaccination.<br><br>Previously administered products included for Vaccination: SPIKEVAX. Past adverse reactions to the above products included No adverse event with SPIKEVAX.<br><br>On 26-Aug-2021 at 2:00 PM, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 28-Aug-2021, the patient experienced PERICARDITIS (Pericarditis) (seriousness criterion hospitalization). At the time of the report, PERICARDITIS (Pericarditis) had not resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 14-Oct-2021, Computerised tomogram thorax: normal (normal) No pulmonary embolism.<br>On 14-Oct-2021, Echocardiogram: abnormal (abnormal) Pericarditis, Pericardial fluid.<br>On 14-Oct-2021, Fibrin D dimer: negative (Negative) Negative. |

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| | | For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered PERICARDITIS (Pericarditis) to be possibly related.<br><br>No concomitant medication was reported.<br>No treatment medication use was reported.<br><br>Company Comment:<br>This case concerns a 25-year-old, female patient with no relevant medical history, who experienced the expected AESI of pericarditis. The event, which resulted in hospitalization, occurred 2 days after administration of the second dose of the Moderna COVID-19 Vaccine. Echocardiography done on 14Oct2021 showed 'pericarditis, pericardial fluid'. The Computerized Tomography of the Chest showed 'no pulmonary embolism' and the Fibrin D dimer test was 'negative'. The event had not resolved at the time of the report. The rechallenge was not applicable as no additional dosing will be given. The benefit-risk relationship of the Moderna COVID-19 Vaccine is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 08-Nov-2021: Translation received on 10-Nov-2021 and contains No New Information.<br>On 04-Jan-2022: Follow up received is non significant. |
| 4.1(b) | 4.1(b) | This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) ) on 05-Nov-2021 and was forwarded to Moderna on 09-Nov-2021.<br>This case, initially reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref, 4.1(b)<br><br>The patient had a pollinosis and took an over-the-counter fexofenadine hydrochloride depending on the season.<br><br>On an unknown date, the patient received the 1st dose of this vaccine.<br><br>On 01-Oct-2021, the patient received the 2nd dose of this vaccine.<br><br>On 03-Oct-2021, the patient had a pyrexia of the highest 39.1 degrees Celsius. The event was considered to be a side effect and was treated with antipyretics. Subsequently, the fever went down.<br><br>On 04-Oct-2021, around 06:00, acute myocarditis developed. Chest pain was noted. The patient visited the previous physician. High sensitive troponin I was positive, and post-vaccination myocarditis was suspected, and the patient was referred to and visited the reporting hospital. At the time of medical examination, precordial discomfort was persisted, electrocardiogram showed suspected slight ST elevation in V3-6. There was no increase in CK or CK-MB, but the value of sensitive troponin was high as 4,000 pg/mL. The patient was hospitalized on the purpose of follow-up and medical treatment. Medical treatment with ACE inhibitor and ibuprofen was started.<br><br>On an unknown date, no abnormal findings were found at the time of hospitalization on echocardiography. Thereafter, no new findings were |

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| | | noted. Coronary artery CT was performed, but there was no significant stenosis.<br><br>On 08-Oct-2021, the patient was doing well and was discharged from the hospital.<br><br>On 26-Oct-2021, the resolution of the symptoms was confirmed.<br><br>The outcome of pyrexia and acute myocarditis was reported as resolved.<br><br>Follow-up investigation will be made.<br><br>Reporter comments continuation:<br><br>Blood tests were submitted to exclude viral myocarditis, but the results have not been reported. The cardiac contrast-enhanced MRI performed after discharge from the hospital showed myocardial edema and late gadolinium enhancement, which was consistent with myocarditis. If viral myocarditis is excluded, the event falls into the CDC's confirmed case" of post-COVID-19 mRNA vaccination myocarditis.<br><br>Company Comment:<br><br>The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. |
| 4.1(b) | 4.1(b) | This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 05-Nov-2021 and was forwarded to Moderna on 10-Nov-2021.<br>This case, initially reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref 4.1(b)<br><br>The patient was under treatment with 1 tablet of perampanel hydrate 4 mg, 6 tablets of levetiracetam 500 mg, and 1 tablet of sodium valproate 200 mg.<br><br>On an unknown date, the patient received the 1st dose of the vaccine.<br><br>On an unknown date, body temperature before the vaccination: 36.2 degrees Celsius.<br><br>On 17-Oct-2021, the patient received the 2nd dose of the vaccine.<br><br>On 30-Oct-2021, in the early evening, the patient was aware of malaise, pyrexia of 38s degrees Celsius, and chills. Around 20:00, the patient experienced anterior chest pain, which was gradually exacerbated.<br><br>On 31-Oct-2021, as the symptom did not improve, the patient called an ambulance and was transported to a nearby hospital. Blood sampling, electrocardiogram, and CT inspection showed no abnormal findings, and the patient was prescribed acetaminophen and returned home. |

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| | | On 02-Nov-2021, as there was no improvement of the symptom, the patient visited the reporting hospital. Electrocardiogram showed negative T-waves in III and V4- V6, and the result of blood sampling showed high level of troponin I of 2,789 pg/mL. Although echocardiography did not show reduced cardiac function, a diagnosis of acute myocarditis was made based on the course of the disease and the results of electrocardiogram and blood sampling. The patient was hospitalized on the same day.<br><br>On an unknown date, after the hospitalization, the symptom showed a tendency of improvement.<br><br>On 04-Nov-2021, troponin I also decreased to around 300 in 2 days, and the symptom was confirmed to be resolving.<br><br>The outcome of acute myocarditis was reported as resolving.<br><br>Follow-up investigation will be made.<br><br>Company Comment:<br><br>The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. |
| 4.1(b) | 4.1(b) | This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 05-Nov-2021 and was forwarded to Moderna on 10-Nov-2021.<br>This case, initially reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref, 4.1(b)<br><br>On an unknown date, the patient received the 1st dose of the vaccine.<br><br>On an unknown date, body temperature before the vaccination: 36.5 degrees Celsius.<br><br>On 29-Oct-2021, at 19:30, the patient received the 2nd dose of the vaccine. At 23:00, acute myocarditis developed.<br><br>On 31-Oct-2021, in the morning, the patient had pyrexia. At night, chest pain developed, and thus the patient was emergently transported. The patient was diagnosed with acute myocarditis from blood collection and electrocardiogram and hospitalized for treatment.<br><br>The outcome of acute myocarditis was unknown.<br>Follow-up investigation will be made.<br><br>Company Comment:<br><br>The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. |
| 4.1(b) | 4.1(b) | This case was received via 4.1(b) (Reference number: 4.1(b) on 09-Nov-2021 and was forwarded to Moderna on 09-Nov-2021.<br>This regulatory authority case was reported by an other health care professional and describes the occurrence of CARDIOMYOPATHY |

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| | | (Cardiomyopathy), MYOCARDITIS (Myocarditis), OEDEMA (Oedema) and CHEST PAIN (Chest pain) in a 22-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 017f21a) for COVID-19 vaccination.<br><br>The patient's past medical history included Hepatic steatosis and COVID-19 in August 2020.<br>Concurrent medical conditions included Allergy to antibiotic (Amoxicillin), Depression, Anxiety and Vitamin D deficiency.<br>Concomitant products included ESCITALOPRAM OXALATE, VITAMIN D [VITAMIN D NOS], MULTIVITAMIN [VITAMINS NOS] and LINUM USITATISSIMUM SEED OIL (FLAX OIL) for an unknown indication.<br><br>On 22-Oct-2021, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 25-Oct-2021, the patient experienced CHEST PAIN (Chest pain) (seriousness criterion hospitalization). On 28-Oct-2021, the patient experienced CARDIOMYOPATHY (Cardiomyopathy) (seriousness criteria hospitalization and medically significant), MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant) and OEDEMA (Oedema) (seriousness criterion hospitalization). At the time of the report, CARDIOMYOPATHY (Cardiomyopathy), MYOCARDITIS (Myocarditis), OEDEMA (Oedema) and CHEST PAIN (Chest pain) outcome was unknown.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 25-Oct-2021, C-reactive protein: 1.710 (High) 1.710 mg/dL.<br>On 25-Oct-2021, Chest X-ray: normal (normal) Normal.<br>On 25-Oct-2021, Electrocardiogram: st-t segment abnormal (abnormal) ST-T segment abnormal and normal (normal) Normal.<br>On 25-Oct-2021, Fibrin D dimer: 0.27 (normal) less than 0.27 ug/mL.<br>On 25-Oct-2021, Red blood cell sedimentation rate: 7 (normal) 7 mm/hr.<br>On 25-Oct-2021, Troponin I: 1.85 (High) 1.85 ng/mL and 3.22 (High) 3.22 ng/mL.<br>On 26-Oct-2021, Echocardiogram: normal (normal) Normal.<br>On 26-Oct-2021, Ejection fraction: 59 (Low) 59%.<br>On 26-Oct-2021, Troponin I: 2.47 (High) 2.47 ng/mL, 2.78 (High) 2.78 ng/mL and 3.47 (High) 3.47 ng/mL.<br>On 27-Oct-2021, Troponin I: 2757 (High) 2757 ng/L.<br>On 28-Oct-2021, Magnetic resonance imaging heart: acute myocarditis (abnormal) Non-ischemic pattern of edema/ hyperemia suggestive of acute myocarditis.<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments.<br><br>No treatment information provided.<br><br>Company Comment:<br>This case concerns a 22-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) with history of hepatic steatosis who experienced the serious unexpected event of cardiomyopathy and serious |

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| | | expected event (AESI) of myocarditis 6 days after the first dose of the vaccine. Rechallenge is not applicable, since no further dosing is expected. The benefit-risk relationship is not affected by this report |
| 4.1(b) | 4.1(b) | This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 05-Nov-2021 and was forwarded to Moderna on 10-Nov-2021.<br>This case, initially reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref, 4.1(b)<br><br>On an unknown date, the patient received the 1st dose of the vaccine.<br><br>On 22-Oct-2021, at 10:00, the patient received the 2nd dose of the vaccine.<br><br>On 25-Oct-2021, at 05:00, myocarditis developed. The patient was emergently transported with a major complaint of chest pain. On arrival, a wide range of ST elevation was shown by 12-lead electrocardiogram, and high-sensitive troponin I was found to be strongly positive in the results of blood sampling. An emergency coronary catheterization was performed to show no significant stenosis, and thus myocardial infarction was ruled out. The patient was hospitalized.<br><br>On an unknown date, as cardiac MRI after hospitalization revealed high signal intensities at T2* in cardiac muscles and myocardial edema, the patient was diagnosed with myocarditis.<br><br>On 02-Nov-2021, the symptom was confirmed to be resolving, and the patient was discharged from the hospital.<br><br>The outcome of myocarditis was reported as resolving.<br><br>Follow-up investigation will be made.<br><br>Company Comment:<br><br>The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. |
| 4.1(b) | 4.1(b) | This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) ) on 03-Nov-2021 and was forwarded to Moderna on 10-Nov-2021.<br>This case, initially reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref, 4.1(b)<br><br>On an unknown date, the patient received the 1st dose of this vaccine.<br><br>On 28-Oct-2021, at 11:00, the patient received the 2nd dose of the vaccine. In the evening, the patient developed pyrexia and it persisted. occurred<br>On 30-Oct-2021, around 16:00, discomfort around the throat to chest and difficulty breathing were noted. Electrocardiogram showed ST elevation of 1, 2, 3, AVF, and V3 -6, elevation of troponin I, elevation of CKMB, and elevation of inflammatory reaction. The patient was diagnosed with myocarditis. The patient was hospitalized. |

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| | | The outcome of pyrexia and myocarditis was reported as unknown.<br><br>Follow-up investigation will be made.<br><br>Company Comment:<br><br>The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 10-Nov-2021 and was forwarded to Moderna on 10-Nov-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Acute myocarditis) in a 23-year-old male patient who received mRNA-1273 (Spikevax) for Prophylactic vaccination.<br><br>No medical history was provided by the reporter.<br>Concomitant products included TETANUS VACCINE from 09-Aug-2021 to an unknown date for an unknown indication.<br><br>On 23-Jul-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 12-Aug-2021, the patient experienced MYOCARDITIS (Acute myocarditis) (seriousness criteria hospitalization and life threatening). At the time of the report, MYOCARDITIS (Acute myocarditis) outcome was unknown.<br><br>The action taken with mRNA-1273 (Spikevax) (Unknown) was unknown.<br><br>For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.<br><br>No treatment information was provided.<br><br>Company comment-<br>This case concerns a 23-year-old, male patient with relevant medical history of Tetanus vaccination on 09Aug2021, who experienced the expected AESI of myocarditis. The event, which was life-threatening and resulted in hospitalization, occurred 20 days after the second dose of mRNA-1273 vaccine. The rechallenge was unknown. The history of Tetanus vaccination, which may also cause acute myocarditis, 3 days before the event occurred, as well as the patient's gender remain as confounders. The benefit-risk relationship of mRNA-1273 vaccine. is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 10-Nov-2021: Follow-up received on 10-Nov-2021 contain no new information<br>On 10-Nov-2021: Translated doc received (FU1) on 12 Nov 2021 contains dosage details updated |
| 4.1(b) | 4.1(b) | This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) ) on 06-Nov-2021 and was forwarded to Moderna on 11-Nov-2021. |

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| | | This case, initially reported to the 4.1(b) ) by a pharmacist, was received via the 4.1(b) (Ref, 4.1(b)<br><br>On an unknown date, the patient received the 1st dose of this vaccine.<br><br>On 17-Oct-2021, the patient received the 2nd dose of this vaccine.<br><br>On 20-Oct-2021, around 12:00, myocarditis developed. Chest pain and difficulty breathing developed, and an ambulance was called. The patient was transported to the reporting hospital as an emergency visit. On arrival, pyrexia of 37.6 degrees Celsius was observed. Acute myocarditis due to this vaccine was suspected from electrocardiogram and echocardiography, and the patient was hospitalized for further examination and follow-up.<br><br>On an unknown date, after hospitalization, the symptoms improved with infusion of sodium chloride/potassium chloride/calcium chloride hydrate/sodium acetate hydrate, intravenous infusion of acetaminophen, aspirin, and lansoprazole.<br><br>On 24-Oct-2021, resolution of the symptoms was confirmed, and the patient was discharged from the hospital.<br><br>The outcome of myocarditis was reported as recovered.<br><br>Follow-up investigation will be made.<br><br>The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.<br><br>Company comment:<br>This case concerns a 16-year-old, male patient with no relevant medical history, who experienced the expected event of myocarditis. The event myocarditis occurred 3 days after the second dose of Moderna Covid-19 vaccine administration. The rechallenge was not applicable. The patient's age and gender remain confounders. The benefit-risk relationship of Moderna Covid-19 vaccine is not affected by this report. |
| 4.1(b) | 4.1(b) | This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 06-Nov-2021 and was forwarded to Moderna on 11-Nov-2021.<br>This case, initially reported to the 4.1(b) by a (physician), was received via the 4.1(b) (Ref, 4.1(b)<br><br>On an unknown date, the patient received the 1st dose of this vaccine.<br><br>On 26-Sep-2021, the patient received the 2nd dose of this vaccine. Pyrexia developed.<br><br>On 27-Sep-2021, the patient was aware of chest pain.<br><br>On 28-Sep-2021, at 02:38, myocarditis developed. |

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| | | At 02:45, the family member noticed the patient's groan. The patient did not respond, so CPR was started, and an emergency call was made. The initial waveform was VF, and PCPS was established with an estimated cardio-respiratory arrest time of 44 minutes. Myocarditis was strongly suspected from rapidly elevated cardiac enzymes in CAG vitals. The diagnosis was confirmed by findings of myocardial oedema and cardiac swelling in the VCG. Hypoxic encephalopathy was prolonged, and the consciousness did not recover. The patient was hospitalized.<br><br>The outcome of pyrexia, VF, myocarditis, and hypoxic encephalopathy was unknown.<br><br>Follow-up investigation will be made.<br><br>Company Comment:<br><br>The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 10-Nov-2021 and was forwarded to Moderna on 10-Nov-2021.<br><br>This regulatory authority case was reported by a consumer and describes the occurrence of PYREXIA (Pyrexia), FATIGUE (Fatigue) and MYOCARDITIS (Inpatient stay due to acute myocarditis since Oct 29, 2021 (2nd dose of the vaccination on Oct 26, 2021 [rhlatn])) in a 34-year-old male patient who received mRNA-1273 (Spikevax) for Prophylactic vaccination.<br><br>No Medical History information was reported.<br><br>On 26-Oct-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 27-Oct-2021, the patient experienced PYREXIA (Pyrexia) (seriousness criterion hospitalization), FATIGUE (Fatigue) (seriousness criterion hospitalization) and MYOCARDITIS (Inpatient stay due to acute myocarditis since Oct 29, 2021 (2nd dose of the vaccination on Oct 26, 2021 [rhlatn])) (seriousness criteria hospitalization and medically significant). At the time of the report, PYREXIA (Pyrexia) and MYOCARDITIS (Inpatient stay due to acute myocarditis since Oct 29, 2021 (2nd dose of the vaccination on Oct 26, 2021 [rhlatn])) was resolving and FATIGUE (Fatigue) outcome was unknown.<br><br>On Oct 26, 2021, Patient had 2nd vaccination, he received 1st dose at the end of September, since the night of the vaccination, aching limbs, headaches, fever, chills, pressure on the chest.<br>On Jul 29, 2021, Inpatient stay, during which acute myocarditis was diagnosed, Inpatient stay until Nov 1, 2021.<br><br>No concomitant medication was provided by reporter.<br><br>No treatment drug was provided by reporter.<br><br>Company Comment - This case concerns a 34-year-old, male patient with no relevant medical history reported, who experienced the unexpected |

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| | | serious events of PYREXIA, FATIGUE, and the expected serious event of MYOCARDITIS. The events occurred the following day of the second dose of mRNA-1273. The rechallenge was not applicable, as no information about additional dosing was disclosed. The benefit-risk relationship of mRNA-1273 is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 10-Nov-2021: Translation received on 14-Nov-2021. Event verbatim and Sender's comment were updated. |
| 4.1(b) | 4.1(b) | This case was initially received via European Medicines Agency (Reference number: 4.1(b) ) on 10-Nov-2021. The most recent information was received on 24-Nov-2021 and was forwarded to Moderna on 24-Nov-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (4.1(b) in a 27-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 3005835 and 3004218) for COVID-19 vaccination.<br><br>Concurrent medical conditions included Cold induced asthma, Overactive bladder and Micturition urgency.<br>Concomitant products included ALFUZOSIN HYDROCHLORIDE (ALFUZOSIN ORION), BUDESONIDE (GIONA), FESOTERODINE FUMARATE (TOVIAZ) and SALBUTAMOL SULFATE (BUVENTOL) for an unknown indication.<br><br>On 29-Jul-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form.<br>On 22-Sep-2021, received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. On 15-Oct-2021, after starting mRNA-1273 (Spikevax), the patient experienced MYOCARDITIS (4.1(b) (seriousness criterion hospitalization). At the time of the report, MYOCARDITIS (4.1(b) was resolving.<br><br>For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.<br><br>Patient took Buventol Easyhaler at a dose of 100-200 microgram. No treatment medications provided by the reporter. There was no report of late second dose due to an oversight by the patient or HCP (e.g. missed appointment, misunderstood/misinterpreted dosing schedule); however, the second dose was administered more than the recommended window of 25 to 35 days after the first dose.<br>Company Comment : This regulatory case concerns a 27-year-old, male patient with no relevant medical history, who experienced the expected AESI of myocarditis. The event, which resulted in hospitalization, occurred 23 days after administration of the second dose of the Moderna mRNA-1273. No treatment information was provided. However, the event was resolving at the time of the report. The rechallenge was not applicable as no additional dosing will be given. The patient's gender remains a confounder. The benefit-risk relationship of the Moderna mRNA-1273 is not affected by this report. Of note, there was no report of late second dose due to an oversight by the patient or HCP (e.g. missed appointment, misunderstood/misinterpreted dosing schedule); however, |

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| | | the second dose was administered more than the recommended window of 25 to 35 days after the first dose.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 10-Nov-2021: Translation document received on 12 Nov 2021. Translated event verbatim and dosage text was updated.<br>On 24-Nov-2021: Follow up received on 24-NOV-2021 contained significant information Medical History, Concomitant product, Event start date was updated |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 10-Nov-2021 and was forwarded to Moderna on 10-Nov-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of PERICARDITIS (Pericarditis) in a 31-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3005835) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 13-Oct-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form.<br>On an unknown date, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 17-Oct-2021, after starting mRNA-1273 (Spikevax), the patient experienced PERICARDITIS (Pericarditis) (seriousness criterion medically significant). At the time of the report, PERICARDITIS (Pericarditis) had not resolved.<br><br>For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.<br><br>No concomitant medications were provided.<br>No treatment information was provided.<br><br>Follow-up received on 10-NOV-2021 included no new information.<br><br>Company comment: This regulatory case concerns a 31-year-old, male patient with no relevant medical history, who experienced the expected AESI of pericarditis. The event occurred 4 days after administration of the second dose of the Moderna mRNA-1273. The rechallenge was not applicable as no additional dosing will be given. The patient's gender remains a confounder. The benefit-risk relationship of the Moderna mRNA-1273 is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 10-Nov-2021: Translation document received on 12 Nov 2021 includes reaction/event as reported by primary source,dosage text and dosage form translated. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 11-Nov-2021 and was forwarded to Moderna on 11-Nov-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of CHEST PAIN (Retrosternal pain), MYOCARDIAL NECROSIS MARKER INCREASED (Cardiac enzymes NOS abnormal) |

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| | | and MYOCARDITIS (Acute myocarditis) in a 28-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 immunisation.<br><br>No Medical History information was reported.<br><br>On 27-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 28-Sep-2021, the patient experienced CHEST PAIN (Retrosternal pain) (seriousness criterion medically significant). On 30-Sep-2021, the patient experienced MYOCARDITIS (Acute myocarditis) (seriousness criterion medically significant). On an unknown date, the patient experienced MYOCARDIAL NECROSIS MARKER INCREASED (Cardiac enzymes NOS abnormal) (seriousness criterion medically significant). At the time of the report, CHEST PAIN (Retrosternal pain), MYOCARDIAL NECROSIS MARKER INCREASED (Cardiac enzymes NOS abnormal) and MYOCARDITIS (Acute myocarditis) was resolving.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 14-Oct-2021, Magnetic resonance imaging heart: abnormal (abnormal) ABNORMAL: ACUTE MYOCARDITIS.<br><br>For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.<br><br>No concomitant medication was reported.<br><br>No treatment medication use was reported.<br><br>The action taken for Moderna COVID-19 vaccine was Not Applicable.<br><br>Company Comment: This case concerns a 28-year-old male patient with no relevant medical history provided who experienced serious unexpected events of Chest pain and Myocardial necrosis marker increased and serious expected event of special interest Myocarditis. The events occurred approximately one or three days after the second dose of mRNA-1273. The rechallenge was not applicable as the events occurred following the second dose of the vaccine. It was reported that cardiac MRI findings were consistent with myocarditis, however, very limited information regarding clinical course of the events has been provided at this time. At the time of the report the events were resolving. The benefit risk relationship of mRNA-1273 is not affected by this report. |
| 4.1(b) | 4.1(b) | This case was initially received via European Medicines Agency (Reference number: 4.1(b) ) on 11-Nov-2021. The most recent information was received on 25-Nov-2021 and was forwarded to Moderna on 25-Nov-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of PERICARDITIS (PERICARDITIS) in a 17-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 3005697 and 3005242) for an unknown indication.<br><br>Concurrent medical conditions included ADHD. |

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| | | Concomitant products included METHYLPHENIDATE HYDROCHLORIDE (RITALIN) from 08-May-2018 to an unknown date, MELATONIN (MELATONIN AGB) from 07-Jul-2021 to an unknown date and HYDROXYZINE HYDROCHLORIDE (ATARAX [HYDROXYZINE HYDROCHLORIDE]) from 07-Jul-2021 to an unknown date for an unknown indication.<br><br>On 27-Aug-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form.<br>On 01-Oct-2021, received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. On 08-Oct-2021, after starting mRNA-1273 (Spikevax), the patient experienced PERICARDITIS (PERICARDITIS) (seriousness criterion medically significant). At the time of the report, PERICARDITIS (PERICARDITIS) was resolving.<br><br>For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.<br><br>No treatment medications were provided by reporter.<br><br>Company comment: This regulatory case concerns a 17-year-old, male patient with no relevant medical history, who experienced the expected, serious AESI of pericarditis. The event occurred 1 week after administration of the second dose of the Moderna mRNA-1273. Treatment information was not provided. However, the event was resolving at the time of the report. The rechallenge was not applicable as no additional dosing will be given. The patient's gender remains a confounder. The benefit-risk relationship of the Moderna mRNA-1273 is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 11-Nov-2021: Translation document received on 12-Nov-2021. Description as reported for event was updated.<br>On 25-Nov-2021: Follow-up received contains additional and updated concomitant medication details. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 11-Nov-2021 and was forwarded to Moderna on 11-Nov-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of TROPONIN INCREASED (Cardiac troponin increased), BLOOD CREATINE PHOSPHOKINASE INCREASED (Creatine kinase increased) and MYOCARDITIS (Myocarditis) in an 18-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 214015) for Prophylactic vaccination.<br><br>Previously administered products included for COVID-19 vaccination: COVID-19 Vaccine Moderna dispersion for injectionCOVID-19 mRNA Vaccine (nucleoside modified)SpykeVax on 03-Sep-2021.<br>Past adverse reactions to the above products included No adverse event with COVID-19 Vaccine Moderna dispersion for injectionCOVID-19 mRNA Vaccine (nucleoside modified)SpykeVax. |

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| | | On 15-Oct-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 15-Oct-2021, the patient experienced TROPONIN INCREASED (Cardiac troponin increased) (seriousness criterion hospitalization), BLOOD CREATINE PHOSPHOKINASE INCREASED (Creatine kinase increased) (seriousness criterion hospitalization) and MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, TROPONIN INCREASED (Cardiac troponin increased), BLOOD CREATINE PHOSPHOKINASE INCREASED (Creatine kinase increased) and MYOCARDITIS (Myocarditis) had not resolved.<br><br>For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.<br><br>Concomitant medications were not reported.<br>Treatment medications were not reported.<br><br>Company comment: This case concerns a 18 year old male patient with no relevant medical history, who experienced the expected events of myocarditis and the unexpected events of troponin increased and blood creatine phosphokinase increased, requiring hospitalization. The events occurred on the same day after the second dose of mRNA-1273 vaccine. The rechallenge was unknown. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report. |
| 4.1(b) | 4.1(b) | This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCARDITIS (Vaccine myocarditis) and CHEST PAIN (Chest pain) in a 23-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 019G21A_1101115-CDC) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 14-Jul-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form.<br>On 01-Nov-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to .5 milliliter.<br>On 02-Nov-2021, the patient experienced MYOCARDITIS (Vaccine myocarditis) (seriousness criteria hospitalization and medically significant) and CHEST PAIN (Chest pain) (seriousness criterion hospitalization). The patient was hospitalized on 02-Nov-2021 due to CHEST PAIN and MYOCARDITIS. At the time of the report, MYOCARDITIS (Vaccine myocarditis) and CHEST PAIN (Chest pain) outcome was unknown.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 02-Nov-2021, Fibrin D dimer: 277 (abnormal) 277.<br>On 02-Nov-2021, Platelet aggregation test: 236 (abnormal) 236.<br>On 02-Nov-2021, Polymerase chain reaction: negative (Negative) Negative.<br>On 02-Nov-2021, SARS-CoV-2 test: negative (Negative) Negative.<br>On 02-Nov-2021, Troponin I: 0.13 (abnormal) 0.13.<br>On 02-Nov-2021, White blood cell count: 12600 (abnormal) 12600. |

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| | | For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments.<br><br>No concomitant and treatment medication was reported by patient.<br>No chronic diseases were reported by patient.<br><br>On 3 nov 2021 it was reported that Anti-PF4 test was submitted.<br>Patient was diagnosed with vaccine myocarditis, and was admitted to the ICU for treatment.<br><br>Company Comment : This case concerns a 23-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) with no relevant medical history who experienced the serious expected event (AESI) of myocarditis one day after the second dose of the vaccine. Rechallenge is not applicable, since no further dosing is expected. The benefit-risk relationship is not affected by this report |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number 4.1(b) ) on 12-Nov-2021 and was forwarded to Moderna on 12-Nov-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of PERICARDITIS (Pericarditis) in a 33-year-old male patient who received mRNA-1273 (COVID 19 Vaccine Moderna) for COVID-19 immunisation.<br><br>Previously administered products included for Product used for unknown indication: COVID-19 VACCINE MODERNA on 09-Jul-2021.<br>Past adverse reactions to the above products included No adverse event with COVID-19 VACCINE MODERNA.<br><br>On 13-Aug-2021, the patient received second dose of mRNA-1273 (COVID 19 Vaccine Moderna) (Intramuscular) 1 dosage form. On 14-Aug-2021, after starting mRNA-1273 (COVID 19 Vaccine Moderna), the patient experienced PERICARDITIS (Pericarditis) (seriousness criterion medically significant). At the time of the report, PERICARDITIS (Pericarditis) had not resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>In 2021, C-reactive protein: normal (normal) Normal Not elevated.<br>In 2021, Echocardiogram: abnormal (abnormal) Abnormal Without without pericardial effusion.<br>In 2021, Troponin I: normal (normal) Normal Not elevated.<br><br>For mRNA-1273 (COVID 19 Vaccine Moderna) (Intramuscular), the reporter did not provide any causality assessments.<br><br>Concomitant medications were not reported .<br>Treatment information was not provided.<br><br>Company comment: This case report received from EMA, concerns a 33 year-old male with a BMI of 27,7; whose medical history was not provided; who experienced the expected serious AESI event of Pericarditis 1 day after the second dose and 37 days after the first dose of |

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| | | mRNA-1273 vaccine. Troponin T and C-reactive protein were normal (not elevated). Echocardiography was abnormal but without pericardial effusion.<br>At the time of the report the event was not resolved.<br>The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 12-Nov-2021 and was forwarded to Moderna on 12-Nov-2021.<br>This regulatory authority case was reported by a consumer and describes the occurrence of CHEST PAIN (Chest pain) and MYOCARDITIS (Myopericarditis of viral origin) in a 38-year-old male patient who received mRNA-1273 (Spikevax) for Prophylactic vaccination. The occurrence of additional non-serious events is detailed below.<br><br>No Medical History information was reported.<br><br>On 23-Aug-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) .5 milliliter. On 19-Oct-2021 at 8:00 AM, the patient experienced DISCOMFORT (Discomfort) and PYREXIA (Pyrexia). On 21-Oct-2021, the patient experienced CHEST PAIN (Chest pain) (seriousness criterion hospitalization) and MYOCARDITIS (Myopericarditis of viral origin) (seriousness criterion hospitalization). At the time of the report, CHEST PAIN (Chest pain), DISCOMFORT (Discomfort) and PYREXIA (Pyrexia) outcome was unknown and MYOCARDITIS (Myopericarditis of viral origin) was resolving.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 19-Oct-2021, Body temperature: 39.4 39.4 degree Celsius.<br>On 21-Oct-2021, Angiocardiogram: no stenoses in coronary arteries No stenoses in coronary arteries.<br>On 21-Oct-2021, Electrocardiogram: sinus rhythm 63 bpm, intraventricular conduction d Sinus rhythm 63 BPM, intraventricular conduction delay, possible overexertion of left atrium, subepicardial lesion in upper and possibly - lateral wall of left ventricle.<br>On 23-Oct-2021, Troponin T: 983.8 983.8 ng/L (nanogram per litre).<br>On 24-Oct-2021, Electrocardiogram: sinus rhythm 68 bpm, impaired intraatrial conducti Sinus rhythm 68 BPM, impaired intraatrial conduction, in comparison with previous ECGs ST-elevation in lower and lateral leads is returning to isoline, T wave starting to become negative. Changes in ECG correspond with typical perimyocarditis signs.<br>On 25-Oct-2021, Electrocardiogram: sinus rhythm 61 bpm, ecg normal (normal) Sinus rhythm 61 BPM, ECG normal.<br>On 26-Oct-2021, Echocardiogram: echocardiogram was normal (normal) Echocardiogram was normal.<br><br>Concomitant product use was not provided by the reporter.<br>Treatment information was not provided.<br><br>Company comment: |

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| | | This regulatory case concerns a 38-year-old, male patient with no relevant medical history, who experienced the expected AESI of myocarditis and the unexpected, serious event of chest pain with other associated unexpected and expected, non-serious events. The events myocarditis and chest pain, which resulted in hospitalization, occurred approximately 1 month after administration of the second dose of the Moderna mRNA-1273. The unexpected and expected, non-serious events also occurred approximately 1 month after administration of the second dose of the Moderna mRNA-1273. Electrocardiogram (ECG) done on 21Oct2021 showed 'sinus rhythm, 63 beats/minute, intraventricular conduction delay, possible overexertion of left atrium, subepicardial lesion in upper and possibly lateral wall of left ventricle'. Repeat ECG done on 24Oct2021 showed 'sinus rhythm, 68 beats/minute, impaired intra-atrial conduction, in comparison with previous ECGs ST-elevation in lower and lateral leads is returning to isoline, T wave starting to become negative; changes in ECG correspond with typical perimyocarditis signs'. Final ECG done on 25Oct2021 showed 'normal results; sinus rhythm, 61 beats/minute'. The event myocarditis was resolving at the time of the report. Other laboratory tests done included Troponin T which showed increased results (983.8 ng/L). The Coronary Angiogram and Echocardiogram showed normal results. The outcome of the event chest pain was unknown at the time of the report. Treatment information was not provided. The outcomes of the non-serious events were likewise unknown at the time of the report. The rechallenge was not applicable as no additional dosing will be given. The patient's gender remains a confounder for the event of myocarditis. The benefit-risk relationship of the Moderna mRNA-1273 is not affected by this report. |
| 4.1(b) | 4.1(b) | This regulatory authority case was reported by a pharmacist and describes the occurrence of MYOCARDITIS (Perimyocarditis) in a 19-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 immunisation.<br><br>No Medical History information was reported.<br><br>On 13-Oct-2021, the patient received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) dosage was changed to 100 microgram.<br>On an unknown date, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 100 microgram. On 15-Oct-2021, after starting mRNA-1273 (COVID-19 Vaccine Moderna), the patient experienced MYOCARDITIS (Perimyocarditis) (seriousness criteria hospitalization and medically significant). The patient was hospitalized on 16-Oct-2021 due to MYOCARDITIS. At the time of the report, MYOCARDITIS (Perimyocarditis) was resolving.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 17-Oct-2021, Blood creatine phosphokinase: 397 u/l (High) Elevated.<br>On 17-Oct-2021, C-reactive protein increased: 27 mg/dl (High) Elevated.<br>On 17-Oct-2021, Echocardiogram: normal (normal) Normal pumping function of the heart with unremarkable wall motion; no pericardial effusion was found..<br>On 17-Oct-2021, Electrocardiogram: abnormal (abnormal) revealed discrete ST elevations in leads V5, V6, and II.. |

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| | | On 17-Oct-2021, N-terminal prohormone brain natriuretic peptide: 1098 nanogram per litre (High) Increased.<br>On 17-Oct-2021, Troponin: 439 microgram per litre (High) Elevated.<br>On 17-Oct-2021, White blood cell count: 9 gram per litre (normal) normal.<br><br>For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered MYOCARDITIS (Perimyocarditis) to be possibly related.<br><br>No concomitant medications were reported.<br><br>On 15-Oct-2021, the patient felt stabbing and pressure pain in his left chest, radiating to his back. Since the night before administration, the stabbing pain intensified and had become much stronger (to VAS 7/10), the pain had not been provoked. Treatment with Ponstan (mefenamic acid, dose unknown) helped only slightly. The next day, the patient presented to an emergency department and was hospitalized. Patient presented in good general and nutritional condition. He was hemodynamically stable and afebrile (HR 119/78 mmHg, P 74/min, T 36.8°C, SpO2 99%). There was an increase in heart rate to 110/min on mild exertion (standing up). Auscultation revealed a "crackle" in the right upper lobe, otherwise vesicular breath sounds in the remaining lung fields. Cardiac action was rhythmic, heart sounds pure, peripheral pulses palpable on all sides. There was no peripheral edema, no neck venous congestion. In addition, a macular red exanthema at the level of the clavicles was noticed. The remaining status was unremarkable according to age. This was interpreted as an adverse effect of Spikevax vaccination. A therapy with NSAIDs (substance, commercial preparation and dosage unknown) was started, under which the symptoms rapidly regressed. Cardiopulmonary monitoring was always unremarkable, and evidence of cardiac arrhythmia was not evident on telemetric monitoring.<br><br>Company Comment:<br>This case concerns a 19-year-old, female patient with no relevant medical history, who experienced the expected event of myocarditis, which required hospitalization. Since the night before administration, the stabbing pain intensified and had become much stronger (to VAS 7/10), the pain had not been provoked. The event occurred approximately 2 days after the second dose of mRNA-1273. The patient was hospitalized and electrocardiogram revealed discrete ST elevations in leads V5, V6, and II and troponin was high....Continued in company comment.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 12-Nov-2021: Translated document received on 15-NOV-2021 contains updated event verbatim, lab data and narrative. |
| 4.1(b) | 4.1(b) | This case was received via 4.1(b) Reference number: 4.1(b) ) on 12-Nov-2021 and was forwarded to Moderna on 12-Nov-2021.<br>This regulatory authority case was reported by a consumer and describes the occurrence of FATIGUE (Fatigue/unusual tiredness), CHEST PAIN (Chest pain), DYSPNOEA (Shortness of breath), PALPITATIONS (Heart palpitations), TACHYCARDIA (Racing heart (tachycardia)), COLD SWEAT (clammy), MALAISE (generally unwell), ILLNESS (sickness), PERICARDITIS (Pericarditis) and MYOCARDITIS (Myocarditis) in a 24- |

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| | | year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 29-Jul-2021, the patient received first dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form.<br>On 02-Nov-2021, received second dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 02-Nov-2021, the patient experienced FATIGUE (Fatigue/unusual tiredness) (seriousness criteria hospitalization, disability, medically significant and life threatening) and MALAISE (generally unwell) (seriousness criteria hospitalization, disability, medically significant and life threatening). On 03-Nov-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization, disability, medically significant and life threatening). On 04-Nov-2021, the patient experienced CHEST PAIN (Chest pain) (seriousness criteria hospitalization, disability, medically significant and life threatening), DYSPNOEA (Shortness of breath) (seriousness criteria hospitalization, disability, medically significant and life threatening), COLD SWEAT (clammy) (seriousness criteria hospitalization, disability, medically significant and life threatening) and ILLNESS (sickness) (seriousness criteria hospitalization, disability, medically significant and life threatening). On an unknown date, the patient experienced PALPITATIONS (Heart palpitations) (seriousness criteria hospitalization, disability, medically significant and life threatening), TACHYCARDIA (Racing heart (tachycardia)) (seriousness criteria hospitalization, disability, medically significant and life threatening) and PERICARDITIS (Pericarditis) (seriousness criteria hospitalization, disability, medically significant and life threatening). The patient was hospitalized for 5 days due to CHEST PAIN, COLD SWEAT, DYSPNOEA, FATIGUE, ILLNESS, MALAISE, MYOCARDITIS, PALPITATIONS, PERICARDITIS and TACHYCARDIA. At the time of the report, FATIGUE (Fatigue/unusual tiredness), CHEST PAIN (Chest pain), DYSPNOEA (Shortness of breath), PALPITATIONS (Heart palpitations), TACHYCARDIA (Racing heart (tachycardia)) and PERICARDITIS (Pericarditis) outcome was unknown, COLD SWEAT (clammy), MALAISE (generally unwell) and ILLNESS (sickness) had resolved and MYOCARDITIS (Myocarditis) was resolving.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 04-Nov-2021, SARS-CoV-2 test: no - negative covid-19 test (Negative) No - Negative COVID-19 test.<br>In November 2021, Blood test: 178 (High) Raised troponin 178, Troponin reference range 0-14.<br>In November 2021, Electrocardiogram: presented as a heart attack presented as a heart attack.<br><br>Patient attended Accident and Emergency, blood test taken and ECG, scan results presented as a heart attack. Patient was admitted to hospital with Myocarditis and Pericarditis. In hospital for 5 days. Awaiting MRI and ECHO and further blood tests. |

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| | | The diagnosis was made by a Cardiologist.<br><br>Treatment included paracetamol and unspecified medication. Discharged with medication Bisoprolol and Ramipril.<br><br>Concomitant product use was not provided by the reporter.<br><br>Company Comment: This case concerns a 24-year-old male patient with no relevant medical history reported who experienced the unexpected and serious events of cold sweat, malaise, illness, fatigue, chest pain, dyspnoea, palpitations, tachycardia and the expected and AESI events of myocarditis and pericarditis. The events malaise and fatigue occurred the same day after the second dose of mRNA-1273 vaccine was administered, the event myocarditis the following day, the events cold sweats, illness and dyspnoea two days after and the rest of the events on an unknown day after vaccine was given. The rechallenge was not applicable as the events occurred after the second dose. Patient attended Accident and Emergency, blood test was taken (troponin was high 178 (0-14) and ECG, scan results presented as a heart attack. Patient was admitted to hospital due to myocarditis and pericarditis. He stayed in hospital for 5 days. Treatment included paracetamol and was discharged with bisoprolol and ramipril. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. |
| 4.1(b) | 4.1(b) | This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Perimyocarditis) in a 39-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) (batch nos. 3002912 and 3002186) for COVID-19 immunisation.<br><br>The patient's past medical history included Neuroborreliosis in September 2019.<br><br>On 26-May-2021, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form.<br>On 23-Jun-2021, received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) dosage was changed to 1 dosage form. On 26-Jun-2021, after starting mRNA-1273 (COVID-19 Vaccine Moderna), the patient experienced MYOCARDITIS (Perimyocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Perimyocarditis) outcome was unknown.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 26-Jun-2021, Blood creatine phosphokinase (Unknown-<190): 266 (High) 266 U/l.<br>On 26-Jun-2021, Troponin I (Unknown-<100): 3453 (High) 3453 ng/l.<br>On 29-Jun-2021, Blood creatine phosphokinase (Unknown-<190): 80 (normal) 80 U/l.<br>On 29-Jun-2021, Troponin I (Unknown-<100): 600 (High) 600 ng/l.<br><br>For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered MYOCARDITIS (Perimyocarditis) to be possibly related.<br><br>On 26-Jun-2021, patient suffered thoracic pain and was hospitalized. |

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| | | On an unknown date, tests showed elevation of ST segment, increased creatinine kinase (268 U/L) and coronary angiography was normal. Concomitant medications were not reported.<br>Treatment included Irfen (Ibuprofen), Listril (Lisinopril), Metoprolol (exact preparation not known), Acetaminophen (exact preparation not known) and Pantoprazole (exact preparation not known). Patient showed good response.<br>On 29-Jun-2021, patient was discharged from hospital.<br><br>Company comment: This case concerns a 39-year-old, male patient with no relevant medical history, who experienced the serious expected AESI of Myocarditis. The event occurred 3 days after the second dose of mRNA-1273 vaccine. The lab information of increase in Blood creatine phosphokinase, and Troponin I and ST segment elevation support the diagnosis. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Event seriousness assessed as per Regulatory Authority reporting and retained for consistency with the RA report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 15-Nov-2021: Translated document received on 17-NOV-2021. Updated case narrative and event verbatim. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 16-Nov-2021 and was forwarded to Moderna on 16-Nov-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Acute myocarditis) in a 23-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3005242) for COVID-19 vaccination.<br><br>The patient's past medical history included Edema Quincke's (Quincke's edema due to Amoxicillin Paralysis of right UL<br>after H1N1 vaccine without sequelae.) and Right sided paralysis (after H1N1 vaccine).<br><br>On 31-Aug-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 02-Sep-2021, the patient experienced MYOCARDITIS (Acute myocarditis) (seriousness criterion hospitalization). At the time of the report, MYOCARDITIS (Acute myocarditis) had resolved.<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.<br><br>Concomitant medication was not provided.<br><br>Treatment information was not provided.<br><br>Company comment: This case concerns a 23-year-old male patient with no relevant medical history, who experienced serious expected AESI of Myocarditis. The event occurred two days after the second dose of mRNA-1273. The rechallenge was not applicable as the event occurred after the second dose of the vaccine. The benefit risk relationship of mRNA-1273 is not affected by this report. |

| Case ID | WW Identifier | Narrative |
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| | | Most recent FOLLOW-UP information incorporated above includes: On 16-Nov-2021: Translated document received on 17-Nov-2021, included Relevant medical histroy translated. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 16-Nov-2021 and was forwarded to Moderna on 16-Nov-2021.<br>This regulatory authority case was reported by a consumer and describes the occurrence of PERICARDITIS (Acute pericarditis after administration of the second dose of the Moderna vaccine) in a 21-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 214019) for COVID-19 immunisation.<br><br>No Medical History information was reported.<br><br>On 12-Aug-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to .5 milliliter in total. On an unknown date, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 13-Aug-2021, after starting mRNA-1273 (Spikevax), the patient experienced PERICARDITIS (Acute pericarditis after administration of the second dose of the Moderna vaccine). At the time of the report, PERICARDITIS (Acute pericarditis after administration of the second dose of the Moderna vaccine) had not resolved.<br><br>No concomitant medication reported.<br><br>No treatment information was provided.<br><br>The 1st dose was administered on 01Jul2021 with batch no. 214003.<br><br>Company Comment: This regulatory case concerns a 21-year-old, female patient with no relevant medical history, who experienced the expected AESI of pericarditis.The event occurred 1 day after administration of the second dose of the Moderna mRNA-1273. The rechallenge was not applicable as no additional dosing will be given. The benefit-risk relationship of the Moderna mRNA-1273 is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes: On 16-Nov-2021: Translation document received on 17 NOV 2021 include- Dose details from Sender's comments and Event Verbatim. |
| 4.1(b) | 4.1(b) | This case was received via 4.1(b) (Reference number: 4.1(b) on 16-Nov-2021 and was forwarded to Moderna on 16-Nov-2021.<br>This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCARDITIS (Myocarditis) in a 36-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 062E21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below.<br><br>No Medical History information was reported. |

| Case ID | WW Identifier | Narrative |
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| | | On 28-Oct-2021, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 30-Oct-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criterion medically significant), C-REACTIVE PROTEIN INCREASED (C-reactive protein increased), CHEST PAIN (Chest pain), ECHOCARDIOGRAM (Echocardiogram) and PAIN (Pain). At the time of the report, MYOCARDITIS (Myocarditis), C-REACTIVE PROTEIN INCREASED (C-reactive protein increased), CHEST PAIN (Chest pain), ECHOCARDIOGRAM (Echocardiogram) and PAIN (Pain) had not resolved.<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments.<br><br>Med Hist: Allergic rhinitis, PCOS, constipation, BMI 27.<br><br>Lab Data: Elevated cardiac CRP, echocardiogram.<br><br>Patient has dull constant chest pain and increased cardiac CRP level.<br><br>No Treatment medication was reported.<br><br>Other medications included Singulair, Zyrtec, PNV, Flonase, magnesium, vitamin D, Colace, 4.1(b) low dose metformin.<br><br>Company Comment:<br>This case concerns a 36-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) with no relevant medical history who experienced the serious expected event (AESI) of myocarditis after the third dose of the vaccine. Rechallenge is not applicable, since no further dosing is expected. The benefit-risk relationship is not affected by this report |
| 4.1(b) | 4.1(b) | This case was received via 4.1(b) (Reference number: 4.1(b) on 16-Nov-2021 and was forwarded to Moderna on 16-Nov-2021.<br>This regulatory authority case was reported by an other health care professional and describes the occurrence of BLOOD TEST ABNORMAL (Blood test abnormal), CARDIAC MONITORING (Cardiac monitoring), CHEST X-RAY NORMAL (Chest X-ray normal), CHEST DISCOMFORT (Chest discomfort), CHEST PAIN (Chest pain), DYSPNOEA (Dyspnoea), ELECTROCARDIOGRAM (Electrocardiogram), HYPOPNOEA (Hypopnoea), MONOCYTE COUNT INCREASED (Monocyte count increased), NEUTROPHIL COUNT INCREASED (Neutrophil count increased), PAINFUL RESPIRATION (Painful respiration), RESPIRATORY VIRAL PANEL (Respiratory viral panel), TROPONIN INCREASED (Troponin increased), WHITE BLOOD CELL COUNT INCREASED (White blood cell count increased) and MYOCARDITIS (Myocarditis) in a 25-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 939904 and 078C21A) for COVID-19 vaccination.<br><br>No Medical History information was reported. |

| Case ID | WW Identifier | Narrative |
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| | | On 01-Oct-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form.<br>On 01-Oct-2021, received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 02-Oct-2021, the patient experienced BLOOD TEST ABNORMAL (Blood test abnormal) (seriousness criteria hospitalization and life threatening), CARDIAC MONITORING (Cardiac monitoring) (seriousness criteria hospitalization and life threatening), CHEST X-RAY NORMAL (Chest X-ray normal) (seriousness criteria hospitalization and life threatening), CHEST DISCOMFORT (Chest discomfort) (seriousness criteria hospitalization and life threatening), CHEST PAIN (Chest pain) (seriousness criteria hospitalization and life threatening), DYSPNOEA (Dyspnoea) (seriousness criteria hospitalization and life threatening), ELECTROCARDIOGRAM (Electrocardiogram) (seriousness criteria hospitalization and life threatening), HYPOPNOEA (Hypopnoea) (seriousness criteria hospitalization and life threatening), MONOCYTE COUNT INCREASED (Monocyte count increased) (seriousness criteria hospitalization and life threatening), NEUTROPHIL COUNT INCREASED (Neutrophil count increased) (seriousness criteria hospitalization and life threatening), PAINFUL RESPIRATION (Painful respiration) (seriousness criteria hospitalization and life threatening), RESPIRATORY VIRAL PANEL (Respiratory viral panel) (seriousness criteria hospitalization and life threatening), TROPONIN INCREASED (Troponin increased) (seriousness criteria hospitalization and life threatening), WHITE BLOOD CELL COUNT INCREASED (White blood cell count increased) (seriousness criteria hospitalization and life threatening) and MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization, medically significant and life threatening). At the time of the report, BLOOD TEST ABNORMAL (Blood test abnormal), CARDIAC MONITORING (Cardiac monitoring), CHEST X-RAY NORMAL (Chest X-ray normal), CHEST DISCOMFORT (Chest discomfort), CHEST PAIN (Chest pain), DYSPNOEA (Dyspnoea), ELECTROCARDIOGRAM (Electrocardiogram), HYPOPNOEA (Hypopnoea), MONOCYTE COUNT INCREASED (Monocyte count increased), NEUTROPHIL COUNT INCREASED (Neutrophil count increased), PAINFUL RESPIRATION (Painful respiration), RESPIRATORY VIRAL PANEL (Respiratory viral panel), TROPONIN INCREASED (Troponin increased), WHITE BLOOD CELL COUNT INCREASED (White blood cell count increased) and MYOCARDITIS (Myocarditis) had not resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 02-Oct-2021, Chest X-ray: normal (normal) Normal.<br>On 02-Oct-2021, Monocyte count (0.2-1.0): 2.6 (High) MONOCYTES ELEVATED AT 2.6 (RANGE .2-1.0).<br>On 02-Oct-2021, Neutrophil count (0.00-0.04): 0.06 (High) IMMATURE NEUTROPHILS ELEVATED .06 (RANGE .00-.04).<br>On 02-Oct-2021, Troponin: 176 (High) WITH A SECOND 2 HOUR TROPONIN ADDITIONALLY ELEVATED AT 176 and 159 (High) BLOODWORK RESULTS SHOWED AN ELEVATED TROPONIN AT 159(OVER 22 IS POSITIVE.).<br>On 02-Oct-2021, White blood cell count (1.1-6.1): 16.1 (High) WBC BLOODWORK SHOWED ELEVATED AT 16.1 (RANGE 1.1-6.1). |

| Case ID | WW Identifier | Narrative |
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| | | For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments.<br><br>No concomitant medication was given.<br>Patient had to take shallow breaths due to pain in chest when a normal breath is taken<br>Laboratory data was mentioned as patient done respiratory panel and EKG in ED but results was not given.<br>As doctor suspect patient have myocarditis heart acho scheduled for tomorrow.<br>No treatment medication was given.<br>The patient presented to ED with chest pain, tightness and shortness of breath after receiving second covid shot 2 days ago. Patient had shallow breaths due to pain in chest when a normal breath is taken. The patient had bloodwork, respiratory panel, ekg, xray completed with bloodwork results showing an elevated troponin at 159(over 22 is positive.) with a second 2 hour troponin additionally elevated at 176. Impression from xray shows normal chest xray but findings reported image was obscured by overlying wires from heart monitor. WBC bloodwork showed elevated at 16.1 (range 1.1-6.1) monocytes elevated at 2.6 (range .2-1.0) immature neutrophils elevated 0.06 (range .00-.04) MD suspected myocarditis and the patient was admitted with no communicated discharge date until echo results.<br><br>Company Comment:<br>This case concerns a 25-year-old, male patient with no relevant medical history, who experienced the unexpected events of Blood test abnormal, Cardiac monitoring, Chest X-ray normal, Chest discomfort, Dyspnoea, Electrocardiogram, Hypopnoea, Monocyte count increased, Neutrophil count increased, Painful respiration, Respiratory viral panel, Troponin increased, White blood cell count increased and expected event of Myocarditis. The events occurred approximately 1 day after the second dose of mRNA-1273. It was reported that both first and second dose was administered on the same date, which seems unlikely. The patient presented to ED with chest pain, tightness and shortness of breath after receiving second covid shot 2 days<br>….. continued in company comment section. |
| 4.1(b) | 4.1(b) | This case was initially received via 4.1(b) (Reference number: 4.1(b) ) on 16-Nov-2021. The most recent information was received on 18-Nov-2021 and was forwarded to Moderna on 18-Nov-2021.<br>This regulatory authority case was reported by a consumer and describes the occurrence of ERECTILE DYSFUNCTION (Erection failure), URINARY RETENTION (Unable to urinate), HEART RATE (Heart rate), TACHYCARDIA (Racing heart), EJECTION FRACTION DECREASED (Ejection fraction low), HYPERHIDROSIS (Excess sweating), PARAESTHESIA (Tingling sensation), NIGHT SWEATS (excessive sweating), DYSPNOEA (Short of breathe), ARTHRALGIA (painful chest), PAIN (shooting pain), FATIGUE (Fatigue/unusual tiredness), CHEST PAIN (painful chest), PYREXIA (Fever), DYSPNOEA (Shortness of breath), PALPITATIONS (Heart palpitations), INCOHERENT (Incoherent), TACHYCARDIA (Tachycardia), HYPERHIDROSIS (Excess sweating ), FATIGUE (Fatigue) and MYOCARDITIS (Myocarditis) in a 29-year-old |

| Case ID | WW Identifier | Narrative |
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| | | male patient who received mRNA-1273 (COVID 19 Vaccine Moderna) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br><br>On 17-Sep-2021, the patient received second dose of mRNA-1273 (COVID 19 Vaccine Moderna) (unknown route) 1 dosage form. On 19-Sep-2021, the patient experienced ERECTILE DYSFUNCTION (Erection failure) (seriousness criterion hospitalization), URINARY RETENTION (Unable to urinate) (seriousness criterion hospitalization), HEART RATE (Heart rate) (seriousness criterion hospitalization), EJECTION FRACTION DECREASED (Ejection fraction low) (seriousness criterion hospitalization), HYPERHIDROSIS (Excess sweating) (seriousness criterion hospitalization), PARAESTHESIA (Tingling sensation) (seriousness criterion hospitalization), INCOHERENT (Incoherent) (seriousness criterion hospitalization) and MYOCARDITIS (Myocarditis) (seriousness criterion hospitalization). 19-Sep-2021, the patient experienced HYPERHIDROSIS (Excess sweating ) (seriousness criterion hospitalization) and FATIGUE (Fatigue) (seriousness criterion hospitalization). On 19-Oct-2021, the patient experienced TACHYCARDIA (Racing heart) (seriousness criterion hospitalization). 19-Oct-2021, the patient experienced TACHYCARDIA (Tachycardia) (seriousness criterion hospitalization). On an unknown date, the patient experienced NIGHT SWEATS (excessive sweating) (seriousness criterion hospitalization), DYSPNOEA (Short of breathe) (seriousness criterion hospitalization), ARTHRALGIA (painful chest) (seriousness criterion hospitalization), PAIN (shooting pain) (seriousness criterion hospitalization), FATIGUE (Fatigue/unusual tiredness) (seriousness criterion hospitalization), CHEST PAIN (painful chest) (seriousness criterion hospitalization), PYREXIA (Fever) (seriousness criterion hospitalization), DYSPNOEA (Shortness of breath) (seriousness criterion hospitalization) and PALPITATIONS (Heart palpitations) (seriousness criterion hospitalization). At the time of the report, ERECTILE DYSFUNCTION (Erection failure), URINARY RETENTION (Unable to urinate), HEART RATE (Heart rate), TACHYCARDIA (Racing heart), EJECTION FRACTION DECREASED (Ejection fraction low), HYPERHIDROSIS (Excess sweating), PARAESTHESIA (Tingling sensation), TACHYCARDIA (Tachycardia), HYPERHIDROSIS (Excess sweating ) and MYOCARDITIS (Myocarditis) had not resolved, NIGHT SWEATS (excessive sweating), DYSPNOEA (Short of breathe), ARTHRALGIA (painful chest), PAIN (shooting pain), FATIGUE (Fatigue/unusual tiredness), CHEST PAIN (painful chest), PYREXIA (Fever), DYSPNOEA (Shortness of breath) and PALPITATIONS (Heart palpitations) outcome was unknown and INCOHERENT (Incoherent) and FATIGUE (Fatigue) was resolving.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On an unknown date, Ejection fraction: 47 percent (Low) 47 percent.<br>On an unknown date, SARS-CoV-2 test: negative (Negative) Negative.<br>On an unknown date, Troponin: raised (High) raised. |

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| | | The action taken with mRNA-1273 (COVID 19 Vaccine Moderna) (Unknown) was unknown.<br><br>Patient had shooting pain through the heart, Increased heart rate, unable to think clearly, unable to urinate without focusing, extreme tiredness and tingling sensation across his head and neck frequently.<br>No concomitant drugs were provided.<br>Patient underwent ECG, echocardiogram, 24 hour heart holter test, blood tests and the results were not provided.<br>Patient referred to cardiologist. Cardiologist diagnosed regional myocarditis and LVEF in his heart working at 47% due to inflammation on his heart. Patient was hospitalized for 2 days<br>Treatment medication reported included Ramparil and biosoprolol. More tests were pending<br>Patient underwent troponin test ,which were raised.<br><br>This case concerns a 29 year-old male patient with no reported medical history, who experienced the expected serious AESI of Myocarditis, and the unexpected serious events of Tachycardia, Ejection fraction decreased, Chest pain, Dyspnoea, and Pyrexia. The events of Myocarditis with Ejection fraction decreased occurred 2 days after the second dose of mRNA-1273 vaccine, the event of Tachycardia occurred 32 days after the second dose, and the events of Chest pain, Dyspnoea, and Pyrexia occurred an unknown number of days after the second dose.Troponin levels were found raised. Patient reported evaluation with ECG, echocardiogram, 24 hr Holter, but results were not provided. Additional information is not expected for this RA case. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes: On 18-Nov-2021: Follow-up received on 18-NOV-2021 contains significant information- Lab data updated. |
| 4.1(b) [redacted] | 4.1(b) [redacted] | This case was received via 4.1(b) [redacted] (Reference number: 4.1(b) ) on 16-Nov-2021 and was forwarded to Moderna on 16-Nov-2021.<br>This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCARDITIS (Myocarditis) in a 38-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 80777-0273-15) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 29-Oct-2021, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 30-Oct-2021, after starting mRNA-1273 (Moderna COVID-19 Vaccine), the patient experienced MYOCARDITIS (Myocarditis) (seriousness criterion medically significant). At the time of the report, MYOCARDITIS (Myocarditis) had resolved. |

| Case ID | WW Identifier | Narrative |
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| | | For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments.<br><br>No concomitant medications were reported.<br>No treatment details were reported.<br><br>Patient reported myocarditis-like symptoms.<br><br>Company comment: This case concerns a 38-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) with no relevant medical history who experienced the serious expected event (AESI) of myocarditis one day after the third dose of the vaccine. Rechallenge is not applicable, since no further dosing is expected. The benefit-risk relationship is not affected by this report. |
| 4.1(b) | 4.1(b) | This case was initially received via Takeda Pharmaceuticals (Reference number: 4.1(b) ) on 10-Nov-2021. The most recent information was received on 10-Nov-2021 and was forwarded to Moderna on 24-Nov-2021.<br><br>This case, initially reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref, 4.1(b)<br><br>On 10-Nov-2021, this case, as follow-up information, reported by a vaccinator other than a physician, was received by Takeda via Moderna's adverse reaction reporting site (4.1(b) and this case, initially reported to the 4.1(b) by a vaccinator other than a physician, was received via the 4.1(b) (Ref, 4.1(b)<br><br>On an unknown date, the patient received the 1st dose of this vaccine.<br><br>On 07-Nov-2021, at 14:00, the patient received the 2nd dose of this vaccine. Pyrexia developed at night. Pyrexia did not subside with oral administration of acetaminophen.<br><br>On 09-Nov-2021, pyrexia persisted, and in the morning, the patient experienced chest pain for about one hour. At 13:30, the patient visited the reporting hospital and was hospitalized. ST elevation was observed in the electrocardiogram. Blood test showed WBC: 9,450, CPR: 5.77, AST: 72, ALT: 28, LDH: 247, CK: 804, CK-MB: 35.7, myoglobin: 233, and troponin I: 17.8. Elevated cardiac enzymes were observed. Cardiac ultrasound showed diffuse hypokinesis of the left ventricular wall with EF of approximately 50%. The patient was transferred to another hospital with a diagnosis of myocarditis.<br><br>On an unknown date, electrocardiogram showed widespread ST, CK, and CK-MB elevation; thus, acute myocarditis could not be ruled out. The patient was therefore hospitalized for follow-up and detailed examinations. Currently, the symptoms subsided.<br><br>The outcome of myocarditis was reported as ongoing and unchanged.<br><br>Follow-up investigation will be made. |

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| | | Follow-up received on 10-NOV-2021<br><br>Updated: Reporter Information, Patient Information, Other Relevant History, Lab Data, Product Information, Narrative<br><br>Company Comment:<br><br>The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. |
| 4.1(b) | 4.1(b) | This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 10-Nov-2021 and was forwarded to Moderna on 17-Nov-2021.<br>This case, initially reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref, 4.1(b)<br><br>Myocarditis was assessed as serious by the MAH.<br><br>On 21-Sep-2021, at 14:30, the patient received the 1st dose of this vaccine.<br><br>On unknown date, Myalgia and pyrexia developed.<br><br>On 19-Oct-2021, at 11:00, the patient received the 2nd dose of this vaccine.<br><br>On 20-Oct-2021, myocarditis developed. Chest discomfort, chest pain, breathlessness, and the like developed.<br><br>On 22-Oct-2021, as the symptoms were persisting, the patient visited a nearby hospital. The patient was referred to the reporting department because of positive TnT. Myocardial enzymes were positive with CK 279 U/L, CK-MB 28 U/L, TnT 0.30 pg/mL-MB 28 U/L, and TnT 0.30 pg/mL, and CRP was weakly positive at 1.19 mg/dL. Cardiac function slightly decreased to LVEF 50%, but there were no signs of heart failure. The myocarditis was suspected to be due to this vaccine, but there were almost no serious cases in the previous reports, and the patient was thus followed up at home.<br><br>On 01-Nov-2021, the patient visited the hospital again. Myocardial enzymes became negative, LVEF normalized, and the symptoms resolved, and the treatment was terminated.<br><br>The outcome of myalgia and pyrexia was unknown. The outcome of myocarditis was reported as resolved.<br><br>Follow-up investigation will be made.<br><br>Company Comment:<br><br>The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. |
| 4.1(b) | 4.1(b) | This case was received via 4.1(b) (Reference number: 4.1(b) on 16-Nov-2021 and was forwarded to Moderna on 16-Nov-2021. |

| Case ID | WW Identifier | Narrative |
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| | 4.1(b) | This regulatory authority case was reported by an other health care professional and describes the occurrence of ARTHRALGIA (Arthralgia), CHILLS (Chills), EYE PAIN (Eye pain), HEADACHE (Headache), MYALGIA (Myalgia), PYREXIA (Pyrexia), TROPONIN INCREASED (Troponin increased) and MYOCARDITIS (Myocarditis) in a 20-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 13-Jun-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form.<br>On 13-Jun-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 07-Jul-2021, the patient experienced ARTHRALGIA (Arthralgia) (seriousness criterion hospitalization), CHILLS (Chills) (seriousness criterion hospitalization), EYE PAIN (Eye pain) (seriousness criterion hospitalization), HEADACHE (Headache) (seriousness criterion hospitalization), MYALGIA (Myalgia) (seriousness criterion hospitalization), PYREXIA (Pyrexia) (seriousness criterion hospitalization), TROPONIN INCREASED (Troponin increased) (seriousness criterion hospitalization) and MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, ARTHRALGIA (Arthralgia), CHILLS (Chills), EYE PAIN (Eye pain), HEADACHE (Headache), MYALGIA (Myalgia), PYREXIA (Pyrexia), TROPONIN INCREASED (Troponin increased) and MYOCARDITIS (Myocarditis) outcome was unknown.<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments.<br><br>No concomitant medications were reported.<br><br>Patient developed fever, myalgia, headache, chills, joint pain, and pain behind the eye following recent travel and 20 days post second dose of Moderna vaccine. Troponin of 0.44/high, Troponin 507.94. Patient was managed for a broad differential including Myocarditis (viral vs. COVID vaccine) and received Vancomycin, Unasyn, Doxycycline, Ibuprofen and colchicine. Patient was currently stable and discharged after 3 days of admission.<br><br>Company Comment:<br>This case concerns a 20-years-old patient, with no relevant medical history reported, who experienced the serious expected event of MYOCARDITIS and the unexpected events of ARTHRALGIA, CHILLS, EYE PAIN, HEADACHE, MYALGIA and PYREXIA. The events occurred twenty-four days after the dose of the mRNA-1273 vaccine. The rechallenge was not applicable since the administration date for both doses was reported as the same. The benefit-risk relationship of the mRNA-1273 is not affected by this report. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 17-Nov-2021 and was forwarded to Moderna on 17-Nov-2021. |

| Case ID | WW Identifier | Narrative |
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| | | This regulatory authority case was reported by a physician and describes the occurrence of NAUSEA (Nausea that lasted a day), DYSPNOEA (Woke up with Dyspnoea. Later the dyspnoea was only exertional and not at rest), CHILLS (Chills), DIZZINESS (Little dizzy after emerged chest pain), CHEST PAIN (Woke up with acute chest pain. Pressure-like pain over breastbone radiating to left arm was experienced. The Chest pain was aggravated by breathing and when the patient was in standing position), VOMITING (Vomiting that lasted a day), PYREXIA (Fever) and MYOCARDITIS (Myocarditis) in a 30-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 immunisation.<br><br>Previously administered products included for COVID-19 immunisation: COVID-19 VACCINE MODERNA in 2021.<br>Past adverse reactions to the above products included No adverse reaction with COVID-19 VACCINE MODERNA.<br><br>On 08-Oct-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 13-Oct-2021, the patient experienced DYSPNOEA (Woke up with Dyspnoea. Later the dyspnoea was only exertional and not at rest) (seriousness criterion hospitalization), CHEST PAIN (Woke up with acute chest pain. Pressure-like pain over breastbone radiating to left arm was experienced. The Chest pain was aggravated by breathing and when the patient was in standing position) (seriousness criterion hospitalization) and MYOCARDITIS (Myocarditis) (seriousness criterion hospitalization). In October 2021, the patient experienced NAUSEA (Nausea that lasted a day) (seriousness criterion hospitalization), CHILLS (Chills) (seriousness criterion hospitalization), DIZZINESS (Little dizzy after emerged chest pain) (seriousness criterion hospitalization), VOMITING (Vomiting that lasted a day) (seriousness criterion hospitalization) and PYREXIA (Fever) (seriousness criterion hospitalization). In October 2021, NAUSEA (Nausea that lasted a day) and VOMITING (Vomiting that lasted a day) had resolved. At the time of the report, DYSPNOEA (Woke up with Dyspnoea. Later the dyspnoea was only exertional and not at rest), CHILLS (Chills), DIZZINESS (Little dizzy after emerged chest pain), CHEST PAIN (Woke up with acute chest pain. Pressure-like pain over breastbone radiating to left arm was experienced. The Chest pain was aggravated by breathing and when the patient was in standing position) and PYREXIA (Fever) outcome was unknown and MYOCARDITIS (Myocarditis) was resolving.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 13-Oct-2021, Auscultation: normal (normal) Regular heart rhythm and no murmurs.<br>On 13-Oct-2021, Blood pressure measurement: 121/72 (normal) 121/72 mmHg.<br>On 13-Oct-2021, Electrocardiogram: normal (normal) No signs of ischemia. Regular sinus rhythm and frequency of 71 Beats per minute.<br>On 13-Oct-2021, Fibrin D dimer: < 0.3 (normal) < 0.3 Unit not specified.<br>On 13-Oct-2021, Heart rate: 75 (normal) 75 Beats per minute.<br>On 13-Oct-2021, International normalised ratio: 1.0 (normal) 1.0 Unit not specified.<br>On 13-Oct-2021, Oxygen saturation: 98 (normal) 98 percent. |

| Case ID | WW Identifier | Narrative |
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| | | On 13-Oct-2021, Physical examination: normal (normal) Do not seem acutely or chronically affected. Do not seem pain affected.<br>On 13-Oct-2021, Respiratory rate: 16 (normal) 16 Breaths per minute.<br>On 13-Oct-2021, Troponin T: 281 (High) 281 Unit not specified.<br>In October 2021, Computerised tomogram: abnormal (abnormal) with heterogenous charge supporting myocarditis and normal (normal) Of heart, no cardiac sclerosis or stenosis.<br>In October 2021, Electrocardiogram: normal (normal) No EKG changes during the hospitalisation.<br>In October 2021, Troponin T: 529 (High) Maximum measured value of 529 Unit not specified.<br>On 18-Oct-2021, Troponin T: low (Low) Immeasurable low.<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.<br><br>No concomitant medication reported. No Treatment Medication reported.<br><br>On 13-OCT-2021, patient went for Blood test with unknown result<br><br>Company comment: This case concerns a 30-year-old male patient, with no reported relevant medical history, who experienced the unexpected serious events of NAUSEA, DYSPNOEA, CHILLS, DIZZINESS, CHEST PAIN, VOMITING, PYREXIA and MYOCARDITIS (AESI). The events occurred approximately 6 days after the administration of the second dose of mRNA-1273 Vaccine. The rechallenge was not applicable. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report. |
| 4.1(b) | 4.1(b) | This spontaneous case was reported by a consumer and describes the occurrence of ARRHYTHMIA (irregular heart rhythm continues /Heart palpitations), PERICARDIAL EFFUSION (Fluid around heart muscle), VENTRICULAR EXTRASYSTOLES (Sporadic PVCs), VENTRICULAR TACHYCARDIA (Ventricular Tachycardia) and MYOCARDITIS (myocarditis/pain felt deep, into his lungs) in a 22-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 02SB21A and 003C21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below.<br><br>No medical history was provided.<br><br>On 02-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form.<br>On 30-Apr-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 01-May-2021, the patient experienced MALAISE (felt sick), PYREXIA (Fever) and MYALGIA (Pain and achiness all over). On 03-May-2021, the patient experienced MYOCARDITIS (myocarditis/pain felt deep, into his lungs) (seriousness criteria hospitalization and medically significant), CHEST DISCOMFORT (chest pressure) and C-REACTIVE PROTEIN INCREASED (C-reactive protein 6.9 mg/dl). On 04-May-2021, the patient experienced PERICARDIAL EFFUSION (Fluid around heart muscle) (seriousness criteria hospitalization and medically significant) and TROPONIN T INCREASED (Troponin T 593). In 2021, the patient experienced VENTRICULAR EXTRASYSTOLES (Sporadic PVCs) |

| Case ID | WW Identifier | Narrative |
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| | | (seriousness criterion hospitalization). On 07-Oct-2021, the patient experienced VENTRICULAR TACHYCARDIA (Ventricular Tachycardia) (seriousness criterion medically significant). In November 2021, the patient experienced ARRHYTHMIA (irregular heart rhythm continues /Heart palpitations) (seriousness criteria hospitalization and medically significant). The patient was hospitalized from 03-May-2021 to 05-May-2021 due to PERICARDIAL EFFUSION and VENTRICULAR EXTRASYSTOLES. The patient was treated with METOPROLOL SUCCINATE (TOPROL XL) on 15-Nov-2021 at an unspecified dose and frequency and TOPIRAMATE (TOPAMAX) at a dose of Topamax593. On 01-May-2021, MALAISE (felt sick) had resolved. On 02-May-2021, PYREXIA (Fever) and MYALGIA (Pain and achiness all over) had resolved. On 14-Jul-2021, MYOCARDITIS (myocarditis/pain felt deep, into his lungs) and CHEST DISCOMFORT (chest pressure) had resolved. At the time of the report, ARRHYTHMIA (irregular heart rhythm continues /Heart palpitations), PERICARDIAL EFFUSION (Fluid around heart muscle), VENTRICULAR EXTRASYSTOLES (Sporadic PVCs) and VENTRICULAR TACHYCARDIA (Ventricular Tachycardia) had not resolved and TROPONIN T INCREASED (Troponin T 593) and C-REACTIVE PROTEIN INCREASED (C-reactive protein 6.9 mg/dl) outcome was unknown.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 03-May-2021, C-reactive protein (0-0.5): 6.9 6.9 mg/dl.<br>On 03-May-2021, Chest X-ray: normal (normal) Normal.<br>On 03-May-2021, Electrocardiogram: nsr (normal) NSR.<br>On 03-May-2021, Fibrin D dimer (0-0.49): 0.36 0.36 mg/L.<br>On 04-May-2021, Echocardiogram: normal liver function showed normal liver function 55-60 percentage.<br>On 04-May-2021, Magnetic resonance imaging: abnormal (abnormal) showed fluid around his heart muscle..<br>On 04-May-2021, Red blood cell sedimentation rate (0-15): 15 15 mm/hr.<br>On 04-May-2021, Troponin T (0-19): 593 593 ng/L.<br>In May 2021, Troponin: abnormal (abnormal) elevated at 93,later at it's peak it reached 550-560.<br>On 28-Sep-2021, Cardiac monitoring: abnormal (abnormal) heart palpitation.<br>On 05-Nov-2021, Magnetic resonance imaging: increased t2 weighted signal increased t2 weighted signal, pseudo cardiology lge, EF 60 percentage.<br>In November 2021, Heart rate: heart beats abnormal heart beats abnormal.<br>On an unknown date, Cardiac monitoring: abnormal (abnormal) worn a 7 day heart monitor and it showed sporadic "PVCs"..<br>On an unknown date, Magnetic resonance imaging heart: myocarditis and normal function LGE suggesting myocarditis and normal function.<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments.<br><br>The patient was admitted with chest pain. Initially his troponin level was elevated at 93 (units unknown) and later at it was peak it reached 550-560 (units unknown). He remained in the hospital for two nights and |

| Case ID | WW Identifier | Narrative |
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| | | received supportive care with intravenous fluids and monitoring. He was released on 05-MAY-2021. He has been prescribed a beta blocker to control his heart rate. Relationship with the vaccine dose: after 2nd dose. Cardiologist stated it was likely due to the 2nd dose of the vaccine. Treatment: Supportive care with IV and constant monitoring. Was instructed for following 3 months do not lift heavy weights, no contact sports or anything intense for the body. Recently started a beta blocker to control heart rate. He stopped exercise and observed light duty immediately after myocarditis diagnosis. Clinical outcome: Released from the hospital but was still being monitored and has experienced PVCs and ventricular tachycardia. Now he was given liberty to participation in regular exercise as before.<br><br>Company comment: This case concerns a 22-year-old, male patient with no relevant medical history reported, who experienced the unexpected serious AESI events of Arrhythmia, Ventricular tachycardia and Ventricular extrasystoles, the expected serious AESI events of Myocarditis and the unexpected serious event of Pericardial effusion. The events pericardial effusion and myocarditis occurred approximately 3 to 4 days after the second dose of mRNA-1273 vaccine and patient required hospitalization. It is reported that troponin level was elevated. Ventricular tachycardia was detected 6 months after the second dose. The rechallenge was not applicable since the events happened after the second dose and no information on additional dosing is available. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 01-Dec-2021: Follow-up information received on 01-Dec-2021, event details, lab data, treatment medication were updated. |
| 4.1(b) [redacted] | 4.1(b) [redacted] | This case was initially received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 18-Nov-2021.<br>The most recent information was received on 26-Nov-2021 and was forwarded to Moderna on 26-Nov-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Pericarditis and myocarditis), PERICARDITIS (PERICARDITIS) and COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine) in a 29-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3004224) for Vaccination. The occurrence of additional non-serious events is detailed below.<br><br>Previously administered products included for Vaccination: COMIRNATY. Past adverse reactions to the above products included No adverse event with COMIRNATY.<br>Concomitant products included VITAMINS NOS for an unknown indication.<br><br>On 15-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 15-Sep-2021, the patient experienced COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine) (seriousness criterion hospitalization). On 08-Nov-2021, the patient experienced MYOCARDITIS (Pericarditis and myocarditis) (seriousness criterion hospitalization). 08-Nov-2021, the |

| Case ID | WW Identifier | Narrative |
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| | | patient experienced PERICARDITIS (PERICARDITIS) (seriousness criterion hospitalization). On an unknown date, the patient experienced HYPERSOMNIA (Sleep excessive), DYSPNOEA EXERTIONAL (Dyspnea on effort) and PYREXIA (FEVER). At the time of the report, MYOCARDITIS (Pericarditis and myocarditis), PERICARDITIS (PERICARDITIS) and COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine) was resolving and HYPERSOMNIA (Sleep excessive), DYSPNOEA EXERTIONAL (Dyspnea on effort) and PYREXIA (FEVER) outcome was unknown.<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered MYOCARDITIS (Pericarditis and myocarditis) and PERICARDITIS (PERICARDITIS) to be possibly related. No further causality assessments were provided for COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine), HYPERSOMNIA (Sleep excessive), DYSPNOEA EXERTIONAL (Dyspnea on effort) and PYREXIA (FEVER).<br><br>No treatment medications were reported.<br><br>Company Comment -This is a case of revaccination with a different Covid-19 vaccine concerning a 29-year-old, male patient with no reported medical history, who experienced the expected serious AESI events of Myocarditis and Pericarditis. The events occurred approximately 1 month 25 days after the dose of mRNA-1273 vaccine and required hospitalization. The patient received a dose of Comirnaty Covid-19 vaccine at an unknown date prior to mRNA 1273. The rechallenge was not applicable since no additional dosing is expected. The reporter assessed the events Myocarditis and pericarditis as related to the product. Comirnaty vaccination remains as a confounder to the events. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 26-Nov-2021: Follow up received consists updated information regarding reporter information, patient demographics, vaccination site,added concomitant medication and events(fever, sleep excessive, dyspnea on effort)<br>On 26-Nov-2021: Follow-up received contains, translated events verbatim with no new information |
| 4.1(b) [redacted] | 4.1(b) [redacted] | This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 18-Nov-2021 and was forwarded to Moderna on 18-Nov-2021.<br>This regulatory authority case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of PERICARDITIS (Pericarditis) in a 38-year-old female patient who received mRNA-1273 (Spikevax) for Vaccination. The occurrence of additional non-serious events is detailed below.<br><br>No Medical History information was reported.<br><br>On 01-Sep-2021 at 2:15 PM, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 02-Sep-2021, the patient experienced PERICARDITIS (Pericarditis) (seriousness criterion |

| Case ID | WW Identifier | Narrative |
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| | | medically significant). On an unknown date, the patient experienced FEELING ABNORMAL (I feel woozy and hazy), DIZZINESS (I feel woozy and hazy), CHEST PAIN (Acute and severe chest pain), GENERAL PHYSICAL HEALTH DETERIORATION (Severely reduced general condition for 6 weeks), CHEST DISCOMFORT ("Tightness" in the chest) and FATIGUE (TIREDNESS). At the time of the report, PERICARDITIS (Pericarditis) had resolved with sequelae, FEELING ABNORMAL (I feel woozy and hazy), DIZZINESS (I feel woozy and hazy), CHEST PAIN (Acute and severe chest pain), CHEST DISCOMFORT ("Tightness" in the chest) and FATIGUE (TIREDNESS) had not resolved and GENERAL PHYSICAL HEALTH DETERIORATION (Severely reduced general condition for 6 weeks) outcome was unknown.<br><br>No concomitant medication was provided by reporter.<br>No treatment drug was provided by reporter.<br><br>Company comment<br>This case concerns a 38-year-old female subject, with no medical history reported, who experienced the serious, expected, and AESI event of Pericarditis. The event occurred 1 day, 9 hours and 45 minutes after after the second dose of mRNA-1273 vaccine. The rechallenge is not applicable, as no additional dosing will be given. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 18-Nov-2021: Follow-up received on 18-Nov-2021 : contains Translated event verbatim . |
| 4.1(b) | 4.1(b) | This case was initially received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 13-Nov-2021. The most recent information was received on 07-Dec-2021 and was forwarded to Moderna on 14-Dec-2021.<br>This case, initially reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref, 4.1(b) On 07-Dec-2021, follow-up information, reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref, 4.1(b) On 31-Aug-2021, at 14:00, the patient received the 1st dose of the vaccine. On 28-Sep-2021, at 14:00, the patient received the 2nd dose of the vaccine. On 29-Sep-2021, around 17:00, acute myocarditis developed. On 30-Sep-2021, the patient visited the reporting department. At the time of hospital visit, the patient had a high fever. Electrocardiogram showed ST elevation in I, aVL, and V2-6 with circumferential wall hypokinesis by echocardiography. Blood collection showed increased CPK of 424 IU/L, and thus the patient was diagnosed with acute myocarditis. The patient was hospitalized and followed up. On an unknown date, CPK decreased, and cardiac function and electrocardiographic ST elevation also improved. On 08-Oct-2021, the patient was discharged from the hospital. On 12-Nov-2021, the symptom was resolving. The outcome of acute myocarditis was reported as resolving. No follow-up investigation will be made. Follow-up received on 07-DEC-2021 Updated: Lab Data, Event Information, Narrative, Reporter Comments Company Comment: The event developed after the |

| Case ID | WW Identifier | Narrative |
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| | | administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. |
| 4.1(b) | 4.1(b) | This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) ) on 13-Nov-2021 and was forwarded to Moderna on 19-Nov-2021.<br>This case, initially reported to the 4.1(b) by a (pharmacist), was received via the 4.1(b) (Ref, 4.1(b)<br><br>On 21-Sep-2021, the patient received the 1st dose of the vaccine.<br><br>On an unknown date, body temperature before the vaccination: 35.1 degrees Celsius.<br><br>On 19-Oct-2021, at 16:15, the patient received the 2nd dose of the vaccine.<br><br>On 20-Oct-2021, perimyocarditis developed. The patient experienced pyrexia of 39.0-39.9 degrees Celsius.<br><br>On 21-Oct-2021, the patient had pyrexia of 38.0-38.9 degrees Celsius. At night, the patient experienced chest pain which was exacerbated during inspiration and feeling of dyspnea.<br><br>On 22-Oct-2021, the patient had pyrexia of 37.8 degrees Celsius. Body temperature was reduced to 36.0-36.9 degrees Celsius after loxoprofen sodium hydrate was taken orally, but the patient felt that feeling of dyspnea and chest pain got worse than the previous day. The patient was urgently transported to a hospital. BP: 120/86, PR: 83, BT: 36.3 degrees Celsius, and SpO2: 98% (RA). Blood test showed CK/CKMB 323/19, CRP 7.5, and BNP 139. Electrocardiogram and echocardiography were performed, and left ventricular ejection fraction was 40% on echocardiography. The patient was referred and transported to the reporting hospital for suspected myocarditis. Chest pain reached its peak before the emergency transportation to the reporting hospital.<br><br>At 14:00, on arrival at the reporting hospital, the patient had no chest pain. There was also no feeling of dyspnea in the supine position. The patient was hospitalized for fluid replacement, bed rest, and symptomatic treatment.<br><br>On 23-Oct-2021, CK decreased to 242 while TnT slightly increased to 0.464. Although electrocardiogram showed 61 bpm and ST elevation in I, aVL, II, III, aVF, and V1-6, an improving tendency was seen in the findings compared to those on admission. Echocardiography also showed a slight improving tendency in wall motion.<br><br>On 25-Oct-2021, subjective symptoms improved. Regarding the test values, CK was within the reference range, and electrocardiographic waveform showed an improving tendency of ST.<br><br>On 27-Oct-2021, the clinical status had peaked out, and there was an improving tendency. The symptoms resolved, and the patient was discharged from the hospital. |

| Case ID | WW Identifier | Narrative |
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| | | The outcome of perimyocarditis was reported as resolved.<br><br>Follow-up investigation will be made.<br><br>Company Comment:<br>The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 19-Nov-2021 and was forwarded to Moderna on 19-Nov-2021.<br>This regulatory authority case was reported by a consumer and describes the occurrence of HEART RATE INCREASED (High pulse on exertion up to the point of circulatory problems), PERFORMANCE STATUS DECREASED (Severe decline in performance status, no longer physically fit), INJECTION SITE SWELLING (Swelling at the injection site) and MYOCARDITIS (Diagnosed perimyocarditis) in a 29-year-old female patient who received mRNA-1273 (COVID 19 Vaccine Moderna) for Prophylactic vaccination.<br><br>Previously administered products included for Prophylactic vaccination: Spikevax on 19-May-2021.<br>Past adverse reactions to the above products included No adverse event with Spikevax.<br><br>On 30-Jun-2021, the patient received second dose of mRNA-1273 (COVID 19 Vaccine Moderna) (unknown route) 1 dosage form. On 02-Jul-2021, the patient experienced INJECTION SITE SWELLING (Swelling at the injection site) (seriousness criterion hospitalization). On 04-Jul-2021, the patient experienced HEART RATE INCREASED (High pulse on exertion up to the point of circulatory problems) (seriousness criterion hospitalization) and PERFORMANCE STATUS DECREASED (Severe decline in performance status, no longer physically fit) (seriousness criterion hospitalization). On 10-Oct-2021, the patient experienced MYOCARDITIS (Diagnosed perimyocarditis) (seriousness criterion hospitalization). On 30-Jul-2021, INJECTION SITE SWELLING (Swelling at the injection site) had resolved. At the time of the report, HEART RATE INCREASED (High pulse on exertion up to the point of circulatory problems), PERFORMANCE STATUS DECREASED (Severe decline in performance status, no longer physically fit) and MYOCARDITIS (Diagnosed perimyocarditis) had not resolved.<br><br>No concomitant medications were reported.<br>Treatment of peri myocarditis was performed first in hospital and reported that she was currently in use of high-dose analgesics for several months. After second dose of vaccination the patient experienced significant decline in performance status, high pulse on exertion at some point, then severe chest pain with shortness of breath.<br><br>Company comment: This case concerns a 29-year-old, female patient with no relevant medical history, who experienced the unexpected events of Injection site swelling, Heart rate increased and Performance status |

| Case ID | WW Identifier | Narrative |
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| | | decreased . The events occurred approximately 3 days after the second dose of mRNA-1273 Vaccine. The expected serious AESI event of Myocarditis occurred approximately 3 months after the second dose of the vaccine which resulted in Hospitalization. The rechallenge was unknown since no information about the events of the first dose was disclosed. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 19-Nov-2021: Translated document was received on 19 Nov 2021. Event verbatim and narrative was updated. |
| 4.1(b) | 4.1(b) | This case was initially received via European Medicines Agency (Reference number: 4.1(b) ) on 19-Nov-2021. The most recent information was received on 14-Dec-2021 and was forwarded to Moderna on 14-Dec-2021.<br>This regulatory authority case was reported by a consumer and describes the occurrence of PERICARDITIS (PERICARDIAL INFLAMMATION) in a 27-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3004955) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 31-Aug-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 14-Sep-2021, the patient experienced PERICARDITIS (PERICARDIAL INFLAMMATION) (seriousness criterion medically significant). At the time of the report, PERICARDITIS (PERICARDIAL INFLAMMATION) had not resolved.<br><br>No concomitant medications were reported.<br>No treatment medications were reported.<br><br>Company comment: This is a regulatory case concerning a 27 year-old, male patient with no reported medical history, who experienced the serious (due to medically important condition) expected/unexpected, according CCDS, AESI of pericarditis. The event occurred approximately 14 days after the second dose of mRNA-1273 vaccine. The outcome was reported as not recovered. The rechallenge was not applicable, as the event was reported exclusively after the second dose and no information on additional dosing is available. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 19-Nov-2021: Translated document received on 19 Nov 2021 contains updated event verbatim.<br>On 14-Dec-2021: Follow-up received included event verbatim and suspect product indication updated. |
| 4.1(b) | 4.1(b) | This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 12-Nov-2021 and was forwarded to Moderna on 19-Nov-2021.<br>This case, reported by a physician, was received by Takeda via Moderna's adverse reaction reporting site 4.1(b) |

| Case ID | WW Identifier | Narrative |
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| | | On 20-Sep-2021, at 14:00, the patient received the 1st dose of this vaccine.<br><br>On an unknown date, body temperature before the vaccination: 36.6 degrees Celsius.<br><br>On 31-Oct-2021, at 14:00, the patient received the 2nd dose of this vaccine.<br><br>On 01-Nov-2021, the patient experienced generalized aching and pyrexia.<br><br>On 02-Nov-2021, at 08:00, the patient experienced chest pain during deep inspiration and mild breathlessness from early morning. Because chest pain at rest was noted, the patient saw a nearby physician. The patient was hospitalized for suspected myocarditis that was indicated by electrocardiogram.<br><br>On 06-Nov-2021, the symptoms were resolving, and the patient was discharged from the hospital.<br><br>The outcome of generalized aching, pyrexia, chest pain, mild breathlessness, and suspected myocarditis was reported as resolving.<br><br>Follow-up investigation will be not possible due to lack of cooperation of the reporter.<br><br>Company Comment:<br><br>The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. |
| 4.1(b) | 4.1(b) | This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 13-Nov-2021 and was forwarded to Moderna on 19-Nov-2021.<br>This case, initially reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref 4.1(b)<br><br>On unknown date, the patient received the 1st dose of this vaccine.<br><br>On 04-Nov-2021, around 16:30, the patient received the 2nd dose of this vaccine.<br><br>A few hours after the vaccination, the patient experienced malaise and pyrexia.<br><br>On 05-Nov-2021, around 17:30, pain in the left precordial region developed, and the patient visited the emergency outpatient department of the reporting hospital. Electrocardiogram showed ST elevation in I, aVL, and V1-5.<br><br>On 06-Nov-2021, the patient was hospitalized with a diagnosis of acute pericarditis. |

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| | | On 09-Nov-2021, the disease was not complicated by heart failure, and no elevation of cardiac enzymes was noted. The symptoms improved only with oral medications such as analgesics, and thus the patient was discharged from the hospital.<br><br>The outcome of malaise, pyrexia, acute pericarditis was reported as resolving.<br><br>Follow-up investigation will be made.<br><br>Company Comment:<br><br>The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 19-Nov-2021 and was forwarded to Moderna on 19-Nov-2021.<br>This regulatory authority case was reported by an attorney and describes the occurrence of PNEUMONIA (subsequent pneumonia) and PERICARDITIS (Pericarditis) in a 29-year-old male patient who received mRNA-1273 (COVID 19 Vaccine Moderna) (batch no. 3004959) for COVID-19 immunisation.<br><br>Previously administered products included for COVID-19 immunisation: COVID-19 VACCINE MODERNA on 14-Jul-2021.<br>Past adverse reactions to the above products included No adverse event with COVID-19 VACCINE MODERNA.<br><br>On 11-Aug-2021, the patient received second dose of mRNA-1273 (COVID 19 Vaccine Moderna) (unknown route) 1 dosage form. In 2021, the patient experienced PNEUMONIA (subsequent pneumonia) (seriousness criterion medically significant). On 15-Aug-2021, after starting mRNA-1273 (COVID 19 Vaccine Moderna), the patient experienced PERICARDITIS (Pericarditis) (seriousness criterion medically significant). At the time of the report, PNEUMONIA (subsequent pneumonia) and PERICARDITIS (Pericarditis) had not resolved.<br><br>No concomitant medications were reported.<br><br>No treatment information was reported.<br><br>Company comment: This regulatory case concerns a 29-year-old, male patient with no relevant medical history, who experienced the unexpected, serious event of Pneumonia and expected serious AESI of Pericarditis. The event Pneumonia occurred on an unknown date during 2021 and event Pericarditis occurred after administration of the second dose of mRNA-1273 vaccine. The events had not resolved at the time of the report. The rechallenge was not applicable as no additional dosing is expected. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. |

| Case ID | WW Identifier | Narrative |
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| 4.1(b) | 4.1(b) | This regulatory authority case was reported by a consumer and describes the occurrence of PERICARDITIS (Heart problems/pericarditis. The ECHO showed fluid accumulation of 12- 14mm in the pericardium (pericardial effusion). Treatment: 0.5mg colchicine 2 tablets per day Course: there were...) in a 39-year-old female patient who received mRNA-1273 (COVID-19 Vaccine Moderna) (batch nos. 3003188 and 3002541) for an unknown indication.<br><br>No medical history was reported.<br>Concomitant products included ESTRADIOL, NORETHISTERONE ACETATE (SYSTEN CONTI) from 01-Jan-2021 to an unknown date for Menopause.<br><br>On 01-Jun-2021, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form.<br>On 29-Jun-2021, received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) dosage was changed to 1 dosage form. On 28-Jul-2021, after starting mRNA-1273 (COVID-19 Vaccine Moderna), the patient experienced PERICARDITIS (Heart problems/pericarditis. The ECHO showed fluid accumulation of 12- 14mm in the pericardium (pericardial effusion). Treatment: 0.5mg colchicine 2 tablets per day Course: there were...) (seriousness criterion medically significant). At the time of the report, PERICARDITIS (Heart problems/pericarditis. The ECHO showed fluid accumulation of 12- 14mm in the pericardium (pericardial effusion). Treatment: 0.5mg colchicine 2 tablets per day Course: there were..) had not resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On an unknown date, Echocardiogram: abnormal (abnormal) The ECHO showed fluid accumulation of ....<br><br>On Jul 28, the patient had pericarditis with pericardial effusion (accumulation of 12-14 mm of fluid) revealed by ECHO. The patient was treated with colchicine 0.5 mg, 2 tablets per day. The patient reported that the fluid accumulation (3-4 mm) continues and that the treatment also continues, presumably at the time<br>of the report. Heart problems/pericarditis.<br>The ECHO showed fluid accumulation of 12- 14mm in the pericardium (pericardial effusion).<br>Treatment: 0.5mg colchicine 2 tablets per day. Course: there was fluid accumulation of 12-<br>14mm, The treatment is still ongoing. At the time of reporting, the symptoms have not resolved.<br>Reaction reported as non-serious. Further course unknown. Heart problems/pericarditis. The ECHO showed fluid accumulation of 12- 14mm in the pericardium (pericardial effusion). Treatment: 0.5mg colchicine 2 tablets per day Course: there was fluid accumulation of 3-4mm. (deu).<br><br>Company comment: This regulatory authority case concerns a 39-year-old female patient with no relevant medical history, who experienced the expected serious (medically significant) event/AESI of Pericarditis after |

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| | | mRNA- 1273 Moderna vaccine. The event occurred approximately 29 days after the second dose of mRNA- 1273 vaccine. Very limited information is available regarding clinical manifestations. Echocardiogram showed fluid accumulation of 12-14mm in the pericardium. Treatment with colchicine was prescribed with reduction of the pleural effusion to 3-4mm. At the time of the report, treatment was ongoing and the event had not yet resolved. The rechallenge is not applicable, since the event was reported exclusively after the second dose. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report<br><br>Most recent FOLLOW-UP information incorporated above includes: On 19-Nov-2021: Translation received on 23-Nov-2021 contains translated event verbatim, lab test result, senders comment and reporters comment which is updated. |
| 4.1(b) | 4.1(b) | This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (Mild myocarditis. Since the 2nd dose, I had exactly the same symptoms again.) in a 38-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination.<br><br>Concurrent medical conditions included Myocarditis (Mild myocarditis. Already shortly before the start of the pandemic and was therefore in the s...).<br><br>On 05-Aug-2021, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form.<br>On 07-Sep-2021, received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) dosage was changed to 1 dosage form. On 08-Sep-2021, after starting mRNA-1273 (COVID-19 Vaccine Moderna), the patient experienced MYOCARDITIS (Mild myocarditis. Since the 2nd dose, I had exactly the same symptoms again.) (seriousness criterion medically significant). At the time of the report, MYOCARDITIS (Mild myocarditis. Since the 2nd dose, I had exactly the same symptoms again.) had not resolved.<br><br>Relevant concomitant product usage were not reported by the reporter. No treatment details were provided.<br><br>Mild Myocarditis was diagnosed there after heart catheterization and MRI examination. The symptoms disappeared by themselves after a few weeks, except for beta blockers. Patient rarely drinks alcohol. The first dose of Spikevax was administered on Aug 05, 2021. Patient is not willing to go to the hospital and assume it will heal by itself.<br><br>Company's comment: This regulatory case concerns a 38-year-old, male patient with medical history of myocarditis, who experienced the expected, serious and AESI of Myocarditis. The patient described suspected myocarditis, with no medical diagnosis, he reported having the same symptoms as the myocarditis he had in the past, before the pandemic, without detailing them, 1 day after the second dose of mRNA-1273 vaccine. He declares that he will not go to the doctor. The rechallenge is not applicable, as the outcome of the event is not |

| Case ID | WW Identifier | Narrative |
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| | | recovered. The medical history of Myocarditis remains as a confounder. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 19-Nov-2021: Translation received on 23-NOV-2021includes translated Sender's comments and Reaction/event as reported. |
| 4.1(b) | 4.1(b) | This regulatory authority case was reported by a physician and describes the occurrence of PERICARDITIS (Pericarditis) in a 23-year-old female patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for an unknown indication.<br><br>Concurrent medical conditions included Deafness neurosensory.<br><br>On 28-Jul-2021, the patient received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form. On 16-Sep-2021, after starting mRNA-1273 (COVID-19 Vaccine Moderna), the patient experienced PERICARDITIS (Pericarditis) (seriousness criterion medically significant). At the time of the report, PERICARDITIS (Pericarditis) outcome was unknown.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 16-Sep-2021, Abdomen scan: normal (normal) Absence of organic damage, absence of lithiasis.<br>On 16-Sep-2021, Echocardiogram: abnormal (abnormal) Diffuse pericardial effusion posteral, anteral.<br>On 16-Sep-2021, Electrocardiogram: 80 beats/min (normal) Sinus rhythm 80 beats/min. Alterations to.<br><br>For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered PERICARDITIS (Pericarditis) to be possibly related.<br><br>No relevant concomitant medications were reported.<br>No treatment information was provided.<br>Company's comment: This is a regulatory case concerning a 23-year-old female patient, with no relevant medical history reported except for being an aid wearer for sensorineural middle deafness, who experienced the serious expected and AESI event of Pericarditis approximately 7 weeks after receiving the second dose of mRNA-1273 . A Color Doppler echocardiography after physical testing showed diffuse pericardial effusion posterior, anterior, and apical. Patient was Treated with Prednisone 2.5 mg 2 x day for 10 days, Brufen 400 mg 2 x day for 10 days, Aspirin Cardio 100 mg 1 x day, Pantozole 20 mg 1 x day is initiated. The benefit-risk relationship of mRNA-1273 is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 19-Nov-2021: Translation received on 23-Nov-2021.Significant information include lab investigation results, Product dosage text, event verbatim, senders and narrative comments were updated to English |
| 4.1(b) | 4.1(b) | This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 17-Nov-2021 and was forwarded to Moderna on 22-Nov-2021. |

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| | | This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Suspected myocarditis) in a 34-year-old male patient who received mRNA-1273 (COVID 19 Vaccine Moderna) (batch nos. 3005890 and 3005788) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below.<br><br>No Medical History information was reported.<br><br>On 10-Oct-2021, the patient received first dose of mRNA-1273 (COVID 19 Vaccine Moderna) (Intramuscular) 1 dosage form.<br>On 07-Nov-2021, received second dose of mRNA-1273 (COVID 19 Vaccine Moderna) (Intramuscular) dosage was changed to 1 dosage form. On 08-Nov-2021, the patient experienced PYREXIA (Pyrexia). On 09-Nov-2021, the patient experienced MYOCARDITIS (Suspected myocarditis) (seriousness criterion medically significant) and ABDOMINAL PAIN UPPER (Epigastric pain). In November 2021, PYREXIA (Pyrexia) had resolved. At the time of the report, MYOCARDITIS (Suspected myocarditis) and ABDOMINAL PAIN UPPER (Epigastric pain) outcome was unknown.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 08-Nov-2021, Body temperature: 38.8 (High) 38.8 Cel (degree Celsius) and 38.8 degree Celsius.<br>On an unknown date, Body temperature: 36.7 (normal) 36.7 Cel (degree Celsius) and 36.7 degree Celsius.<br><br>For mRNA-1273 (COVID 19 Vaccine Moderna) (Intramuscular), the reporter considered MYOCARDITIS (Suspected myocarditis), ABDOMINAL PAIN UPPER (Epigastric pain) and PYREXIA (Pyrexia) to be possibly related.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 06-Jan-2022: Follow-up added on 06-Jan-2022 contains no new information. |
| 4.1(b) | 4.1(b) | This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) ) on 17-Nov-2021 and was forwarded to Moderna on 22-Nov-2021.<br>This case, initially reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref, 4.1(b)<br><br>On an unknown date, the patient received the 1st dose of this vaccine.<br><br>On an unknown date, body temperature before the vaccination: 37.2 degrees Celsius.<br><br>On 05-Nov-2021, at 18:45, the patient received the 2nd dose of this vaccine.<br><br>On 06-Nov-2021, in the morning, pyrexia and chest discomfort developed. The patient was considered to experience myocarditis. |

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| | | On 07-Nov-2021, at night, the symptoms were exacerbated, and the patient was unable to sleep. Analgesics were ineffective.<br><br>On 08-Nov-2021, the patient visit a nearby physician. WBC: 7,500, and CRP: 4.9. Electrocardiogram of V2-6 showed ST elevation, and the patient was referred to the reporting hospital because myocarditis was suspected. CPK increased, and troponin I increased markedly to 4,952. The patient was hospitalized for treatment as myocarditis with electrocardiogram findings.<br><br>On 15-Nov-2021, the symptoms were resolving, and the patient was discharged from the hospital.<br><br>The outcome of myocarditis was reported as resolving.<br><br>Follow-up investigation will be made.<br><br>Company Comment:<br><br>The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 22-Nov-2021 and was forwarded to Moderna on 22-Nov-2021.<br>This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (Myocarditis) in a 33-year-old female patient who received mRNA-1273 (Spikevax) (batch nos. 3004955 and 3006273) for an unknown indication.<br><br>No Medical History information was reported.<br><br>On 07-Sep-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form.<br>On 07-Sep-2021, received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. On 08-Sep-2021, after starting mRNA-1273 (Spikevax), the patient experienced MYOCARDITIS (Myocarditis) (seriousness criterion medically significant). At the time of the report, MYOCARDITIS (Myocarditis) was resolving.<br><br>No concomitant medications were reported.<br><br>No treatment information was provided.<br><br>Company Comment : This regulatory case concerns a 33-year-old, female patient with no relevant medical history, who experienced the expected, serious AESI of myocarditis. The event occurred 1 day after administration of a dose of the Moderna mRNA-1273. Treatment information was not provided. However, the event was resolving at the time of the report. The rechallenge was not applicable as no additional dosing will be given. The benefit-risk relationship of the Moderna mRNA-1273 is not affected by this report. |

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| | | Most recent FOLLOW-UP information incorporated above includes: On 22-Nov-2021: Translation received on 23-NOV-2021. Translated event verbatim updated. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 22-Nov-2021 and was forwarded to Moderna on 22-Nov-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Acute myocarditis) in a 34-year-old male patient who received mRNA-1273 (Spikevax) for Prophylactic vaccination.<br><br>Previously administered products included for COVID-19 vaccination: COVID-19 VACCINE MODERNA in September 2021.<br>Past adverse reactions to the above products included No adverse event with COVID-19 VACCINE MODERNA.<br><br>On 26-Oct-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 27-Oct-2021, the patient experienced MYOCARDITIS (Acute myocarditis) (seriousness criterion hospitalization). At the time of the report, MYOCARDITIS (Acute myocarditis) had not resolved.<br><br>For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.<br><br>No concomitant medication was reported.<br>Treatment medication was not provided by the reporter.<br><br>Company comment: This regulatory case concerns a 34-year-old, male patient with no relevant medical history, who experienced the expected AESI of myocarditis. The event, which resulted in hospitalization, occurred 1 day after administration of the second dose of the Moderna mRNA-1273. The rechallenge was not applicable as no additional dosing will be given. The patient's gender remains a confounder. The benefit-risk relationship of the Moderna mRNA-1273 is not affected by this report. |
| 4.1(b) | 4.1(b) | This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Retrosternal pressure) in a 17-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for SARS-CoV-2 immunization.<br><br>No Medical History information was reported.<br><br>On 05-Nov-2021, the patient received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form. On 09-Nov-2021, after starting mRNA-1273 (COVID-19 Vaccine Moderna), the patient experienced MYOCARDITIS (Retrosternal pressure) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Retrosternal pressure) outcome was unknown.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): |

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| | | On an unknown date, C-reactive protein increased: 23 mg/l (abnormal) 23 mg/l.<br>On an unknown date, Electrocardiogram: normal (normal) Rhythm normal, ST changes anterior wall (V1-V2)..<br>On an unknown date, Troponin T: 872 ng/l (abnormal) 872 ng/l.<br><br>For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered MYOCARDITIS (Retrosternal pressure) to be possibly related.<br><br>Concomitant medications was not reported.<br>A small pericardial effusion was noted in the TTE.<br>On Nov 08, 2021, Patinet felt slight pressure on his chest. He had then taken Dafalgan® (paracetamol,dose unknown.<br>On the day following the second vaccination, the patient developed a mild headache.<br><br>Company comment: This is a regulatory case concerning a 17 year-old male patient, with no relevant medical history reported, who experienced the serious unexpected and AESI event of Myocarditis 3 days after receiving the second dose of a proper vaccination schedule with mRNA-1273 vaccine.3 days after the second dose, patient felt retrosternal pressure, laboratory showed increased levels of CRP and troponin, ECG showed ST change in V1-V2 (anterior wall) and a small pericardial effusion was foun on TTE. The benefit-risk relationship of mRNA-1273 is not affected by this report<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 22-Nov-2021: Translated document received on 23-Nov-2021 Contained Translated Relevant History,Lab section, Event verbatim, Case narrative and Reporter's comments section. |
| 4.1(b) | 4.1(b) | This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) ) on 17-Nov-2021 and was forwarded to Moderna on 23-Nov-2021.<br>This case, initially reported to the 4.1(b) by a (physician), was received via the 4.1(b) (Ref, 4.1(b)<br><br>On an unknown date, the patient received the 1st dose of the vaccine.<br><br>On 02-Aug-2021, the patient received the 2nd dose of the vaccine.<br><br>On 23-Aug-2021, disorder of skilled motor activities in the left upper limb suddenly developed. Around that time, the patient experienced epigastric pain and dyspnea.<br><br>On 27-Aug-2021, paresthesia and incomplete paralysis in the left lower limb developed, and the patient visited a nearby neurosurgeon. Head MRI showed sporadic cerebral infarctions in the right cerebral hemisphere and left occipital lobe.<br><br>On 28-Aug-2021, the patient was hospitalized. |

| Case ID | WW Identifier | Narrative |
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| | | On 31-Aug-2021, on Day 4 of the onset of the disease, cardioembolic stroke was suspected. Electrocardiogram on admission showed sinus tachycardia of 104 bpm, small Q waves in the aVL and V5-V6 leads, and negative T waves in the III and aVF leads, which were non-specific findings. Biochemical examination of blood showed normal cardiac enzymes such as CK/CK-MB, but there were elevations of high-sensitivity troponin T of 0.682 ng/mL and NT-proBNP of 395 pg/mL, which were suggestive of some kind of myocardial damage. Transthoracic echocardiography showed sustained left ventricular ejection fraction of 72%, but pericardial effusions were found circumferentially. Thus, acute myocarditis was strongly suspected. As a result of the medical interview, possibility of myocarditis associated with the vaccine was considered based on the timeline. Cardiac MRI showed a sporadic macular delayed image in the lateral side of both ventricles and near the apex of the interventricular septum, which were consistent with findings of myocarditis. No appreciable findings were found by the right heart catheter, without coronary artery stenosis. Myocardial biopsy of endocardium was performed at the right ventricular septum. Light microscopy showed infiltration of various inflammatory cells mainly consisting of lymphocytes, without remarkable aggregation, and degenerated cardiomyocytes were detected. Since the extreme phase of myocarditis had passed and hemodynamic disruption was not noted, the use of corticosteroids was avoided.<br><br>On an unknown date, pericardial effusions decreased spontaneously.<br><br>On 18-Sep-2021, high-sensitivity troponin T almost returned to normal. The symptoms were resolving with favorable course of the disease, and thus the patient was discharged from the hospital.<br><br>The outcome of myocarditis, sporadic cerebral infarction, and suspected cardioembolic stroke was reported as resolving.<br><br>Follow-up investigation will be made.<br><br>Company Comment:<br><br>The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. |
| 4.1(b) | 4.1(b) | This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) ) on 13-Nov-2021 and was forwarded to Moderna on 23-Nov-2021.<br>This case, initially reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref, 4.1(b)<br><br>On an unknown date, the patient received the 1st dose of this vaccine.<br><br>On 07-Nov-2021, at 09:21, the patient received the 2nd dose of this vaccine.<br><br>At 5 to 6 hours after the vaccination, headache and pyrexia of the highest 40.1 degrees Celsius. |

| Case ID | WW Identifier | Narrative |
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| | | On 08-Nov-2021, the patient had a feeling of heaviness as if the chest was compressed, and antipyretics were taken every 6 hours. The onset of myocarditis and pericarditis were suspected.<br><br>On 09-Nov-2021, because pyrexia in the 38s degrees Celsius and chest pain persisted, the patient visited a previous hospital. The patient was referred to our hospital with WBC of 10, 100/mcL and CRP of 10.3 mg/dL. Troponin T positive, CK 376, CK-MB 27, AST 39, CRP 8.63. Echocardiography showed no pericardial effusion and decreased cardiac function, or local changes. The patient was hospitalized for observation.<br><br>On 12-Nov-2021, the patient recovered from the symptoms and was discharged from the hospital.<br><br>The outcome of headache, pyrexia, chest pressure sensation, chest pain, suspected myocarditis and pericarditis was reported as resolved.<br><br>Follow-up investigation will be made.<br><br>Company Comment:<br><br>The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. |
| 4.1(b) | 4.1(b) | This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) ) on 18-Nov-2021 and was forwarded to Moderna on 23-Nov-2021.<br><br>This case, initially reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref, 4.1(b)<br><br>On an unknown date, the patient received the 1st dose of this vaccine.<br><br>On 13-Nov-2021, at 11:10, the patient received the 2nd dose of this vaccine.<br><br>On 15-Nov-2021, at 23:55, the patient was aware of chest pain, and myocarditis developed.<br><br>On 16-Nov-2021, late at night, cold sweat and chest pain developed. The patient was raced to a hospital. The patient was hospitalized for follow-up.<br><br>On 18-Nov-2021, the symptoms resolved. The patient was scheduled to be discharged from the hospital on the same day.<br><br>The outcome of myocarditis (chest pain) was reported as resolved.<br><br>Follow-up investigation will be made.<br><br>Company Comment:<br><br>The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. |

| Case ID | WW Identifier | Narrative |
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| 4.1(b) | 4.1(b) | This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) ) on 19-Nov-2021 and was forwarded to Moderna on 23-Nov-2021.<br><br>This case, initially reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref 4.1(b)<br><br>On an unknown date, the patient received the 1st dose of this vaccine.<br><br>On an unknown date, body temperature before vaccination: 36.4 degrees Celsius.<br><br>On 06-Nov-2021, at 12:00 to 12:30, the patient received the 2nd dose of this vaccine. Around 21:00, pyrexia of 39 degrees Celsius developed. The patient took over-the-counter drugs.<br><br>On 08-Nov-2021, breathlessness and chest pain developed.<br><br>On 09-Nov-2021, the patient was diagnosed with myocarditis and underwent cardiac catheterization. The patient was hospitalized. There was no significant stenosis in the coronary artery, and myocardial biopsy was performed on the right ventricular apex considering myocarditis. Echocardiography showed a decrease in left ventricular ejection fraction of 40%, which improved over time.<br><br>On 16-Nov-2021, the patient recovered from the symptoms and was discharged from the hospital.<br><br>The outcome of pyrexia and myocarditis was reported as recovered.<br><br>Follow-up investigation will be made.<br><br>Company Comment:<br>The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. |
| 4.1(b) | 4.1(b) | This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) ) on 20-Nov-2021 and was forwarded to Moderna on 23-Nov-2021.<br>This case, initially reported to the 4.1(b) by a pharmacist, was received via the 4.1(b) (Ref, 4.1(b)<br><br>On an unknown date, the patient received the 1st dose of this vaccine.<br><br>On 23-Oct-2021, the patient received the 2nd dose of this vaccine.<br><br>On 25-Oct-2021, around 17:30, precordial pain appeared. Deep breathing aggravated the pain. There was no comfortable position for the patient.<br><br>At 19:30, the patient visited an emergency outpatient department at the reporting hospital and was hospitalized for suspected myocarditis associated with the vaccine. There were no wall motion abnormalities in echocardiography, and wide range of ST elevation and positive Tn-T |

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| | | were shown in electrocardiogram; therefore, the patient was diagnosed with myocarditis. The patient was hospitalized to be followed up.<br><br>On an unknown date, the peak CPK was 25/39. The inflammatory response gradually decreased, and the patient's subjective symptoms almost disappeared.<br><br>On 27-Oct-2021, echocardiography was performed, and there was no abnormality in a localized wall motion.<br><br>On 29-Oct-2021, cardiac MRI was performed, and delayed imaging was not found.<br><br>On 30-Oct-2021, the patient was discharged from the hospital as the symptoms improved.<br><br>The outcome of myocarditis was reported as resolving.<br><br>Follow-up investigation will be made.<br><br>Company Comment:<br><br>The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. |
| 4.1(b) | 4.1(b) | This case was received via 4.1(b) (Reference number: 4.1(b) on 23-Nov-2021 and was forwarded to Moderna on 23-Nov-2021.<br>This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCARDITIS (Myocarditis), PERICARDITIS (Pericarditis), ABDOMINAL PAIN UPPER (Abdominal pain upper), ACTIVATED PARTIAL THROMBOPLASTIN TIME (Activated partial thromboplastin time), BLOOD TEST (Blood test), C-REACTIVE PROTEIN (C-reactive protein), CARDIAC MONITORING (Cardiac monitoring), CHEST X-RAY ABNORMAL (Chest X-ray abnormal), CHEST PAIN (Chest pain), DIARRHOEA (Diarrhoea), ECHOCARDIOGRAM (Echocardiogram), ELECTROCARDIOGRAM (Electrocardiogram), ELECTROCARDIOGRAM ABNORMAL (Electrocardiogram abnormal), FULL BLOOD COUNT (Full blood count), HEADACHE (Headache), HUMAN CHORIONIC GONADOTROPIN (Human chorionic gonadotropin), INFLAMMATION (Inflammation), LIPASE (Lipase), METABOLIC FUNCTION TEST (Metabolic function test), MUSCLE INJURY (Muscle injury), NAUSEA (Nausea), PROTHROMBIN TIME (Prothrombin time), RED BLOOD CELL SEDIMENTATION RATE (Red blood cell sedimentation rate), RESPIRATORY VIRAL PANEL (Respiratory viral panel), SLEEP DISORDER (Sleep disorder), TROPONIN I (Troponin I), TROPONIN INCREASED (Troponin increased), URINE ANALYSIS (Urine analysis) and VOMITING (Vomiting) in a 26-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 033F21A) for COVID-19 vaccination.<br><br>The patient's past medical history included Gastritis.<br>Concurrent medical conditions included Drug allergy (Doxycycline), Soy allergy, Food allergy (Sesame allergy) and Allergy to molds. |

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| | | On 05-Nov-2021, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 08-Nov-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant), PERICARDITIS (Pericarditis) (seriousness criteria hospitalization and medically significant), ABDOMINAL PAIN UPPER (Abdominal pain upper) (seriousness criterion hospitalization), ACTIVATED PARTIAL THROMBOPLASTIN TIME (Activated partial thromboplastin time) (seriousness criterion hospitalization), BLOOD TEST (Blood test) (seriousness criterion hospitalization), C-REACTIVE PROTEIN (C-reactive protein) (seriousness criterion hospitalization), CARDIAC MONITORING (Cardiac monitoring) (seriousness criterion hospitalization), CHEST X-RAY ABNORMAL (Chest X-ray abnormal) (seriousness criterion hospitalization), CHEST PAIN (Chest pain) (seriousness criterion hospitalization), DIARRHOEA (Diarrhoea) (seriousness criterion hospitalization), ECHOCARDIOGRAM (Echocardiogram) (seriousness criterion hospitalization), ELECTROCARDIOGRAM (Electrocardiogram) (seriousness criterion hospitalization), ELECTROCARDIOGRAM ABNORMAL (Electrocardiogram abnormal) (seriousness criterion hospitalization), FULL BLOOD COUNT (Full blood count) (seriousness criterion hospitalization), HEADACHE (Headache) (seriousness criterion hospitalization), HUMAN CHORIONIC GONADOTROPIN (Human chorionic gonadotropin) (seriousness criterion hospitalization), INFLAMMATION (Inflammation) (seriousness criterion hospitalization), LIPASE (Lipase) (seriousness criterion hospitalization), METABOLIC FUNCTION TEST (Metabolic function test) (seriousness criterion hospitalization), MUSCLE INJURY (Muscle injury) (seriousness criterion hospitalization), NAUSEA (Nausea) (seriousness criterion hospitalization), PROTHROMBIN TIME (Prothrombin time) (seriousness criterion hospitalization), RED BLOOD CELL SEDIMENTATION RATE (Red blood cell sedimentation rate) (seriousness criterion hospitalization), RESPIRATORY VIRAL PANEL (Respiratory viral panel) (seriousness criterion hospitalization), SLEEP DISORDER (Sleep disorder) (seriousness criterion hospitalization), TROPONIN I (Troponin I) (seriousness criterion hospitalization), TROPONIN INCREASED (Troponin increased) (seriousness criterion hospitalization), URINE ANALYSIS (Urine analysis) (seriousness criterion hospitalization) and VOMITING (Vomiting) (seriousness criterion hospitalization). At the time of the report, MYOCARDITIS (Myocarditis), PERICARDITIS (Pericarditis), ABDOMINAL PAIN UPPER (Abdominal pain upper), ACTIVATED PARTIAL THROMBOPLASTIN TIME (Activated partial thromboplastin time), BLOOD TEST (Blood test), C-REACTIVE PROTEIN (C-reactive protein), CARDIAC MONITORING (Cardiac monitoring), CHEST X-RAY ABNORMAL (Chest X-ray abnormal), CHEST PAIN (Chest pain), DIARRHOEA (Diarrhoea), ECHOCARDIOGRAM (Echocardiogram), ELECTROCARDIOGRAM (Electrocardiogram), ELECTROCARDIOGRAM ABNORMAL (Electrocardiogram abnormal), FULL BLOOD COUNT (Full blood count), HEADACHE (Headache), HUMAN CHORIONIC GONADOTROPIN (Human chorionic gonadotropin), INFLAMMATION (Inflammation), LIPASE (Lipase), METABOLIC FUNCTION TEST (Metabolic function test), MUSCLE INJURY (Muscle injury), NAUSEA (Nausea), PROTHROMBIN TIME (Prothrombin time), RED BLOOD CELL SEDIMENTATION RATE (Red |

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| | | blood cell sedimentation rate), RESPIRATORY VIRAL PANEL (Respiratory viral panel), SLEEP DISORDER (Sleep disorder), TROPONIN I (Troponin I), TROPONIN INCREASED (Troponin increased), URINE ANALYSIS (Urine analysis) and VOMITING (Vomiting) outcome was unknown.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 08-Nov-2021, Troponin: 1 (High) Troponin 1 high-sensitivity.<br>On 09-Nov-2021, Troponin: 1 (High) Troponin 1 high-sensitivity.<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments.<br><br>On 08-NOV-2021 Lab tests ECG 12-Lead, PT- APTT, Lipase, Comprehensive metabolic panel, CBC, POC HCG Qualitative, Urinalysis Auto only, XR chest 1 view, C-reactive protein, Sedimentation rate, Troponin 1 high-sensitivity Transthoracic E., Respiratory virus comprehensive panel were done, results were not reported. On 09-NOV-2021 Lab tests Basic metabolic panel, CBC were done, results were not reported.<br>Concomitant medication included Omeprazole, Zyrtec, Sucralfate, Montelukast, birth control pills, Fluticasone nasal spray, Acetaminophen.<br>On 08-Nov-2021 around 2:30 am, Patient awoke to diarrhea stomach pains and began using the toilet and began to feel nauseas. She began vomiting while still using the restroom. Once she had finished using the restroom and vomiting, she began having chest pains. The chest pain would not subside, and it increased when she tried to lay back down. She went to ER where they discovered an abnormal EKG and elevated troponin levels. she was given Tramadol in the ER to help with the pain and chest x-ray then she was in the hospital and from 08-NOV-2021 to 09-NOV-2021.<br>The doctors believed she was suffering from myocarditis or pericarditis. Her blood levels were examined every few hours and heart was monitored through an EKG. She was given morphine when her pain increased around 12 pm on 08-NOV-2021 and then tramadol at the end of 09-NOV-2021 when her head was throbbing. The cardiologist did an ultrasound of heart to see if the inflammation visible on the x-ray was pericarditis or myocarditis.<br>On 09-NOV-2021 she was told the inflammation had decreased on its own which lead the doctors to believe it was the result of the booster covid vaccine. The cardiologist told she have microscopic damage to heart muscles based on the elevated troponin levels and she believed she had pericarditis. They prescribed Tramadol to take in case of more chest pain.<br><br>Company comment: This is a regulatory case concerning a 26-year-old female patient with no relevant medical history, who experienced the serious expected events of special interest Myocarditis and pericarditis . The events occurred approximately 3 days after the third dose of mRNA-1273. Patient went to ER due to chest pain. EKG was abnormal and troponin increased. Heart monitor was placed. Chest pain were treated with morphine and tramadol and patient was discharged the other day |

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| | | with analgesic. The benefit-risk relationship of mRNA-1273 is not affected by this report. |
| 4.1(b) | 4.1(b) | This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 19-Nov-2021 and was forwarded to Moderna on 24-Nov-2021.<br>This case, initially reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref, 4.1(b)<br><br>On an unknown date, the patient received the 1st dose of this vaccine.<br>On an unknown date, body temperature before the vaccination: 36.5 degrees Celsius.<br>On 28-Oct-2021, at 10:30, the patient received the 2nd dose of this vaccine.<br>On 30-Oct-2021, at 04:00, chest pain was noted, and acute pericardial myocarditis developed.<br>At 12:30, because the symptoms persisted, the patient made a visit to an emergency outpatient department. The patient was hospitalized because 12-lead ECG showed ST elevation in wide range of leads and blood data showed elevations in CPK of 425, CPK-MB of 34, troponin I of 4,247, and CRP of 4.31.<br>On 31-Oct-2021, echocardiography showed hypokinesis of the localized area of the left ventricular wall and pericardial effusion. NSAIDS was administered, and the patient was hospitalized for a follow-up at rest.<br>On 03-Nov-2021, the patient was discharged from the hospital as the symptoms resolved.<br><br>The outcome of acute pericardial myocarditis was reported as resolving.<br><br>Follow-up investigation will be made.<br><br>Company Comment:<br>The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. |
| 4.1(b) | 4.1(b) | This case was received via 4.1(b) (Reference number: 4.1(b) on 23-Nov-2021 and was forwarded to Moderna on 23-Nov-2021.<br>This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCARDITIS (Myocarditis) in a 25-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for an unknown indication.<br><br>No Medical History information was reported.<br><br>On 27-Oct-2021, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 28-Oct-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criterion medically significant). At the time of the report, MYOCARDITIS (Myocarditis) had resolved.<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. |

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| | | Concomitant medication included Vitamin D Magnesium.<br><br>Treatment medication included Advil was taken for general pain relief.<br><br>It was reported that myocarditis was the main concerning symptom patient experienced day after vaccination. The symptom started around 14 hours after the vaccination. Within 24 hours, the Myocarditis was recovered.<br><br>Company Comment:<br>This case concerns a 25-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) with no relevant medical history who experienced the serious expected event (AESI) of myocarditis one day after the third dose of the vaccine. Rechallenge is not applicable, since no further dosing is expected. The benefit-risk relationship is not affected by this report |
| 4.1(b) | 4.1(b) | This case was received via 4.1(b) (Reference number: 4.1(b) on 23-Nov-2021 and was forwarded to Moderna on 23-Nov-2021.<br>This regulatory authority case was reported by an other health care professional and describes the occurrence of CHEST PAIN (Left Chest pain), MALAISE (Malaise), HYPERHIDROSIS (Hyperhidrosis), FATIGUE (Fatigue), CHILLS (Chills), NAUSEA (Nausea), HEADACHE (Headache), PYREXIA (Pyrexia), ANXIETY (Anxiety), C-REACTIVE PROTEIN INCREASED (C-reactive protein increased), CARDIAC IMAGING PROCEDURE ABNORMAL (Cardiac imaging procedure abnormal), CHEST DISCOMFORT (Chest discomfort), COUGH (Cough), EAR PAIN (Ear pain), ECHOCARDIOGRAM NORMAL (Echocardiogram normal), EJECTION FRACTION NORMAL (Ejection fraction normal), ELECTROCARDIOGRAM T WAVE INVERSION (Electrocardiogram T wave inversion), ELECTROCARDIOGRAM ABNORMAL (Electrocardiogram abnormal), LEFT VENTRICULAR DILATATION (Left ventricular dilatation), MAGNETIC RESONANCE IMAGING HEART (Magnetic resonance imaging heart), MYOCARDIAL OEDEMA (Myocardial oedema), N-TERMINAL PROHORMONE BRAIN NATRIURETIC PEPTIDE INCREASED (N-terminal prohormone brain natriuretic peptide increased), PAIN (Pain), PERICARDIAL FIBROSIS (Pericardial fibrosis), PLEURITIC PAIN (Pleuritic pain), RED BLOOD CELL SEDIMENTATION RATE INCREASED (Red blood cell sedimentation rate increased), RETCHING (Retching), SLEEP DISORDER (Sleep disorder), TROPONIN INCREASED (Troponin increased), VENTRICULAR HYPOKINESIA (Ventricular hypokinesia), VOMITING (Vomiting) and MYOCARDITIS (Myocarditis) in a 39-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 014F21A) for COVID-19 vaccination.<br><br>Concurrent medical conditions included Penicillin allergy (caused hives in patient) and Allergy to NSAIDs (avoiding due to history of idiopathic angioedema).<br><br>On 05-Nov-2021, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 05-Nov-2021, the patient experienced CHEST PAIN (Left Chest pain) (seriousness criterion hospitalization), MALAISE (Malaise) (seriousness |

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| | | criterion hospitalization), HYPERHIDROSIS (Hyperhidrosis) (seriousness criterion hospitalization), FATIGUE (Fatigue) (seriousness criterion hospitalization), CHILLS (Chills) (seriousness criterion hospitalization), NAUSEA (Nausea) (seriousness criterion hospitalization), HEADACHE (Headache) (seriousness criterion hospitalization), PYREXIA (Pyrexia) (seriousness criterion hospitalization), ANXIETY (Anxiety) (seriousness criterion hospitalization), C-REACTIVE PROTEIN INCREASED (C-reactive protein increased) (seriousness criterion hospitalization), CARDIAC IMAGING PROCEDURE ABNORMAL (Cardiac imaging procedure abnormal) (seriousness criterion hospitalization), CHEST DISCOMFORT (Chest discomfort) (seriousness criterion hospitalization), COUGH (Cough) (seriousness criterion hospitalization), EAR PAIN (Ear pain) (seriousness criterion hospitalization), ECHOCARDIOGRAM NORMAL (Echocardiogram normal) (seriousness criterion hospitalization), EJECTION FRACTION NORMAL (Ejection fraction normal) (seriousness criterion hospitalization), ELECTROCARDIOGRAM T WAVE INVERSION (Electrocardiogram T wave inversion) (seriousness criteria hospitalization and medically significant), ELECTROCARDIOGRAM ABNORMAL (Electrocardiogram abnormal) (seriousness criterion hospitalization), LEFT VENTRICULAR DILATATION (Left ventricular dilatation) (seriousness criterion hospitalization), MAGNETIC RESONANCE IMAGING HEART (Magnetic resonance imaging heart) (seriousness criterion hospitalization), MYOCARDIAL OEDEMA (Myocardial oedema) (seriousness criteria hospitalization and medically significant), N-TERMINAL PROHORMONE BRAIN NATRIURETIC PEPTIDE INCREASED (N-terminal prohormone brain natriuretic peptide increased) (seriousness criterion hospitalization), PAIN (Pain) (seriousness criterion hospitalization), PERICARDIAL FIBROSIS (Pericardial fibrosis) (seriousness criteria hospitalization and medically significant), PLEURITIC PAIN (Pleuritic pain) (seriousness criterion hospitalization), RED BLOOD CELL SEDIMENTATION RATE INCREASED (Red blood cell sedimentation rate increased) (seriousness criterion hospitalization), RETCHING (Retching) (seriousness criterion hospitalization), SLEEP DISORDER (Sleep disorder) (seriousness criterion hospitalization), TROPONIN INCREASED (Troponin increased) (seriousness criterion hospitalization), VENTRICULAR HYPOKINESIA (Ventricular hypokinesia) (seriousness criteria hospitalization and medically significant), VOMITING (Vomiting) (seriousness criterion hospitalization) and MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, CHEST PAIN (Left Chest pain), MALAISE (Malaise), HYPERHIDROSIS (Hyperhidrosis), FATIGUE (Fatigue), CHILLS (Chills), NAUSEA (Nausea), HEADACHE (Headache), PYREXIA (Pyrexia), ANXIETY (Anxiety), C-REACTIVE PROTEIN INCREASED (C-reactive protein increased), CARDIAC IMAGING PROCEDURE ABNORMAL (Cardiac imaging procedure abnormal), CHEST DISCOMFORT (Chest discomfort), COUGH (Cough), EAR PAIN (Ear pain), ECHOCARDIOGRAM NORMAL (Echocardiogram normal), EJECTION FRACTION NORMAL (Ejection fraction normal), ELECTROCARDIOGRAM T WAVE INVERSION (Electrocardiogram T wave inversion), ELECTROCARDIOGRAM ABNORMAL (Electrocardiogram abnormal), LEFT VENTRICULAR DILATATION (Left ventricular dilatation), MAGNETIC RESONANCE IMAGING HEART (Magnetic resonance imaging heart), MYOCARDIAL OEDEMA (Myocardial oedema), N-TERMINAL PROHORMONE BRAIN NATRIURETIC PEPTIDE INCREASED (N-terminal prohormone brain |

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| | | natriuretic peptide increased), PAIN (Pain), PERICARDIAL FIBROSIS (Pericardial fibrosis), PLEURITIC PAIN (Pleuritic pain), RED BLOOD CELL SEDIMENTATION RATE INCREASED (Red blood cell sedimentation rate increased), RETCHING (Retching), SLEEP DISORDER (Sleep disorder), TROPONIN INCREASED (Troponin increased), VENTRICULAR HYPOKINESIA (Ventricular hypokinesia), VOMITING (Vomiting) and MYOCARDITIS (Myocarditis) had not resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 08-Nov-2021, C-reactive protein: 29.9 (High) 29.9.<br>On 08-Nov-2021, Electrocardiogram: normal (normal) inverted T waves in V1-2, no ST segment abnormalities.<br>On 08-Nov-2021, Magnetic resonance imaging heart: abnormal (abnormal) hypokinesis of LV mid to tdistal inferior walls, mid myocardial and subepicardial late gadolinium enhancement at basal to apical inferior, basal to mid inferolateral, and mid anterolateral segments of LV, myocardial edema, focal thickening of pericardium with late gadolinium enhancement of the pericardium adjacent to the inferior, inferolateral and anterolateral walls, consistent with acute peri myocarditis.<br>On 08-Nov-2021, N-terminal prohormone brain natriuretic peptide: 657 (High) 657.<br>On 08-Nov-2021, Red blood cell sedimentation rate: 65 (High) 65.<br>On 08-Nov-2021, Troponin: 344 (High) greater than 352, greater than 351, greater than 296.<br>On 09-Nov-2021, Echocardiogram: normal (normal) LV systolic function normal, no segmental LV wall motion abnormalities, EF 60%, global longitudinal strain normal.<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments.<br><br>Concomitant medications included Calcium/Vitamin D.<br>Treatment medication: Tylenol - Colchicine and Ibuprofen.<br><br>It was reported that patient developed left chest pain within a few hours of shot, along with malaise, diaphoresis. Accompanied by fatigue, chills, fever, nausea, headache over next 48 hours. Other symptoms resolved after 48 hours with rest and 500-650 mg Tylenol 2-3x/day, except chest pain, pleuritic at times, associated at times with nausea, retching, cough, fatigue. Chest pain was 3-5/10 and intermittent, until escalated to 10/10 and awoke patient from sleep 60 hours after shot, no longer pleuritic but crushing, associated with sense of doom, nausea/vomiting, and radiation to left ear. This episode lasted about an hour and returned to 1-2/10 pain after 650 mg Tylenol by the time patient reached the ED. Found to have elevated troponin, and cardiac MRI identified myopericarditis. Admitte |
| 4.1(b) | 4.1(b) | This case was received via 4.1(b) (Reference number: 4.1(b) ) on 23-Nov-2021 and was forwarded to Moderna on 23-Nov-2021.<br>This regulatory authority case was reported by a consumer and describes the occurrence of FATIGUE (Fatigue/unusual tiredness), CHEST PAIN (Chest pain), DYSPNOEA (Shortness of breath), TACHYCARDIA (Racing heart (tachycardia)) and MYOCARDITIS (Myocarditis) in a 19-year-old |

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| | | female patient who received mRNA-1273 (COVID 19 Vaccine Moderna) (batch no. 3004222) for COVID-19 immunisation.<br><br>No Medical History information was reported.<br><br>On 10-Sep-2021, the patient received second dose of mRNA-1273 (COVID 19 Vaccine Moderna) (unknown route) 1 dosage form. On 13-Sep-2021, after starting mRNA-1273 (COVID 19 Vaccine Moderna), the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). On an unknown date, the patient experienced FATIGUE (Fatigue/unusual tiredness) (seriousness criteria hospitalization and medically significant), CHEST PAIN (Chest pain) (seriousness criteria hospitalization and medically significant), DYSPNOEA (Shortness of breath) (seriousness criteria hospitalization and medically significant) and TACHYCARDIA (Racing heart (tachycardia)) (seriousness criteria hospitalization and medically significant). At the time of the report, FATIGUE (Fatigue/unusual tiredness), CHEST PAIN (Chest pain), DYSPNOEA (Shortness of breath) and TACHYCARDIA (Racing heart (tachycardia)) outcome was unknown and MYOCARDITIS (Myocarditis) was resolving.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On an unknown date, Troponin: 160 (High) 160 and raised (High) Raised.<br><br>Patient reported that her symptoms lead to hospital stay, duration was 4 days and diagnosis was made by Cardiologist. Hospitalized with crushing chest pain there for 4 days. Multiple blood tests, echocardiogram (EEG), chest X-ray. Fatigue, myocarditis, shortness of breath and tachycardia. Additional lab tests include: Later Heart MRO outpatient, blood tests that signal heart muscle damage and other imaging tests.<br>No Concomitant medication information was reported.<br>No treatment medications were provided. |
| 4.1(b) [redacted] | 4.1(b) [redacted] | This case was received via 4.1(b) [redacted] (Reference number: 4.1(b) [redacted] on 23-Nov-2021 and was forwarded to Moderna on 23-Nov-2021.<br>This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCARDITIS (Myocarditis) in a 39-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below.<br><br>Concurrent medical conditions included Penicillin allergy, Diabetes, Hypertension and High cholesterol.<br><br>On 01-Mar-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 16-Oct-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criterion medically significant), CHEST PAIN (Chest pain), BLOOD TEST (Blood test), CARDIAC STRESS TEST (Cardiac stress |

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| | | test), ECHOCARDIOGRAM (Echocardiogram), ELECTROCARDIOGRAM ABNORMAL (Electrocardiogram abnormal) and SARS-COV-2 TEST (SARS-CoV-2 test). At the time of the report, MYOCARDITIS (Myocarditis), CHEST PAIN (Chest pain), BLOOD TEST (Blood test), CARDIAC STRESS TEST (Cardiac stress test), ECHOCARDIOGRAM (Echocardiogram), ELECTROCARDIOGRAM ABNORMAL (Electrocardiogram abnormal) and SARS-COV-2 TEST (SARS-CoV-2 test) had not resolved.<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments.<br><br>Other medication includes: Atorvorstatin, Aspirin, Lisonopril (I think I started it), Hydroxizine<br>No treatment medications were reported<br><br>Lab data includes: EKG, blood tests, echo nuclear stress test<br><br>Symptoms: It was reported that, On 17-Oct-2021, patient went to the urgent care for chest pain, EKG showed abnormal results, patient was then taken to the hospital and was diagnosed with Myocarditis and released on next day, COVID-19 tests were negative, and the main diagnosis was Myocarditis which was not related to COVID-19 or to the vaccine.<br><br>Company's comment: This case concerns a 39-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) with relevant medical history of diabetes, hypertension and high cholesterol who experienced the serious expected event (AESI) of myocarditis 229 days after the second dose of the vaccine. Medical history of diabetes, hypertension and high cholesterol are confounders. Rechallenge is not applicable, since no further dosing is expected. The benefit-risk relationship is not affected by this report |
| 4.1(b) | 4.1(b) | This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) ) on 18-Nov-2021 and was forwarded to Moderna on 24-Nov-2021.<br>This case, initially reported to the 4.1(b) by a (pharmacist), was received via the 4.1(b) (Ref, 4.1(b)<br><br>On an unknown date, the patient received the 1st dose of this vaccine.<br><br>On 19-Oct-2021, the patient received the 2nd dose of this vaccine. The patient was hospitalized.<br><br>On 20-Oct-2021, headache and pyrexia developed.<br><br>On 21-Oct-2021, chest pain developed.<br><br>On 23-Oct-2021, the symptoms did not improve, and the patient visited a nearby physician. Although electrocardiographic changes and predominant findings in the echocardiography were not indicated, the patient was urgently transferred to the reporting hospital due to suspected myocarditis after the vaccination with this vaccine because of positive |

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| | | troponin. After admission, coronary angiography showed no ischemic lesion. Left ventriculography, myocardial biopsy, and hemodynamic evaluation were performed, and the patient was diagnosed with myocarditis and admitted to the ICU. On the monitor, AF rhythm, which developed during myocardial biopsy, persisted, but it was confirmed that troponin T peaked out on the same day.<br><br>At 14:27 CK: 264 U/L, and highly sensitive TNT: 0.358 ng/mL.<br><br>At 20:00 CK: 258 U/L, and highly sensitive TNT: 0.486 ng/mL.<br><br>At 23:00 CK: 227 U/L, and highly sensitive TNT: 0.481 ng/mL.<br><br>On 24-Oct-2021, the patient returned to sinus rhythm. Cardiac ultrasonography showed no significant findings.<br><br>At 08:09, CK: 166 U/L, and highly sensitive TNT: 0.341 ng/mL.<br><br>On 25-Oct-2021, at 06:48, CK: 84 U/L, and highly sensitive TNT: 0.140 ng/mL.<br><br>On 26-Oct-2021, the patient was transferred to a general ward for stable symptoms. Since then, there was no chest pain, and there was no remarkable change in examination findings.<br><br>At 07:35, CK: 83 U/L, and highly sensitive TNT: 0.028 ng/mL.<br><br>At 08:46, highly sensitive TNT: 0.007 ng/mL.<br><br>On 01-Nov-2021, at 08:25, highly sensitive TNT: 0.003 ng/mL<br><br>On 02-Nov-2021, the symptoms were resolving, and the patient was discharged from the hospital.<br><br>The outcome of chest pain and acute myocarditis was reported as resolving.<br><br>Follow-up investigation will be made.<br><br>Company Comment:<br><br>The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 24-Nov-2021 and was forwarded to Moderna on 24-Nov-2021.<br>This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (Heart rhythm disorders occurred approx. eight weeks after the vaccination. After checking with the cardiologist, he confirmed that I had heart muscle inflammation.), TACHYCARDIA (Heart palpitations and rapid heartbeat.) and DYSPNOEA (I only experience shortness of breath when walking) in a 31-year-old female patient who received mRNA-1273 (Spikevax) for Prophylactic vaccination. |

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| | | No medical history was reported.<br>Concurrent medical conditions included Hashimoto's disease.<br><br>On 16-Jul-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 24-Oct-2021, the patient experienced MYOCARDITIS (Heart rhythm disorders occurred approx. eight weeks after the vaccination. After checking with the cardiologist, he confirmed that I had heart muscle inflammation.) (seriousness criterion medically significant), TACHYCARDIA (Heart palpitations and rapid heartbeat.) (seriousness criterion medically significant) and DYSPNOEA (I only experience shortness of breath when walking) (seriousness criterion medically significant). At the time of the report, MYOCARDITIS (Heart rhythm disorders occurred approx. eight weeks after the vaccination. After checking with the cardiologist, he confirmed that I had heart muscle inflammation.), TACHYCARDIA (Heart palpitations and rapid heartbeat.) and DYSPNOEA (I only experience shortness of breath when walking) had not resolved.<br><br>The patient had long-term ECG, stress ECG, ultrasound, blood draw. Result was normal.<br>Patient had hay fever allergy.<br><br>No concomitant medication was reported.<br>No treatment information was reported.<br>Company Comment : This case concerns a 31-year-old, female patient, with medical history of Hashimoto's disease, who experienced the serious, expected, AESI event of myocarditis and serious unexpected events of tachycardia and dyspnea. The events occurred 3 months after second dose of mRNA 1273 vaccine. The rechallenge is not applicable as there is no information regarding a third dose. The patient's history of hashimoto's disease and long onset latency of event myocarditis remain as confounder to the event myocarditis. The benefit-risk relationship of mRNA 1273 vaccine is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 24-Nov-2021: Translated document received on 24-Nov-2021: Event Verbatim and Sender's Comment updated. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 24-Nov-2021 and was forwarded to Moderna on 24-Nov-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myocarditis) in a 21-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3002542) for Prophylactic vaccination.<br><br>Previously administered products included for COVID-19 vaccination: SPIKEVAX on 08-May-2021.<br>Past adverse reactions to the above products included No adverse event with SPIKEVAX. |

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| | | On 16-Jun-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 23-Aug-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criterion hospitalization). At the time of the report, MYOCARDITIS (Myocarditis) had not resolved.<br><br>For mRNA-1273 (Spikevax) (Unknown), the reporter considered MYOCARDITIS (Myocarditis) to be possibly related.<br><br>No Concomitant informations were reported.<br><br>No Treatment informations were reported.<br><br>Company Comment : This regulatory case concerns a 21-year-old, male patient with no relevant medical history, who experienced the expected AESI of myocarditis. The event, which resulted in hospitalization, occurred approximately 2 months after administration of the second dose of the Moderna mRNA-1273. The rechallenge was not applicable as no additional dosing will be given. The patient's gender remains a confounder. The benefit-risk relationship of the Moderna mRNA-1273 is not affected by this report. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 24-Nov-2021 and was forwarded to Moderna on 24-Nov-2021.<br>This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (Myocarditis) and INFLUENZA LIKE ILLNESS (Flu-like symptoms) in a 27-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 214012) for Prophylactic vaccination.<br><br>No Medical History information was reported.<br><br>On 11-Aug-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 12-Aug-2021, the patient experienced INFLUENZA LIKE ILLNESS (Flu-like symptoms) (seriousness criterion hospitalization). On 13-Aug-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Myocarditis) and INFLUENZA LIKE ILLNESS (Flu-like symptoms) had not resolved.<br><br>No concomitant medications were reported<br>No treatment medications were reported<br>After about 12 hours, onset of chills, sore throat and limb pain, fever and<br>After about 48 hours, stabbing pain in the left chest and shortness of breath.<br><br>Company Comment: This case concerns a 27 year old male, with no reported medical history , who experienced Serious ( Hospitalizaiton ) , expected, AESI event of myocarditis which occurred 3 days after vaccination with the 2nd dose of mRNA -1273 vaccine ( Moderna Covid |

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| | | 19 Vaccine ) and serious ( hospitalization ) , unexpected event of Influenza like Illness which occurred 2 days after vaccination with the 2nd dose. The re-challenge for this case is not applicable since the events had not resolved and the events occurred after the 2nd dose and no additional doses will be given. The benefit -risk relationship of mRNA - 1273 ( Moderna Covid 19 Vaccine) is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes: On 24-Nov-2021: Translation received on 25-Nov 2021 Include event verbatim and Sender's comments updated |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 24-Nov-2021 and was forwarded to Moderna on 24-Nov-2021.<br>This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (Myocarditis) in a 29-year-old male patient who received mRNA-1273 (COVID 19 Vaccine Moderna) (batch no. 214020) for Prophylactic vaccination.<br><br>No Medical History information was reported.<br><br>On 08-Nov-2021, the patient received third dose of mRNA-1273 (COVID 19 Vaccine Moderna) (unknown route) 1 dosage form. On 11-Nov-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criterion hospitalization). At the time of the report, MYOCARDITIS (Myocarditis) had not resolved.<br><br>No concomitant medications was reported.<br>No treatment drug details was reported.<br><br>Patient had no any known allergies and no Information on risk factors or previous illnesses. After vaccination on 08-Nov-2021., he had not have chills, headache and fever until following night. Fever rose to 39 degrees and subsided again with other mentioned symptoms by Nov 10. On 11 morning he noticed a strong tight feeling in his chest, with racing heart, stabbing pain in the chest. got an appointment with his family doctor for next day. From there, he was sent to emergency room, they diagnosed with myocarditis based on blood results.<br><br>Company comment: This case concerns a 29-year-old male with no relevant medical history reported in this case, who experienced the serious unexpected AESI event of Myocarditis The event occurred approximately 3 days after the administration of the 3rd dose of the mRNA-1273 vaccine. At the time of the report, the outcome for the event was Not Recovered/Not Resolved. The rechallenge is not applicable since the event occurred after the 3rd dose of the of the mRNA-1273 vaccine and another dose will not be administered. Seriousness was automatically upgraded per IME list for the event “Myocarditis” as Medically Significant; as no available information regarding the severity and outcome of the event, in accordance with the RA criteria, this severity was manually downgraded to mirror with SD. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report. |

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| | | Most recent FOLLOW-UP information incorporated above includes:<br>On 24-Nov-2021: Translation document received on 25-NOV-2021 includes translated event verbatim and senders comment. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 24-Nov-2021 and was forwarded to Moderna on 24-Nov-2021.<br>This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (I had severe heart muscle inflammation and was in hospital for a few days.) in a 27-year-old male patient who received mRNA-1273 (Spikevax) for Prophylactic vaccination.<br><br>No Medical History information was reported.<br><br>On 20-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 29-Sep-2021, the patient experienced MYOCARDITIS (I had severe heart muscle inflammation and was in hospital for a few days.) (seriousness criterion hospitalization). On 27-Oct-2021, MYOCARDITIS (I had severe heart muscle inflammation and was in hospital for a few days.) had resolved with sequelae.<br><br>No concomitant medications were mentioned.<br><br>No treatment details were reported.<br><br>A few days after the vaccination, the patient started having increasing chest pains and was permanently out of breath. The pain got worse day by day until he collapsed at work and was taken to the hospital.<br><br>This regulatory case concerns a 27-year-old, male patient with no relevant medical history, who experienced the expected, serious AESI of myocarditis. The event, which resulted in hospitalization, occurred 9 days after administration of the second dose of the Moderna mRNA-1273. The patient started having increasing chest pains and was permanently out of breath. The pain got worse day by day until he collapsed at work and was brought to the hospital. The patient was in the hospital for an unspecified number of days. Laboratory test/s or treatment information were not provided. The event lasted for 29 days and had resolved with sequelae at the time of the report. The rechallenge was not applicable as no additional dosing will be given. The patient's gender remains a confounder. The benefit-risk relationship of the Moderna mRNA-1273 is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 24-Nov-2021: Translation Received on 25Nov21 Contains event verbatim and senders comment with event details updated and added in I narrative. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 24-Nov-2021 and was forwarded to Moderna on 24-Nov-2021. |

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| | | This regulatory authority case was reported by a pharmacist and describes the occurrence of MYOCARDITIS (Myopericarditis) in an 18-year-old male patient who received mRNA-1273 (COVID 19 Vaccine Moderna) (batch no. 079F21A) for COVID-19 vaccination.<br><br>Concomitant products included mRNA-1273 (COVID 19 Vaccine Moderna) for COVID-19 vaccination.<br><br>On 27-Oct-2021, the patient received second dose of mRNA-1273 (COVID 19 Vaccine Moderna) (Intramuscular) 1 dosage form. On 28-Oct-2021, the patient experienced MYOCARDITIS (Myopericarditis) (seriousness criterion hospitalization prolonged). At the time of the report, MYOCARDITIS (Myopericarditis) had resolved.<br><br>For mRNA-1273 (COVID 19 Vaccine Moderna) (Intramuscular), the reporter did not provide any causality assessments.<br><br>No treatment information was provided.<br><br>Company comment-This regulatory authority case concerns a 18-year-old male patient with no details on relevant medical history, who experienced the expected serious (hospitalization) event of Myopericarditis after mRNA- 1273 Moderna vaccine. The event occurred approximately 1 day after the second dose of mRNA- 1273 vaccine. Very limited information is available regarding clinical manifestations and diagnosis. The rechallenge is not applicable, since the event was reported exclusively after the second dose. The benefit-risk relationship of mRNA- 1273 vaccine is not affected by this report<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 24-Nov-2021: Translation document received on 25 Nov 2021 include suspect product name, concomitant product name translated and narrative was updated accordingly |
| 4.1(b) | 4.1(b) | This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCARDITIS (Perimyocarditis + chest pain) in a 27-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) (batch nos. 3004494 and 3004219) for an unknown indication.<br><br>No Medical History information was reported.<br><br>On 14-Sep-2021, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form.<br>On 14-Oct-2021, received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) dosage was changed to 1 dosage form. On 18-Oct-2021, after starting mRNA-1273 (COVID-19 Vaccine Moderna), the patient experienced MYOCARDITIS (Perimyocarditis + chest pain) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Perimyocarditis + chest pain) was resolving. |

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| | | For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered MYOCARDITIS (Perimyocarditis + chest pain) to be possibly related.<br><br>No concomitant medications reported by reporter.<br>Patient was rarely drinking alcohol.<br>No treatment medications provided by the reporter.<br>Four days after the second dose of Spikevax, the patient manifested perimyocarditis with subsequent chest pain. Severe reaction which led to hospitalization.<br><br>Company comment -This case concerns a 27 year-old, male patient with no relevant medical history, who experienced the serious (due to hospitalization and medically important condition) expected AESI of Myocarditis. The event occurred approximately 4 days after the second dose of mRNA-1273 vaccine. The rechallenge was not applicable, as the event was reported exclusively after the second dose and no information on additional dosing is available. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 23-Nov-2021: Translation received on 25-Nov-2021 and event verbatim and narrative updated. |
| 4.1(b) | 4.1(b) | This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) ) on 19-Nov-2021 and was forwarded to Moderna on 24-Nov-2021.<br>This case, initially reported to the 4.1(b) by a (physician), was received via the 4.1(b) (Ref, 4.1(b)<br><br>The patient has a history of bundle branch block right.<br><br>On 29-Sep-2021, the patient received the 1st dose of this vaccine.<br><br>On an unknown date, body temperature before vaccination: 36.7 degrees Celsius.<br><br>On 27-Oct-2021, at 15:30, the patient received the 2nd dose of this vaccine.<br><br>On 30-Oct-2021, from the morning, the patient experienced left precordial pain and cold sweat. At 10:00, acute pericardial myocarditis developed.<br><br>On 31-Oct-2021, in the morning, the patient had chest pain and made an emergency visit to the reporting hospital. The patient originally had right bundle branch block, and electrocardiogram showed ST elevation in I, II, III, aVF, and V4-6 leads, and the results of a blood test showed elevation of cardiac enzymes (CK, CKMB, and TropI). Echocardiography showed diffuse hypokinesis mainly in the inferior wall. The patient was hospitalized to receive treatments, and analgesics were used.<br><br>On an unknown date, improvements were shown in electrocardiogram, cardiac enzymes, and echocardiography. |

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| | | On 04-Nov-2021, the patient was discharged with improvement of the symptoms.<br><br>On 06-Nov-2021, cardiac MRI was performed, and the findings were consistent with myocarditis.<br><br>The outcome of acute pericardial myocarditis was reported as resolving.<br><br>Follow-up investigation will be made.<br><br>Company Comment:<br><br>The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. |
| 4.1(b) | 4.1(b) | This case was initially received via 4.1(b) (Reference number: 4.1(b) ) on 24-Nov-2021. The most recent information was received on 22-Dec-2021 and was forwarded to Moderna on 22-Dec-2021.<br>This regulatory authority case was reported by a consumer and describes the occurrence of CHEST PAIN (Chest pain), CHEST DISCOMFORT (Chest pressure), BACK PAIN (Back pain), PAIN IN EXTREMITY (Pain in extremity), MUSCULAR WEAKNESS (Muscular weakness), TACHYCARDIA (Racing heart (tachycardia)), PALPITATIONS (Heart palpitations) and PERICARDITIS (Pericarditis) in a 34-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) (batch no. 3003651) for an unknown indication.<br><br>Previously administered products included for Product used for unknown indication: COVID-19 VACCINE MODERNA.<br>Past adverse reactions to the above products included No adverse event with COVID-19 VACCINE MODERNA.<br><br>On 08-Aug-2021, the patient received second dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 19-Aug-2021, the patient experienced CHEST PAIN (Chest pain) (seriousness criteria hospitalization and medically significant) and PERICARDITIS (Pericarditis) (seriousness criteria hospitalization and medically significant). On an unknown date, the patient experienced CHEST DISCOMFORT (Chest pressure) (seriousness criteria hospitalization and medically significant), BACK PAIN (Back pain) (seriousness criteria hospitalization and medically significant), PAIN IN EXTREMITY (Pain in extremity) (seriousness criteria hospitalization and medically significant), MUSCULAR WEAKNESS (Muscular weakness) (seriousness criteria hospitalization and medically significant), TACHYCARDIA (Racing heart (tachycardia)) (seriousness criteria hospitalization and medically significant) and PALPITATIONS (Heart palpitations) (seriousness criteria hospitalization and medically significant). At the time of the report, CHEST PAIN (Chest pain), CHEST DISCOMFORT (Chest pressure), BACK PAIN (Back pain), PAIN IN EXTREMITY (Pain in extremity), MUSCULAR WEAKNESS (Muscular weakness) and PERICARDITIS (Pericarditis) had not resolved and TACHYCARDIA (Racing heart (tachycardia)) and PALPITATIONS (Heart palpitations) outcome was unknown. |

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| | | DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 20-Aug-2021, SARS-CoV-2 test: no - negative covid-19 test (Negative) Negative.<br>On an unknown date, Blood test: results not reported (Inconclusive) Results not reported.<br>On an unknown date, Chest X-ray: results not reported (Inconclusive) Results not reported.<br>On an unknown date, Echocardiogram: slightly bright pericardium (abnormal) slightly bright Pericardium.<br>On an unknown date, Electrocardiogram: st segment which indicated pericarditis, (abnormal) ST segment which indicated Pericarditis.<br><br>Concomitant product use was not provided by the reporter.<br>Patient had no underlying health conditions or medical problems prior to the vaccine. Started with Chest pains on the 19-Aug-2021, went to the emergency department and was kept on the heart care ward for 4 days. All tests showed pericarditis induced by the vaccine as per the doctors and cardiologist reports. Till the present day of report, which was 3 months on the chest pain/pressure which had radiated into back and shoulder. The patient stayed in hospital with respect to the events for 4 nights. He was unable to work because was a firefighter which was very physical. The patient's bloods tests, electrocardiogram (ECG), echocardiogram and X-ray was carried out. The patient took treatment of anti inflammatories medications and blood thinner while in hospital. Currently he was taking colchicine and ibuprofen. Patient had not tested positive for COVID-19 since he had received the vaccine. He was prescribed NSAIDS for 5 weeks then introduced Colchicine. He was currently 3.5 months with no exercise and still with the same symptoms. On 19-Aug-2021, he had done no exercise on the day but ran 5 miles the previous day. The patient took no medication. He rarely drank alcohol and had not had any near the time. He did not use recreational drugs and had never smoked. Never any steroids, never a reaction to any other vaccine, and not had Covid or tested positive on any test.<br><br>Company comment: This case concerns a 34-year-old male, with no reported medical history, who experienced the expected serious AESI event of Pericarditis and the unexpected serious events of Chest pain, Palpitations, Tachycardia Chest discomfort, Back pain, Pain in extremity and Muscular weakness. The events pericarditis and chest pain occurred approximately 11 days after the administration of the second dose of the mRNA-1273 vaccine, the events palpitations, tachycardia and chest discomfort occurred on an unknown date. The patient went to the emergency department and was kept on the heart care ward for 4 days. Blood tests, electrocardiogram (ECG), echocardiogram and X-ray was carried out which showed signs of Pericarditis. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 22-Dec-2021: Significant information that included other medical history, lab data updated, event added and narrative updated. |

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| 4.1(b) | 4.1(b) | This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 22-Nov-2021 and was forwarded to Moderna on 25-Nov-2021.<br>This case, initially reported to the 4.1(b) by a (physician), was received via the 4.1(b) (Ref, 4.1(b)<br><br>On an unknown date, the patient received the 1st dose of this vaccine.<br><br>On 10-Nov-2021, the patient received the 2nd dose of this vaccine.<br><br>On 11-Nov-2021, high fever and back pain developed.<br><br>On 13-Nov-2021, around 07:25, the patient developed convulsions while sleeping, and the family member who noticed the convulsions called an ambulance. With verbal guidance, a family member started chest compressions on the patient.<br><br>At 07:30, when the ambulance arrived, the patient had ventricular fibrillation, so defibrillation was performed once, and cardiac arrest and pulseless electrical activity were repeated.<br><br>At 08:07, the patient arrived at the reporting hospital and extracorporeal cardiopulmonary resuscitation was performed. Coronary angiography showed no significant stenosis in the coronary arteries. Myocardial biopsy was not performed.<br><br>Acute myocarditis after vaccination was suspected based on the clinical history and clinical course. The patient was complicated by hypoxic encephalopathy and there was a high possibility that the patients life could not be saved.<br><br>On 19-Nov-2021, the symptoms were ongoing and unchanged.<br><br>The outcome of convulsion, ventricular fibrillation, asystole, pulseless electrical activity, suspected acute myocarditis and hypoxic encephalopathy was reported as ongoing and unchanged.<br><br>Follow-up investigation will be made.<br><br>Company Comment:<br><br>The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.<br><br>Company comment-<br>This case concerns a 30-year-old male patient with no relevant medical history provided, who experienced the unexpected serious events of Seizure, Ventricular fibrillation, Cardiac arrest, Pulseless electrical activity, Hypoxic-ischaemic encephalopathy, as well as serious expected events of Myocarditis. All reported events occurred three days following the administration of the second dose of the mRNA-1273 vaccine. The patient initially developed convulsions while sleeping, and after the ambulance arrived, it was noted that the patient had ventricular fibrillation, so |

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| | | defibrillation was performed once, and cardiac arrest and pulseless electrical activity were repeated. The patient was hospitalized and extracorporeal cardiopulmonary resuscitation was performed. Coronary angiography showed no significant stenosis in the coronary arteries. Myocardial biopsy was not performed. Acute myocarditis after vaccination was suspected based on the clinical history and clinical course, as reported. The patient was complicated by hypoxic encephalopathy. At the time of the report, all events were ongoing and unchanged. The re-challenge is not applicable, in line with the source document (no rechallenge was done and recurrence is not applicable). The events were considered related to the product per the reporter's and MAH assessment. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report. |
| 4.1(b) | 4.1(b) | This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) ) on 17-Nov-2021 and was forwarded to Moderna on 25-Nov-2021.<br><br>This case, initially reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref 4.1(b)<br><br>On 21-Sep-2021, the patient received the 1st dose of the vaccine.<br><br>On 22-Sep-2021, the patient merely had a low-grade fever of 37s degrees Celsius.<br><br>From 28-Sep-2021 to 01-Oct-2021, the patient experienced pyrexia of 38s degrees Celsius, chest discomfort, malaise, and headache.<br><br>On an unknown date, the patient visited an ENT physician, and the symptoms improved with oral administration of prescribed medication. Chest discomfort during activities remained.<br><br>On an unknown date, body temperature before the vaccination: 36.5 degrees Celsius.<br><br>On 20-Oct-2021, at 17:00, the patient received the 2nd dose of the vaccine.<br><br>On 21-Oct-2021, the patient had pyrexia of 38s degrees Celsius. Chest tightness and breathlessness began to appear during activities. Particularly at inspiration, the patient sometimes had dry cough because of difficulty breathing in. Although the patient took acetaminophen and over-the-counter ibuprofen, body temperature was not reduced.<br><br>On 25-Oct-2021, the patient visited the previous physician for the first time. Pyrexia of 38s degrees Celsius and dyspnea on exertion were noted. The results of a blood test showed elevations of WBC and CRP. Chest X-ray showed no obvious image of pneumonia, but CTR was expanded to 58%, which was suggestive of accumulation of pleural fluid. The patient visited the reporting department by ambulance with a referral for suspected myocarditis and pericarditis after vaccination with the vaccine. |

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| | | [Actual symptoms on admission]<br><br>Body temperature: 38.8 degrees Celsius, pulse rate: regular with 96 beats/min, blood pressure: (right) 125/79 mmHg, (left) 141/82 mmHg, SpO2: 96% (RA).<br><br><head and neck> No anemia in the bulbar conjunctiva, no conjunctiva bulbi coloring yellow, no lymph node swelling, no thyroid gland enlargement, no carotid bruit, and no stiffness in the neck. No Jolt accentuation.<br><br><Chest> Cardiac sound: regular without cardiac murmur, respiratory sounds: clear on both lungs.<br><br><Abdomen> Flat and soft, and favorable bowel sounds on auscultation. No tenderness and no pain on percussion. No Murphy signs.<br><br><Limbs and joints> Peripheral vessels were well palpable. No peripheral coldness, no oedema, and no warmth and swelling in joints. Pain in the shoulder joints was noted when pyrexia developed.<br><br>Based on the episode and symptoms, myocarditis and/or pericarditis associated with the COVID-19 vaccine was suspected. The results of blood tests showed no elevation in cardiac enzymes such as CK and troponin, and echocardiography showed no myocardial oedema or markedly abnormal wall motions, with a small amount of pericardial fluid. There was an impression that a large amount of adipose tissues was found. There was some awkwardness in the movement of the heart, and since pericardial effusion was suspected based on the CT image provided by the previous physician, it was decided to perform detailed examinations and medical treatments in hospitalization for suspected pericarditis and myocarditis. BNP was elevated to 92.3 pg/mL, and the cardiac shadow was clearly enlarged compared to that of chest X-ray in 2019. WBC increased predominantly in neutrophils and CRP was high, but PCT was not markedly elevated. Urinalysis, chest CT, and X-ray showed no evidence of respiratory infection. Considering the possibility of changes associated with pericarditis or myocarditis, administration of three tablets of acetaminophen 500 mg in three divided doses was started. Thrombocytosis, increased D-dimer, and low albumin, which had not been found in 2019, were considered to be caused by the inflammation that was found this time. Leg vein echography was performed, and the obvious leg vein thrombus was not found.<br><br>On 26-Oct-2021, the patient had no pyrexia, and the chest symptom was gradually relieved over time. BMIPP myocardial scintigraphy was performed for evaluation of myocardial damages. The uptake into the myocardia was uniformly favorable except for a part in the anterior wall. Therefore, myocardial damage was not completely ruled out.<br><br>On 28-Oct-2021, although the inflammatory responses decreased in the results of follow-up blood sampling, platelet and D-dimer levels showed a further increasing tendency. Since the risk of thrombus formation was also considered, continuous infusion of 10,000 units of heparin was started. The patient was diagnosed with thrombocytosis. In reference to |

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| | | ACT and APTT, the dose of heparin was increased to 20,000 units, but the inflammatory response decreased and both platelet count and D-dimer tended to decrease.<br><br>On 31-Oct-2021, findings of Wenckebach type second degree atrioventricular block were intermittently found in the monitor electrocardiogram. There were no subjective symptoms.<br><br>On 01-Nov-2021, the result of a blood test showed findings that suggested hepatic disorder due to acetaminophen. Decreased pericardial effusion was confirmed by echocardiography, and administration of acetaminophen after dinner was discontinued on the same day.<br><br>From 02-Nov-2021 to 03-Nov-2021, holter electrocardiography was performed for detailed examination. Pause of 2 seconds or more was observed 7 times a day, and the maximum RR interval was 2.4 seconds, both of which were waveforms of Wenckebach type second degree atrioventricular block.<br><br>On 04-Nov-2021, the result of a blood test revealed that hepatic disorder was exacerbated even after discontinuation of acetaminophen. It was considered to be due to heparin. Chest CT showed a tendency of decrease in pericardial effusion.<br><br>On 05-Nov-2021, oral administration of 1 tablet of aspirin 100 mg was started, and the dose of heparin was gradually reduced to 10,000 units. As the patient complained of numbness in the right lower limb, echography of the lower limb artery showed no occlusion or stenosis of the artery.<br><br>On 07-Nov-2021, the dose of heparin was gradually decreased to 5,000 units.<br><br>On 08-Nov-2021, blood tests confirmed that both platelets and D-dimer had decreased sufficiently and hepatic dysfunction was also improving. Electrocardiography and echocardiography showed no findings of exacerbation, and it was concluded that outpatient follow-up was possible. The symptoms were resolving, and the patient was discharged from the hospital. On discharge, the patient was prescribed 1 tablet of aspirin (100) and 1 capsule of esomeprazole magnesium hydrate (10) in one dose after breakfasts for each. Administration of aspirin was going to be continued after the discharge from the hospital.<br><br>The outcome of pyrexia, malaise, and headache was reported as resolved. The outcome of chest discomfort was unknown.<br><br>The outcome of myocarditis, pericarditis, thrombocytosis, Wenckebach type second degree atrioventricular block, and numbness in the right lower limb was reported as resolving.<br><br>Follow-up investigation will be made. |

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| | | Laboratory test continuation:<br><br>Leg vein echography: No visible thrombosis was found in the lower extremity venous within the observable range.<br><br>Abdominal echography: Bile ducts: The right and left intrahepatic bile ducts and common bile ducts are not dilated, and there is no apparent wall thickening. Cholangitis seems to be negative on the echo. Gallbladder: swelling, atrophy, and wall thickening were not observed. No stones or masses are found in the gallbladder lumen. Liver: Enlarged (especially in the right lobe), smooth surface but blunted liver margin, and elevated liver parenchymal echo levels. The vessels in the liver are indistinct without no deep attenuation, and the liver parenchyma is heterogeneous. The low echo area was found around the gallbladder. There is no apparent mass. Hepatic cyst was found. Others: kidneys, spleen, and pancreas were normal. No ileus, no ascites.<br><br>Plain chest CT: No evidence of respiratory infection.<br><br>Blood pressure: (right) 125/79 mmHg, (left) 141/82 mmHg.<br><br>APTT: |
| 4.1(b) | 4.1(b) | This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 23-Nov-2021 and was forwarded to Moderna on 25-Nov-2021.<br>This case, initially reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref, 4.1(b)<br><br>Acute pericarditis was assessed as serious by the MAH.<br><br>On an unknown date, the patient received the 1st dose of this vaccine.<br><br>On 17-Oct-2021, at 12:00, the patient received the 2nd dose of this vaccine.<br><br>On 18-Oct-2021, in the morning, pyrexia of 38.0-38.9 degrees Celsius developed.<br><br>At 12:00, acute pericarditis developed. Mild chest pain developed.<br><br>Around 21:00, chest pain was suddenly exacerbated.<br><br>At 22:40, the patient visited the emergency outpatient department of the reporting hospital. Electrocardiogram, chest X-ray, and echocardiography showed no obvious abnormal findings. The results of blood test showed only a slight increase in CRP of 1.26, with troponin I negative. Pain was exacerbated by inspiration, and the possibility of pericarditis was considered high. Afterwards, the pain was reduced to a severity of about one-third of the peak level, and the patient requested to go home. Thus, the patient was prescribed ibuprofen and was allowed to return home. |

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| | | On 19-Oct-2021, chest pain disappeared.<br><br>On 20-Oct-2021, the patient returned to the hospital. The same examination as the initial visit was performed, and the abnormal finding was only a slight increase in BNP of 24.7. CRP decreased to 0.59, and the symptoms were resolving. Ibuprofen for additional two days was prescribed, and treatments and follow-up were completed.<br><br>The outcome of acute pericarditis was reported as resolving.<br><br>Follow-up investigation will be made.<br><br>Company Comment:<br><br>The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. |
| 4.1(b) | 4.1(b) | This spontaneous case was reported by a consumer and describes the occurrence of MYOCARDITIS (Myopericarditis), CHEST PAIN (Chest pain), PLEURITIC PAIN (Pleuritic pain), CHEST DISCOMFORT (Chest pressure), PHOTOPHOBIA (Light sensitivity to eye) and NAUSEA (Nausea) in a 20-year-old female patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) (batch no. 043D21A) for COVID-19 vaccination.<br><br>Previously administered products included for Product used for unknown indication: MARVELON 21, NAPROXEN, PANTOPRAZOLE-40, AVAMYS and VENTOLIN.<br>Past adverse reactions to the above products included No adverse event with AVAMYS, MARVELON 21, NAPROXEN, PANTOPRAZOLE-40 and VENTOLIN.<br>Concurrent medical conditions included Asthma, Drug allergy, GERD and Migraine.<br><br>On 11-Jul-2021, the patient received second dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 15-Jul-2021, the patient experienced MYOCARDITIS (Myopericarditis) (seriousness criteria hospitalization and medically significant), CHEST PAIN (Chest pain) (seriousness criterion hospitalization), PLEURITIC PAIN (Pleuritic pain) (seriousness criterion hospitalization) and CHEST DISCOMFORT (Chest pressure) (seriousness criterion hospitalization). On an unknown date, the patient experienced PHOTOPHOBIA (Light sensitivity to eye) (seriousness criterion hospitalization) and NAUSEA (Nausea) (seriousness criterion hospitalization). At the time of the report, MYOCARDITIS (Myopericarditis), CHEST PAIN (Chest pain), PLEURITIC PAIN (Pleuritic pain), CHEST DISCOMFORT (Chest pressure), PHOTOPHOBIA (Light sensitivity to eye) and NAUSEA (Nausea) had resolved.<br><br>Concomitant medications were not reported .<br>Treatment information was not provided. |

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| | | The report was received from the 4.1(b) program with 4.1(b) ID 4.1(b)<br><br>This case concerns a 20-year-old female patient, with medical history of asthma and migraine, who experienced the serious expected AESI of myocarditis and the serious unexpected events of chest pain, pleuritic pain, chest discomfort, photophobia and nausea after the second dose of mRNA-1273. The events occurred 5 days after vaccination. The re-challenge is unknown since events outcome were recovered and occurred after second dose. Patient´s medical history of migraine remains a confounder for nausea and photophobia. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. |
| 4.1(b) | 4.1(b) | This case was received via 4.1(b) (Reference number: 4.1(b) ) on 25-Nov-2021 and was forwarded to Moderna on 25-Nov-2021.<br>This regulatory authority case was reported by a consumer and describes the occurrence of PERICARDITIS (Pericarditis) in a 39-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) (batch no. 3004675) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below.<br><br>The patient's past medical history included Suspected COVID-19 (Unsure when symptoms startedUnsure when symptoms stopped).<br>Concurrent medical conditions included Depression.<br>Concomitant products included COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (COVID-19 VACCINE ASTRAZENECA) from 05-Mar-2021 to 15-May-2021 for COVID-19, SERTRALINE from 01-Jan-2017 to an unknown date for Depression.<br><br>On 14-Nov-2021, the patient received third dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 14-Nov-2021, after starting mRNA-1273 (Moderna CoviD-19 Vaccine), the patient experienced PERICARDITIS (Pericarditis) (seriousness criterion medically significant). On an unknown date, the patient experienced CHEST PAIN (Chest pain) and PYREXIA (Fever). On 15-Nov-2021, PERICARDITIS (Pericarditis) had resolved. At the time of the report, CHEST PAIN (Chest pain) and PYREXIA (Fever) outcome was unknown.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On an unknown date, SARS-CoV-2 test: no - negative covid-19 test (Negative) No - Negative COVID-19 test.<br><br>The patient had Covid booster and later in the evening had sharp stabbing pains in upper left hand side and feeling hot<br><br>Patient has not tested positive for COVID-19 since having the vaccine<br><br>Patient is not enrolled in clinical trial<br><br>No treatment information was provided. |

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| | | Company comment: This case concerns a 39-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) with relevant history of previous Covid-19 infection who experienced the serious expected event (AESI) of pericarditis on the same day after the third dose of the vaccine. Rechallenge is not applicable, since no further dosing is expected. The benefit-risk relationship is not affected by this report. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 25-Nov-2021 and was forwarded to Moderna on 25-Nov-2021.<br>This regulatory authority case was reported by a consumer and describes the occurrence of ANGINA PECTORIS (Like heart pain, like two-week heart muscle inflammation (the onset of), like shortness of breath, like being out of breath. Started two days after the second vaccination with Moderna.), DYSPNOEA EXERTIONAL (Like heart pain, like two-week heart muscle inflammation (the onset of), like shortness of breath, like being out of breath. Started two days after the second vaccination with Moderna.) and MYOCARDITIS (Like heart pain, like two-week heart muscle inflammation (the onset of), like shortness of breath, like being out of breath. Started two days after the second vaccination with Moderna.) in a 38-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3004500) for Prophylactic vaccination.<br><br>No Medical History information was reported.<br><br>On 09-Aug-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 11-Aug-2021, the patient experienced ANGINA PECTORIS (Like heart pain, like two-week heart muscle inflammation (the onset of), like shortness of breath, like being out of breath. Started two days after the second vaccination with Moderna.) (seriousness criterion medically significant), DYSPNOEA EXERTIONAL (Like heart pain, like two-week heart muscle inflammation (the onset of), like shortness of breath, like being out of breath. Started two days after the second vaccination with Moderna.) (seriousness criterion medically significant) and MYOCARDITIS (Like heart pain, like two-week heart muscle inflammation (the onset of), like shortness of breath, like being out of breath. Started two days after the second vaccination with Moderna.) (seriousness criterion medically significant). On 23-Aug-2021, ANGINA PECTORIS (Like heart pain, like two-week heart muscle inflammation (the onset of), like shortness of breath, like being out of breath. Started two days after the second vaccination with Moderna.), DYSPNOEA EXERTIONAL (Like heart pain, like two-week heart muscle inflammation (the onset of), like shortness of breath, like being out of breath. Started two days after the second vaccination with Moderna.) and MYOCARDITIS (Like heart pain, like two-week heart muscle inflammation (the onset of), like shortness of breath, like being out of breath. Started two days after the second vaccination with Moderna.) had resolved.<br><br>Translated senders comment reported that patient had like heart failure, difficult to breathe for approximate two weeks, Very strong pulling in the chest, Bronchial region. |

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| | | Concomitant product use was not provided.<br><br>Treatment information was not provided<br><br>Company Comment:This case concerns a 38-year-old, male patient with no relevant medical history reported, who experienced the unexpected events of angina pectoris, dyspnoea exertional and myocarditis. The events occurred 2 days after the second dose of mRNA-1273. The rechallenge was not applicable since the events happened after the second dose. The Benefit-risk relationship of mRNA-1273 is not affected by this report. Event seriousness assessed as per Regulatory Authority reporting.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 25-Nov-2021: Translated Received on 26-Nov-21, event verbatim updated, dose number updated from unknown to dose 2 and senders comment updated. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 26-Nov-2021 and was forwarded to Moderna on 26-Nov-2021.<br>This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (Myocardial inflammation, diagnosed by cardiological MRI. Suspected occurrence after second vaccination) in a 32-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3002334) for Prophylactic vaccination.<br><br>Concurrent medical conditions included Gilbert's syndrome.<br><br>On 01-Jun-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 01-Jun-2021, the patient experienced MYOCARDITIS (Myocardial inflammation, diagnosed by cardiological MRI. Suspected occurrence after second vaccination) (seriousness criterion hospitalization). At the time of the report, MYOCARDITIS (Myocardial inflammation, diagnosed by cardiological MRI. Suspected occurrence after second vaccination) had not resolved.<br><br>No concomitant drugs were reported.<br><br>It was verbally reported that, the patient had fructose and lactose intolerance, otherwise fit (exercise several times a week).<br><br>Company Comment:<br>This regulatory case concerns a 32-year-old, male patient with no relevant medical history, who experienced the expected, serious AESI of myocarditis. The event, which resulted in hospitalization, occurred on the same day after administration of the second dose of the Moderna mRNA-1273 vaccine. The patient experienced a severe reaction with initial fever and weakness. He also had permanent weakness and impairment of daily life. Despite resting for approximately 8 weeks, there was no improvement but rather, persistent deterioration. The Cardiac Magnetic Resonance |

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| | | Imaging done showed myocardial inflammation. The patient received medicinal and conservative therapy in an outpatient setting. However, he still experienced severe impairment in his daily life and it has not been possible for the patient to do his job for weeks. Improvement of the condition occurs in slow and minimal steps. The event had not resolved at the time of the report. The rechallenge was not applicable as no additional dosing will be given. The patient's gender remains a confounder. The benefit-risk relationship of the Moderna mRNA-1273 vaccine is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 26-Nov-2021: Significant follow up appended. Outcome of the event was updated<br>On 26-Nov-2021: Translation received on 27-NOV-21 for initial SD: Event verbatim, medical history and drug information and senders comment were translated. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 25-Nov-2021 and was forwarded to Moderna on 25-Nov-2021.<br>This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (Myocarditis) in a 33-year-old male patient who received mRNA-1273 (Spikevax) (batch no. J07BX03) for COVID-19 vaccination.<br><br>The patient's past medical history included Obesity.<br>Concurrent medical conditions included Blood pressure high.<br><br>On 05-Aug-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 27-Aug-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criterion hospitalization). At the time of the report, MYOCARDITIS (Myocarditis) was resolving.<br><br>No concomitant medications were reported.<br>Treatment information was not provided.<br><br>Company comment:<br>This regulatory case concerns a 33-year-old, male patient with relevant medical history of High blood pressure and Obesity, who experienced the expected, serious AESI of myocarditis. The event, which resulted in hospitalization, occurred 22 days after administration of the second dose of the Moderna mRNA-1273. Treatment information was not provided. However, the event was resolving at the time of the report. The rechallenge was not applicable as no additional dosing will be given. The patient's medical history of High blood pressure and Obesity, as well as gender, which are risk factors for myocarditis, remain as confounders. The benefit-risk relationship of the Moderna mRNA-1273 is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes: |

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| | | On 25-Nov-2021: Translated document received on 27-Nov-2021, included substance specified name was translated. |
| 4.1(b) | 4.1(b) | This spontaneous case was reported by a consumer and describes the occurrence of MYOCARDITIS (Myocarditis) in a 40-year-old male patient who received mRNA-1273 (COVID 19 Vaccine Moderna) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below.<br><br>Concurrent medical conditions included Hypercholesterolemia.<br><br>On 25-May-2021, the patient received second dose of mRNA-1273 (COVID 19 Vaccine Moderna) (unknown route) dosage was changed to 1 dosage form.<br>On an unknown date, the patient received dose of mRNA-1273 (COVID 19 Vaccine Moderna) (unknown route) at an unspecified dose. On 26-May-2021, the patient experienced PALPITATIONS (palpitation/irregular heart beat started) and FATIGUE (unusual tiredness). On 27-May-2021, the patient experienced DYSPNOEA (shortness of breath), ASTHENIA (feeling weak), HYPERHIDROSIS (sudden excessive sweating started) and PAIN (new pain or sensation of pressure in the chest). On 28-May-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criterion medically significant). In August 2021, MYOCARDITIS (Myocarditis) had resolved. At the time of the report, DYSPNOEA (shortness of breath), ASTHENIA (feeling weak), HYPERHIDROSIS (sudden excessive sweating started) and FATIGUE (unusual tiredness) outcome was unknown and PALPITATIONS (palpitation/irregular heart beat started) and PAIN (new pain or sensation of pressure in the chest) had resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 29-May-2021, Blood creatine phosphokinase MB: 244 (High) 244 u/L high.<br>On 29-May-2021, C-reactive protein: 1.06 (High) 1.06 mg/dL high.<br>On 29-May-2021, Echocardiogram: result not provided without pathological result.<br>On 29-May-2021, Electrocardiogram: abnormal (abnormal) ECG with posterior wall: flattened T-wave in D III, aVF pre-terminal.<br>On 29-May-2021, Troponin T: 328 (High) 328 ng/L.<br>On 30-Jun-2021, Echocardiogram: result not provided without pathological result.<br>On 30-Jun-2021, Electrocardiogram: abnormal (abnormal) T-negativity in III, aVF, T-flattening in II and V6.<br>On 02-Jul-2021, Magnetic resonance imaging: abnormal (abnormal) Circumscribed area posterobasal with pathological, mostly subepicardial, contrast enhancement as well as minor edematous changes, image morphologically consistent with circumscribed myocarditis..<br>On 14-Oct-2021, Echocardiogram: result not provided without pathological result.<br>On 14-Oct-2021, Electrocardiogram: abnormal (abnormal) T negative in aVR and V1.<br>On an unknown date, Magnetic resonance imaging: normal (normal) No functional impairment, no wall movement disorders, no evidence of cardiomyopathy.. |

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| | | On an unknown date, Physical examination: normal (normal) Pulsus paradoxus: No Pericardial rubbing:No..<br><br>No concomitant drug details were reported.<br>No treatment details were reported.<br><br>The patient visited central emergency room May 29, 2021 for Myocarditis.The patient participated in swimming 1x weekly & non-competitive sport.The patient took physical rest from 29-May-2021 to 02-Aug-2021.<br><br>This case concerns a 40-year-old male, with no medical history, who experienced the serious expected AESI event of Myocarditis. The event occurred 4 days after the second dose of mRNA1273 vaccine. At the time of the report, myocarditis was resolved. The patient's current condition of Hypercholesterolemia is confounding for the case. The rechallenge was not applicable, as the events happened after the second dose. The benefit-risk relationship of mRNA 1273 Vaccine is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 15-Dec-2021: Follow up received and it contains no new information<br>On 15-Dec-2021: Translation document received on 17-Dec-2021.<br>Patients DOB, Current condition, Lab data, myocarditis start and stop date, outcome, and symptoms were updated. |
| 4.1(b) | 4.1(b) | This case was received via an unknown source (no reference has been entered for a health authority or license partner) on 26-Nov-2021 and was forwarded to Moderna on 26-Nov-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of FATIGUE (Mild fatigue), PYREXIA (Fever up to 38 degrees), ARTHRALGIA (Limb pain) and MYOCARDITIS (Myocarditis) in a 21-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for an unknown indication.<br><br>No Medical History information was reported.<br><br>In September 2021, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form.<br>On 08-Oct-2021, received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) dosage was changed to 1 dosage form. On 09-Oct-2021, the patient experienced FATIGUE (Mild fatigue) (seriousness criteria hospitalization and medically significant), PYREXIA (Fever up to 38 degrees) (seriousness criteria hospitalization and medically significant) and ARTHRALGIA (Limb pain) (seriousness criteria hospitalization and medically significant). On 11-Oct-2021, after starting mRNA-1273 (COVID-19 Vaccine Moderna), the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). On 10-Oct-2021, FATIGUE (Mild fatigue), PYREXIA (Fever up to 38 degrees) and ARTHRALGIA (Limb pain) had resolved. At the time of the report, MYOCARDITIS (Myocarditis) outcome was unknown. |

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| | | DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 12-Oct-2021, Echocardiogram: normal (normal) TTE of Oct 12, 2021 was reported as unremarkable.<br>In October 2021, Blood test: high (High) Trop Peak 1500 ng/l, CRP 200mg/l, CK 147.<br>In October 2021, Electrocardiogram: abnormal (abnormal) EKG result was reported as ST-elevation in II, III, aVF, V3-V6, ST reduction..<br><br>For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered FATIGUE (Mild fatigue), PYREXIA (Fever up to 38 degrees) and ARTHRALGIA (Limb pain) to be probably related and MYOCARDITIS (Myocarditis) to be possibly related.<br><br>No concomitant medications were reported. Treatment drug administered included aspirin, then ibuprofen and colchicine.<br><br>The patient was not known for any pathologies or allergies, kidney, or liver disease, and doesn't smoke or use alcohol. The first dose vaccine administration date was not indicated, but presumably administered in September. On 10 Oct 2021, 3 days after the second dose of Spikevax, the patient experienced chest pain during the night and severe fatigue. The patient was admitted to the hospital and was diagnosed with myocarditis, treated with aspirin, then ibuprofen and colchicine. In particular, the evaluation described that it got subsided the following day i.e., 10 Oct 2021. During the night of 10 Oct 2021 till 11 Oct 2021 the patient awoke during the night due to severe retrosternal pain, which intensified with strong inspiration and no radiation to the arms was reported. Likewise, the patient indicated a decrease in general performance but had no loss of consciousness, dizziness or palpitations. He had no known cardiac conditions or thromboses and was in good general condition.<br><br>BP of 128/80, pulse 130/min, oxygen 97 percent under ambient air, temperature 27.5 degree Celsius and AF of 14/ min was reported. The findings for heart were reported as tachycardic, rhythmic cardiac action without secondary murmurs and no peripheral pulse deficit. For lungs vesicular breath sounds over all lung fields, with no leg swelling. ECG results showed ST elevations ubiquitous, and high suspicion of myocarditis. Thereupon hospitalization was confirmed.<br><br>The symptoms improved and the patient was discharged on 15 Oct 2021. The reaction reported was serious and reporter described as unknown further course of patient.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 26-Nov-2021: Translated document received on 01 Dec 2021. Added senders comment. Event verbatim and narrative was updated. |
| 4.1(b) | 4.1(b) | This regulatory authority case was reported by a physician and describes the occurrence of CHEST DISCOMFORT (Feeling of pressure in the sternum), DYSPNOEA (Dyspnea), PAIN IN EXTREMITY (Limb pain), PYREXIA (Flu-like feeling) and MYOCARDITIS (Perimyocarditis) in a 23-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 immunisation. |

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| | | Concurrent medical conditions included Obstructive sleep apnea syndrome, Nicotine abuse (Infrequent nicotine consumption) and Alcohol use (Infrequent alcohol consumption).<br><br>On 18-Sep-2021, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form.<br>On 16-Oct-2021, received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) dosage was changed to 1 dosage form. On 12-Nov-2021, the patient experienced PAIN IN EXTREMITY (Limb pain) (seriousness criteria hospitalization and medically significant), PYREXIA (Flu-like feeling) (seriousness criteria hospitalization and medically significant) and MYOCARDITIS (Perimyocarditis) (seriousness criteria hospitalization and medically significant). On 15-Nov-2021, the patient experienced CHEST DISCOMFORT (Feeling of pressure in the sternum) (seriousness criteria hospitalization and medically significant) and DYSPNOEA (Dyspnea) (seriousness criteria hospitalization and medically significant). At the time of the report, CHEST DISCOMFORT (Feeling of pressure in the sternum), DYSPNOEA (Dyspnea), PAIN IN EXTREMITY (Limb pain), PYREXIA (Flu-like feeling) and MYOCARDITIS (Perimyocarditis) was resolving.<br><br>For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered CHEST DISCOMFORT (Feeling of pressure in the sternum), DYSPNOEA (Dyspnea), PAIN IN EXTREMITY (Limb pain), PYREXIA (Flu-like feeling) and MYOCARDITIS (Perimyocarditis) to be possibly related.<br><br>Patient had suffered from a febrile sensation with limb pain on 12-NOV-2021 had intermittent episodes of sensation of pressure in the sternum with mild dyspnea on 15-NOV-2021 The patient had to be hospitalized and a tentative diagnosis of perimyocarditis was made. On 16-NOV-2021 the patient's condition was reported as improved.<br><br>Concomitant product use was not provided.<br>Treatment information was not provided<br><br>Company Comment: This case concerns a 23-year-old male with reported personal history of Obstructive sleep apnea syndrome, Nicotine abuse and Alcohol use, who experienced the serious unexpected events Chest discomfort, Dyspnoea, Pain in extremity and Pyrexia and the seroious expected event of Myocarditis. The events occurred approximately 2 months after the administration of the second dose of the mRNA-1273 vaccine and the outcome for the events at the time of the report was Recovering/Resolving. The rechallenge is not applicable since the events occurred after the second dose of the of the mRNA-1273 vaccine and another dose will not be administered. The Obstructive sleep apnea syndrome, Nicotine abuse and Alcohol use remains as a confounder for the events of Chest discomfort and Dyspnoea. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 29-Nov-2021: Translation received on 01-Dec-2021, past medical history ,event information and senders comments was updated. |

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| 4.1(b) | 4.1(b) | This case was received via 4.1(b) (Reference number: 4.1(b) on 30-Nov-2021 and was forwarded to Moderna on 30-Nov-2021.<br>This regulatory authority case was reported by an other health care professional and describes the occurrence of PERICARDITIS (Pericarditis), C-REACTIVE PROTEIN (C-reactive protein), CHEST X-RAY (Chest X-ray), CHEST PAIN (Chest pain) and DIFFERENTIAL WHITE BLOOD CELL COUNT (Differential white blood cell count) in a 27-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 004F21A) for an unknown indication. The occurrence of additional non-serious events is detailed below.<br><br>Concurrent medical conditions included Penicillin allergy, Drug allergy and Seasonal allergy.<br><br>On 10-Sep-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 10-Sep-2021, the patient experienced PERICARDITIS (Pericarditis), C-REACTIVE PROTEIN (C-reactive protein), CHEST X-RAY (Chest X-ray), CHEST PAIN (Chest pain), DIFFERENTIAL WHITE BLOOD CELL COUNT (Differential white blood cell count), DIZZINESS (Dizziness), ELECTROCARDIOGRAM (Electrocardiogram), FIBRIN D DIMER (Fibrin D dimer), FULL BLOOD COUNT (Full blood count), MAGNETIC RESONANCE IMAGING ABNORMAL (Magnetic resonance imaging abnormal), MAGNETIC RESONANCE IMAGING HEART (Magnetic resonance imaging heart), METABOLIC FUNCTION TEST (Metabolic function test), TROPONIN (Troponin) and FATIGUE (Fatigue). At the time of the report, PERICARDITIS (Pericarditis), C-REACTIVE PROTEIN (C-reactive protein), CHEST X-RAY (Chest X-ray), CHEST PAIN (Chest pain), DIFFERENTIAL WHITE BLOOD CELL COUNT (Differential white blood cell count), DIZZINESS (Dizziness), ELECTROCARDIOGRAM (Electrocardiogram), FIBRIN D DIMER (Fibrin D dimer), FULL BLOOD COUNT (Full blood count), MAGNETIC RESONANCE IMAGING ABNORMAL (Magnetic resonance imaging abnormal), MAGNETIC RESONANCE IMAGING HEART (Magnetic resonance imaging heart), METABOLIC FUNCTION TEST (Metabolic function test), TROPONIN (Troponin) and FATIGUE (Fatigue) had not resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 20-Oct-2021, Chest X-ray: unknown (Inconclusive) ER Visit.<br>On 20-Oct-2021, Electrocardiogram: unknown (Inconclusive) ER Visit.<br>On 20-Oct-2021, Fibrin D dimer: unknown (Inconclusive) ER Visit.<br>On 20-Oct-2021, Full blood count: unknown (Inconclusive) ER Visit.<br>On 20-Oct-2021, Magnetic resonance imaging heart: unknown (Inconclusive) ER Visit.<br>On 20-Oct-2021, Metabolic function test: unknown (Inconclusive) ER Visit.<br>On 20-Oct-2021, Troponin I: unknown (Inconclusive) ER Visit.<br>On 22-Oct-2021, C-reactive protein: unknown (Inconclusive) Primary Care Office Visit.<br>On 22-Oct-2021, Red blood cell sedimentation rate: unknown (Inconclusive) Primary Care Office Visit. |

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| | | On 29-Oct-2021, Magnetic resonance imaging heart: abnormal (abnormal) Confirmed Diagnosis of Pericarditis.<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments.<br><br>No concomitant medications were provided.<br>Patient had C-Reactive Protein and Sedimentation Rate - 22-Oct-2021 (Primary Care Office Visit) , CBC with Differential - 20-Oct-2021 (ER Visit), XR Chest 1 VW Portable - 20-Oct-2021 (ER Visit), D-Dimer, Quantitative - 20-Oct-2021 (ER Visit), Comprehensive Metabolic Panel - 20-Oct-2021 (ER Visit) , High-Sensitivity Troponin - 20-Oct-2021 (ER Visit), ECG 12-LEAD - 20-Oct-2021 (ER Visit).<br><br>Patient experienced Chest Pain (Diagnosed as Pericarditis) (persistent-continuing as of 13-Nov-2021) ,Light-headedness (intermittent - occasional onsets as of 13-Nov-2021), Fatigue (persistent - continuing as of 13-Nov-2021).<br>Treatment medication included Indomethacin and Colchicine.<br><br>Company Comment:<br>This case concerns a 27-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) with no relevant medical history who experienced the expected non-serious AESI event of Pericarditis one the same day after the second dose of the vaccine. Rechallenge is not applicable, since no further dosing is expected. The benefit-risk relationship is not affected by this report. |
| 4.1(b) | 4.1(b) | This case was received via 4.1(b) (Reference number: 4.1(b) on 30-Nov-2021 and was forwarded to Moderna on 30-Nov-2021.<br>This regulatory authority case was reported by an other health care professional and describes the occurrence of PERICARDIAL EFFUSION (Pericardial effusion), PERICARDITIS (Pericarditis), CHEST PAIN (Chest pain), BUNDLE BRANCH BLOCK RIGHT (Bundle branch block right), C-REACTIVE PROTEIN INCREASED (C-reactive protein increased), ECHOCARDIOGRAM NORMAL (Echocardiogram normal), ELECTROCARDIOGRAM ABNORMAL (Electrocardiogram abnormal), MYOCARDIAL NECROSIS MARKER INCREASED (Myocardial necrosis marker increased), TENDERNESS (Tenderness), X-RAY (X-ray), PAIN (Pain) and FATIGUE (Fatigue) in a 24-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 002A21A and 046A21A) for an unknown indication.<br><br>Concurrent medical conditions included Asthma (occasional use of advair diskus 100-50 mcg/dose).<br><br>On 11-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form.<br>On 11-Mar-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 21-Jun-2021, the patient experienced PERICARDIAL EFFUSION (Pericardial effusion) (seriousness criterion disability), PERICARDITIS (Pericarditis) (seriousness criterion disability), CHEST PAIN (Chest pain) (seriousness criterion disability), BUNDLE BRANCH |

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| | | BLOCK RIGHT (Bundle branch block right) (seriousness criterion disability), C-REACTIVE PROTEIN INCREASED (C-reactive protein increased) (seriousness criterion disability), ECHOCARDIOGRAM NORMAL (Echocardiogram normal) (seriousness criterion disability), ELECTROCARDIOGRAM ABNORMAL (Electrocardiogram abnormal) (seriousness criterion disability), MYOCARDIAL NECROSIS MARKER INCREASED (Myocardial necrosis marker increased) (seriousness criteria disability and medically significant), TENDERNESS (Tenderness) (seriousness criterion disability), X-RAY (X-ray) (seriousness criterion disability), PAIN (Pain) (seriousness criterion disability) and FATIGUE (Fatigue) (seriousness criterion disability). At the time of the report, PERICARDIAL EFFUSION (Pericardial effusion), PERICARDITIS (Pericarditis), CHEST PAIN (Chest pain), BUNDLE BRANCH BLOCK RIGHT (Bundle branch block right), C-REACTIVE PROTEIN INCREASED (C-reactive protein increased), ECHOCARDIOGRAM NORMAL (Echocardiogram normal), ELECTROCARDIOGRAM ABNORMAL (Electrocardiogram abnormal), MYOCARDIAL NECROSIS MARKER INCREASED (Myocardial necrosis marker increased), TENDERNESS (Tenderness), X-RAY (X-ray), PAIN (Pain) and FATIGUE (Fatigue) had not resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 20-Jul-2021, C-reactive protein: elevated (High) diagnostic pathology: c-reactive protein/cardiac was elevated.<br>On 20-Jul-2021, Electrocardiogram: abnormal (abnormal) abnormal EKG with Incomplete RBBB at medical center..<br>On 14-Oct-2021, Echocardiogram: normal (normal) Results of echocardiogram normal although evidence of pericardial effusion was identified.<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments.<br><br>Patient reported<br>On 20-Jul-2021, 2 view x-ray was performed with unknown results. On 10-Aug-2021, follow-up office visit at medical center and was referred to medical center.On 08-Sep-2021, new EKG at cardiology office with doctor.On 28-Sep-2021, echocardiogram completed at cardiology office with doctor.<br>On 14-Oct-2021, office visit at cardiology office with doctor. Verdict of presumed pericarditis with symptoms of stabbing chest pain which continued to re-occur. Patient stated that previously, exertion did not trigger chest pain but Exertion now triggered chest discomfort and pain. Pain can occur while standing, laying down, exertion (physical activity), or while sedentary (working from home). Prescription was prescribed but did not work. On 20-Jul-2021, Meloxicam 15 mg tab fill date On 10-Aug-2021, Prednisone 20 mg tab Patient reported On 21-Jun-2021, extreme chest pain at approx. 10:00 pm. Chest pain lasted approx. 30 minutes, patient felt like a heart attack and was accompanied with tiredness and burning sensation in chest. Pain was located in middle/left chest area and Left/middle back area was tender.<br>On 03-jul-2021, re-occurring chest pain. Lasted approx 30 minutes. Extreme pain and Stabbing sensation. From 12-Jul-2021 to 20-Jul-2021, |

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| | | re-occurring chest pain. From 06-Aug-2021 to 08-Aug-2021, re-occurring chest pain. Re-occurring chest pain continued in sept, oct and nov of 2021.other medication included: Escitalopram Oxalate 20mg, Mono-Linyah 0.25-35 mg-mcg<br>CC: This case concerns a 24-year-old female patient who experienced serious unexpected events pericardial effusion, chest pain, bundle branch block right, C reactive protein increased, electrocardiogram abnormal, myocardial necrosis marker increased, tenderness, pain, fatigue and serious expected event of pericarditis which occurred approximately 3 months after the second dose of the mRNA-1273 . Rechallenge was not applicable. The benefit-risk relationship is not affected by this report |
| 4.1(b) | 4.1(b) | This case was received via 4.1(b) (Reference number: 4.1(b) on 30-Nov-2021 and was forwarded to Moderna on 30-Nov-2021.<br>This case was received via 4.1(b) (Reference number: 4.1(b) on 30-Nov-2021 and was forwarded to Moderna on 30-Nov-2021.<br>This regulatory authority case was reported by an other health care professional and describes the occurrence of PERICARDITIS (Pericarditis) in a 37-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 033C21A and 050C21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below.<br><br>No Medical History information was reported.<br><br>On 11-May-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form.<br>On 11-May-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 11-May-2021, the patient experienced PERICARDITIS (Pericarditis) (seriousness criterion medically significant), ABDOMINAL PAIN UPPER (Abdominal pain upper), CHEST PAIN (Chest pain), NECK PAIN (Neck pain), PAIN IN EXTREMITY (Pain in extremity), PALPITATIONS (Palpitations), DIARRHOEA (Diarrhoea) and HEADACHE (Headache). At the time of the report, PERICARDITIS (Pericarditis), ABDOMINAL PAIN UPPER (Abdominal pain upper), CHEST PAIN (Chest pain), NECK PAIN (Neck pain), PAIN IN EXTREMITY (Pain in extremity), PALPITATIONS (Palpitations), DIARRHOEA (Diarrhoea) and HEADACHE (Headache) had not resolved.<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments.<br><br>No concomitant medications reported by reporter.<br>Patient figured patient had gotten pericarditis and thought it would go away on its own. So patient waited and patient thought it went away and then got the second dose. It came back and then went away. Patient thought patient would be good now but it came back and seemed to be worse. Patient finally went to see doctor in October and Doctor said patient had Pericarditis. Patient could hear it. Patient wasn't really told to do anything that patient was fine and went on way. It seems to be getting worse and patient was other symptoms of headaches, bad stomach pain with diarrhea, and these strange pulsating pain in legs and neck that |

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| | | come and go as well. Patient now seeing a cardiologist but they seem to think Patient ok too.<br>Patient was experienced racing heart and pain in chest.<br>No treatment medications provided by the reporter.<br><br>Company comment: This case concerns a 37-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) with no medical history who experienced the serious expected event (AESI) of pericarditis on the same day after the second dose of the vaccine. Per RA narrative, patient also noted experienced same event prior to second dose and that the event away. The event of pericarditis reappeared on administration of second dose with additional events of chest pain, abdominal pain, pain in extremity, palpitations, diarrhea and headache.Rechallenge is not applicable, since no further dosing is expected. The benefit-risk relationship is not affected by this report |
| 4.1(b) | 4.1(b) | This case was received via 4.1(b) (Reference number: 4.1(b) on 30-Nov-2021 and was forwarded to Moderna on 30-Nov-2021.<br>This regulatory authority case was reported by an other health care professional and describes the occurrence of PERICARDITIS (Pericarditis) in a 32-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 011F21A) for an unknown indication. The occurrence of additional non-serious events is detailed below.<br><br>No Medical History information was reported.<br><br>On 05-Nov-2021, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 11-Nov-2021, the patient experienced PERICARDITIS (Pericarditis) (seriousness criterion medically significant), BLOOD TEST (Blood test), BREAST PAIN (Breast pain), CHEST PAIN (Chest pain), COMPUTERISED TOMOGRAM (Computerised tomogram), ELECTROCARDIOGRAM (Electrocardiogram), MUSCULOSKELETAL PAIN (Musculoskeletal pain) and PAIN (Pain). At the time of the report, PERICARDITIS (Pericarditis), BLOOD TEST (Blood test), BREAST PAIN (Breast pain), CHEST PAIN (Chest pain), COMPUTERISED TOMOGRAM (Computerised tomogram), ELECTROCARDIOGRAM (Electrocardiogram), MUSCULOSKELETAL PAIN (Musculoskeletal pain) and PAIN (Pain) had not resolved.<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments.<br><br>Lab tests CT, EKG, bloodwork was done, results were not provided.<br>Patient had pain in left shoulder blade radiating to left chest under breast.<br>Pain increased when she was lying down and taking deep breaths.<br>Pain decreased when she was leaning forward.<br>Pain started on 11/11/21 and became worse. ER visit made on 11/17/21 and diagnosed with Pericarditis. No fluid buildup or blood clots.<br>Prescribed Naproxen and encouraged to rest.<br>Concomitant medication of the patient was not reported.<br><br>Company comment |

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| | | This case concerns a 32-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) with no relevant medical history who experienced the serious expected event (AESI) of pericarditis 6 six days after the third dose of the vaccine. Rechallenge is not applicable, since no further dosing is expected. The benefit-risk relationship is not affected by this report. |
| 4.1(b) | 4.1(b) | This case was received via 4.1(b) (Reference number: 4.1(b) on 30-Nov-2021 and was forwarded to Moderna on 30-Nov-2021.<br>This regulatory authority case was reported by an other health care professional and describes the occurrence of PERICARDITIS (Pericarditis), BLOOD TEST (Blood test), BREAST PAIN (Breast pain), CHEST PAIN (Chest pain) and COMPUTERISED TOMOGRAM (Computerised tomogram) in a 26-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 001B21A and 030M20A) for an unknown indication. The occurrence of additional non-serious events is detailed below.<br><br>Concurrent medical conditions included Asthma.<br><br>On 12-Mar-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form.<br>On 12-Mar-2021, received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 15-Apr-2021, the patient experienced PERICARDITIS (Pericarditis), BLOOD TEST (Blood test), BREAST PAIN (Breast pain), CHEST PAIN (Chest pain), COMPUTERISED TOMOGRAM (Computerised tomogram), DYSPNOEA (Dyspnoea), ECHOCARDIOGRAM (Echocardiogram), HEART RATE INCREASED (Heart rate increased), PAIN (Pain), PAIN IN EXTREMITY (Pain in extremity) and X-RAY (X-ray). At the time of the report, PERICARDITIS (Pericarditis), BLOOD TEST (Blood test), BREAST PAIN (Breast pain), CHEST PAIN (Chest pain), COMPUTERISED TOMOGRAM (Computerised tomogram), DYSPNOEA (Dyspnoea), ECHOCARDIOGRAM (Echocardiogram), HEART RATE INCREASED (Heart rate increased), PAIN (Pain), PAIN IN EXTREMITY (Pain in extremity) and X-RAY (X-ray) outcome was unknown.<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments.<br><br>Lab tests CT Scan, x-ray, blood work echocardiogram was done, results were not provided.<br>About a month after Patient's heart rate began to increase tremendously. A few weeks after that, began getting chest pain, which radiated to left arm and under left breast. Doctor diagnosed her with Pericarditis in June 2021 and prescribed medication.<br>In October of 2021, Patient had another diagnosis of pericarditis after experiencing the same chest pain, shortness of breath, speeding heart rate, pain that radiated to left arm and pain underneath left breast.<br>Concomitant medication of the patient was not reported.<br>Company comment<br>This case concerns a 26-year-old female patient, with no reported relevant medical history, who experienced the expected event of PERICARDITIS (AESI). The event occurred approximately 1 month 4 |

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| | | days after the administration of the second dose of mRNA-1273 vaccine. The rechallenge was not applicable. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. |
| 4.1(b) | 4.1(b) | This case was received via 4.1(b) (Reference number: 4.1(b) on 30-Nov-2021 and was forwarded to Moderna on 30-Nov-2021.<br>This regulatory authority case was reported by an other health care professional and describes the occurrence of CHEST PAIN (Chest pain), LABORATORY TEST (Laboratory test), MOVEMENT DISORDER (Movement disorder), PAIN (Pain) and PERICARDITIS (Pericarditis) in a 40-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. O32BZ1A) for COVID-19 vaccination.<br><br>Concurrent medical conditions included Diabetes.<br><br>On 07-Apr-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 22-Apr-2021, the patient experienced CHEST PAIN (Chest pain) (seriousness criterion hospitalization), LABORATORY TEST (Laboratory test) (seriousness criterion hospitalization), MOVEMENT DISORDER (Movement disorder) (seriousness criterion hospitalization), PAIN (Pain) (seriousness criterion hospitalization) and PERICARDITIS (Pericarditis) (seriousness criterion hospitalization). At the time of the report, CHEST PAIN (Chest pain), LABORATORY TEST (Laboratory test), MOVEMENT DISORDER (Movement disorder), PAIN (Pain) and PERICARDITIS (Pericarditis) had resolved.<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments.<br><br>Allergies were None, Current Illness was also None, Lab Data: Several tests were done in the hospital. Other Medications included Metformin/Glyburide 500mg/5mg, 2 tablets, twice a day: Effexor XR 150mg, 1 capsule, once a day. Patient had Pericarditis, chest pain, and was unable to sit up in a chair. Lasted for almost a month. Initial pain was 9-10 on the pain scale, had to take Percocet for the pain.<br>Company comment<br>This case concerns a 40-year-old female patient, with medical history of Diabetes, who experienced the expected serious event of PERICARDITIS (AESI), and the unexpected serious events of CHEST PAIN and MOVEMENT DISORDER. The events occurred approximately 16 days after the administration of the second dose of mRNA-1273 vaccine. The rechallenge was not applicable. Patient´s medical history of Diabetes, remains as a confounder. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. |
| 4.1(b) | 4.1(b) | This case was received via 4.1(b) (Reference number: 4.1(b) on 30-Nov-2021 and was forwarded to Moderna on 30-Nov-2021.<br>This regulatory authority case was reported by a health care professional and describes the occurrence of ANGINA PECTORIS (Angina pectoris), CATHETERISATION CARDIAC (Catheterisation cardiac), ECHOCARDIOGRAM (Echocardiogram), MYOCARDITIS (Myocarditis), SLEEP DISORDER (Sleep disorder) and TROPONIN I (Troponin I) in a |

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| | | 22-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 010M20A) for an unknown indication.<br><br>Concurrent medical conditions included Penicillin allergy.<br><br>On 10-Feb-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 13-Feb-2021, the patient experienced ANGINA PECTORIS (Angina pectoris) (seriousness criterion hospitalization), CATHETERISATION CARDIAC (Catheterisation cardiac) (seriousness criterion hospitalization), ECHOCARDIOGRAM (Echocardiogram) (seriousness criterion hospitalization), MYOCARDITIS (Myocarditis) (seriousness criterion hospitalization), SLEEP DISORDER (Sleep disorder) (seriousness criterion hospitalization) and TROPONIN I (Troponin I) (seriousness criterion hospitalization). At the time of the report, ANGINA PECTORIS (Angina pectoris), CATHETERISATION CARDIAC (Catheterisation cardiac), ECHOCARDIOGRAM (Echocardiogram), MYOCARDITIS (Myocarditis), SLEEP DISORDER (Sleep disorder) and TROPONIN I (Troponin I) had resolved.<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments.<br><br>Other Meds : Occasional ibuprofen or ferrous sulfate pill.<br><br>Most symptoms faded within 4 hours, possibly due to hospital intervention.<br><br>Lab Data: 02/13/2021: Heart catheterization, Troponin I levels 02/14/2021: Troponin I levels 06/07/2021: Echocardiogram. results are unknown.<br><br>Company Comment.<br>This case concerns a 22-year-old male subject, with no relevant medical history, who experienced the serious, expected, and AESI event of Myocarditis, and the serious and unexpected events of Angina pectoris, Catheterisation cardiac, Sleep disorder, among others. The events occurred 3 days after the second dose of mRNA-1273 vaccine. The rechallenge is not applicable, as no additional dosing will be given. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. |
| 4.1(b) | 4.1(b) | This case was received via 4.1(b) (Reference number: 4.1(b) on 30-Nov-2021 and was forwarded to Moderna on 30-Nov-2021.<br>This regulatory authority case was reported by an other health care professional and describes the occurrence of CARDITIS (Carditis), MYOCARDITIS (Myocarditis), CHEST DISCOMFORT (Chest discomfort), CHEST PAIN (Chest pain) and DYSPNOEA (Dyspnoea) in a 34-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 05T21A) for an unknown indication. The occurrence of additional non-serious events is detailed below.<br><br>Concurrent medical conditions included Allergy to chemicals (Sulphur). |

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| | | On 03-Nov-2021, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 04-Nov-2021, the patient experienced CARDITIS (Carditis), MYOCARDITIS (Myocarditis), CHEST DISCOMFORT (Chest discomfort), CHEST PAIN (Chest pain), DYSPNOEA (Dyspnoea), PAIN IN EXTREMITY (Pain in extremity), PARAESTHESIA (Paraesthesia), HYPOAESTHESIA (Hypoaesthesia), TROPONIN INCREASED (Troponin increased), ELECTROCARDIOGRAM ABNORMAL (Electrocardiogram abnormal), C-REACTIVE PROTEIN INCREASED (C-reactive protein increased), CHEST X-RAY NORMAL (Chest X-ray normal), ECHOCARDIOGRAM (Echocardiogram), LABORATORY TEST (Laboratory test) and LYMPHADENOPATHY (Lymphadenopathy). At the time of the report, CARDITIS (Carditis), MYOCARDITIS (Myocarditis), CHEST DISCOMFORT (Chest discomfort), CHEST PAIN (Chest pain), DYSPNOEA (Dyspnoea), PAIN IN EXTREMITY (Pain in extremity), PARAESTHESIA (Paraesthesia), HYPOAESTHESIA (Hypoaesthesia), TROPONIN INCREASED (Troponin increased), ELECTROCARDIOGRAM ABNORMAL (Electrocardiogram abnormal), C-REACTIVE PROTEIN INCREASED (C-reactive protein increased), CHEST X-RAY NORMAL (Chest X-ray normal), ECHOCARDIOGRAM (Echocardiogram), LABORATORY TEST (Laboratory test) and LYMPHADENOPATHY (Lymphadenopathy) had not resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On an unknown date, C-reactive protein: high (High) High.<br>On an unknown date, Electrocardiogram: abnormal (abnormal) abnormalities.<br>On an unknown date, Troponin: high (High) High.<br>On an unknown date, X-ray: normal (normal) Nothing in lungs.<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments.<br><br>Patient other Medications included Vyvanse and lexapro<br><br>It was reported that patient developed sore arms and chest pains on her left side and patient went to her doctor because she had shortness of breath and chest pain, Swollen lymph nodes of the left. Friday it got worst, all on her left breast area, got lab work done. Last week it came back really bad on Wednesday, patient went to ER, chest tight and pain sharp pain, tightening in chest. Did labs and test acute carditis and was given meds. On Sunday, Patient went back in ER for tingling and numbness on right foot. Carditis was the same but had confirmed that it was a reaction to the med that was given.<br><br>Patient was advised to stop taking these meds. These were Colchicine, Indomethacin, Pantoprazole. Patient still having chest pains and hard to breath with inflammation of the heart. ER visit was twice.<br><br>Laboratory data included Echocardiogram with unknown results. |

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| | | Company comment: This is a regulatory authority case concerning a 34-year-old female patient with no relevant medical history, who experienced expected event of myocarditis (AESI). The event occurred approximately 2 days after the third dose of mRNA-1273 vaccine. It was reported that patient developed sore arms, chest pain on her left side, shortness of breath and swollen lymph nodes of the left. Patient went to ER, and was diagnosed with carditis. Treatment included Colchicine, Indomethacin and Pantoprazole. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. |
| 4.1(b) | 4.1(b) | This case was received via 4.1(b) (Reference number: 4.1(b) on 30-Nov-2021 and was forwarded to Moderna on 30-Nov-2021.<br>This regulatory authority case was reported by an other health care professional and describes the occurrence of BLOOD CREATINE PHOSPHOKINASE INCREASED (Blood creatine phosphokinase increased), C-REACTIVE PROTEIN INCREASED (C-reactive protein increased), CHEST PAIN (Chest pain), DYSPNOEA (Dyspnoea), ECHOCARDIOGRAM (Echocardiogram), EJECTION FRACTION (Ejection fraction), MYALGIA (Myalgia), PYREXIA (Pyrexia), TROPONIN INCREASED (Troponin increased) and MYOCARDITIS (Myocarditis) in a 19-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for an unknown indication.<br><br>The patient's past medical history included Glomerulonephritis.<br><br>On 15-Nov-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 17-Nov-2021, the patient experienced BLOOD CREATINE PHOSPHOKINASE INCREASED (Blood creatine phosphokinase increased) (seriousness criterion hospitalization), C-REACTIVE PROTEIN INCREASED (C-reactive protein increased) (seriousness criterion hospitalization), CHEST PAIN (Chest pain) (seriousness criterion hospitalization), DYSPNOEA (Dyspnoea) (seriousness criterion hospitalization), ECHOCARDIOGRAM (Echocardiogram) (seriousness criterion hospitalization), EJECTION FRACTION (Ejection fraction) (seriousness criterion hospitalization), MYALGIA (Myalgia) (seriousness criterion hospitalization), PYREXIA (Pyrexia) (seriousness criterion hospitalization), TROPONIN INCREASED (Troponin increased) (seriousness criterion hospitalization) and MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, BLOOD CREATINE PHOSPHOKINASE INCREASED (Blood creatine phosphokinase increased), C-REACTIVE PROTEIN INCREASED (C-reactive protein increased), CHEST PAIN (Chest pain), DYSPNOEA (Dyspnoea), ECHOCARDIOGRAM (Echocardiogram), EJECTION FRACTION (Ejection fraction), MYALGIA (Myalgia), PYREXIA (Pyrexia), TROPONIN INCREASED (Troponin increased) and MYOCARDITIS (Myocarditis) outcome was unknown.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 18-Nov-2021, Blood creatine phosphokinase: 406 (High) 406 at 06:22 and 1038 (High) 1038 at 18:08.<br>On 18-Nov-2021, C-reactive protein increased: 48.7 (High) 48.7. |

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| | | On 18-Nov-2021, Echocardiogram: (normal) Normal left ventricular size, thickness and systolic function with no regional wall motion abnormalities. The left ventricular ejection fraction is 70 % of note.<br>On 18-Nov-2021, Troponin: (High) 0.42 at 05:58 and (High) 1.70 at 18:08.<br>On 19-Nov-2021, Blood creatine phosphokinase: 1061 (High) 1061 at 05:22.<br>On 19-Nov-2021, Troponin: (High) 2.65 at 05:22.<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments.<br><br>Patient had fever and myalgia following the vaccine. Symptoms got better but on day 3 he has developed chest pain and progressed with SOB. He presented to the ED and working diagnosis is perimyocarditis. Patient was still hospitalized. cMRI was not available in our hospital.<br>No concomitant medications provided.<br>No treatment medications provided.<br>Company Comment<br>This case concerns a 19-year-old, male patient with relevant medical history of glomerulonephritis, who experienced the expected event of myocarditis and the unexpected events of dyspnoea, pyrexia, chest pain and myalgia. The events occurred 2 days after the second dose of mRNA-1273. The rechallenge was not applicable since the events happened after the second dose. The benefit-risk relationship of mRNA-1273 is not affected by this report. Event seriousness assessed as per Regulatory Authority reporting. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 30-Nov-2021 and was forwarded to Moderna on 30-Nov-2021.<br>This regulatory authority case was reported by a pharmacist and describes the occurrence of MYOCARDITIS (Myocarditis) in a 31-year-old male patient who received mRNA-1273 (COVID 19 Vaccine Moderna) (batch no. 3006275) for COVID-19 immunisation.<br><br>The patient's past medical history included Blow out fracture of orbit.<br>Previously administered products included for Product used for unknown indication: Moderna vaccine (Right arm, Intramuscular injection and Lot no:214032) on 16-Oct-2021.<br>Past adverse reactions to the above products included No adverse event with Moderna vaccine.<br><br>On 08-Nov-2021, the patient received second dose of mRNA-1273 (COVID 19 Vaccine Moderna) (Intramuscular) 1 dosage form. On 09-Nov-2021, after starting mRNA-1273 (COVID 19 Vaccine Moderna), the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Myocarditis) was resolving.<br><br>For mRNA-1273 (COVID 19 Vaccine Moderna) (Intramuscular), the reporter did not provide any causality assessments.<br><br>No concomitant medications were provided by reporter. |

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| | | No treatment medications were provided.<br>Company comment: This case concerns a 31-year-old, male patient with no relevant medical history, who experienced the expected event of myocarditis, which required hospitalization. The event occurred approximately 1 day after the second dose of mRNA-1273. The rechallenge was not applicable as events occurred after second dose and no further dosing was reported or planned, based on information provided. The benefit-risk relationship of mRNA-1273 is not affected by this report. Event seriousness assessed as per Regulatory Authority reporting.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 30-Nov-2021: Translation received on 02-Dec-2021, Dosage text of dose 1 was translated. |
| 4.1(b) | 4.1(b) | This case was received via 4.1(b) (Reference number: 4.1(b) on 30-Nov-2021 and was forwarded to Moderna on 30-Nov-2021.<br>This regulatory authority case was reported by an other health care professional and describes the occurrence of BLOOD CREATINE PHOSPHOKINASE INCREASED (Blood creatine phosphokinase increased), CHEST PAIN (Chest pain), CHILLS (Chills), DIARRHOEA (Diarrhoea), ECHOCARDIOGRAM NORMAL (Echocardiogram normal), ELECTROCARDIOGRAM ST SEGMENT ELEVATION (Electrocardiogram ST segment elevation), ELECTROCARDIOGRAM ABNORMAL (Electrocardiogram abnormal), FATIGUE (Fatigue), HYPERHIDROSIS (Hyperhidrosis), MYOCARDITIS (Myocarditis), PERICARDITIS (Pericarditis), PYREXIA (Pyrexia), SARS-COV-2 TEST NEGATIVE (SARS-CoV-2 test negative), TROPONIN I INCREASED (Troponin I increased), VIRAL TEST NEGATIVE (Viral test negative) and VOMITING (Vomiting) in a 26-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 032M20A, 045A21A and 033F21A) for COVID-19 vaccination.<br><br>The patient's past medical history included TB in 2009.<br><br>On 05-Nov-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form.<br>On 05-Nov-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form and third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 08-Nov-2021, the patient experienced BLOOD CREATINE PHOSPHOKINASE INCREASED (Blood creatine phosphokinase increased) (seriousness criterion hospitalization prolonged), CHEST PAIN (Chest pain) (seriousness criterion hospitalization prolonged), CHILLS (Chills) (seriousness criterion hospitalization prolonged), DIARRHOEA (Diarrhoea) (seriousness criterion hospitalization prolonged), ECHOCARDIOGRAM NORMAL (Echocardiogram normal) (seriousness criterion hospitalization prolonged), ELECTROCARDIOGRAM ST SEGMENT ELEVATION (Electrocardiogram ST segment elevation) (seriousness criterion hospitalization prolonged), ELECTROCARDIOGRAM ABNORMAL (Electrocardiogram abnormal) (seriousness criterion hospitalization prolonged), FATIGUE (Fatigue) (seriousness criterion hospitalization prolonged), HYPERHIDROSIS (Hyperhidrosis) (seriousness criterion hospitalization prolonged), |

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| | | MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization prolonged and medically significant), PERICARDITIS (Pericarditis) (seriousness criteria hospitalization prolonged and medically significant), PYREXIA (Pyrexia) (seriousness criterion hospitalization prolonged), SARS-COV-2 TEST NEGATIVE (SARS-CoV-2 test negative) (seriousness criterion hospitalization prolonged), TROPONIN I INCREASED (Troponin I increased) (seriousness criterion hospitalization prolonged), VIRAL TEST NEGATIVE (Viral test negative) (seriousness criterion hospitalization prolonged) and VOMITING (Vomiting) (seriousness criterion hospitalization prolonged). At the time of the report, BLOOD CREATINE PHOSPHOKINASE INCREASED (Blood creatine phosphokinase increased), CHEST PAIN (Chest pain), CHILLS (Chills), DIARRHOEA (Diarrhoea), ECHOCARDIOGRAM NORMAL (Echocardiogram normal), ELECTROCARDIOGRAM ST SEGMENT ELEVATION (Electrocardiogram ST segment elevation), ELECTROCARDIOGRAM ABNORMAL (Electrocardiogram abnormal), FATIGUE (Fatigue), HYPERHIDROSIS (Hyperhidrosis), MYOCARDITIS (Myocarditis), PERICARDITIS (Pericarditis), PYREXIA (Pyrexia), SARS-COV-2 TEST NEGATIVE (SARS-CoV-2 test negative), TROPONIN I INCREASED (Troponin I increased), VIRAL TEST NEGATIVE (Viral test negative) and VOMITING (Vomiting) had resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 08-Nov-2021, Blood creatine phosphokinase: increased (High) increased.<br>On 08-Nov-2021, Echocardiogram: normal (normal) normal.<br>On 08-Nov-2021, Troponin: increased (High) 0507, 6266.<br>On 08-Nov-2021, Viral test: negative (Negative) Negative.<br>On 09-Nov-2021, Troponin: increased (High) 0910, 2762.<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments.<br><br>Other Meds : Cetirizine QD prn, Fluticasone Nasal QD, Montelukast 10 mg QD, Loestrin 1.5/30 QD, Omeprazole 40 mg QD.<br>Symptom Text : Moderna COVID-19 Vaccine EUA: Pericarditis / Myocarditis Patient with latent TB s/p 9 mths INH tx with persistent GI symptoms, received Moderna Vaccines on 3/3/2021, 3/31/2021, and 11/05/2021. On 11/6/2021 patient began to have chills, fatigue, 1; fever as high as 101.0. Early on the morning of 11/8/2021 around 2 a.m. she began diarrhea, vomitiing and chest pain which was made worse by lying down. Persistent fevers as well as sweats prompted to come to the ER. EKG was abnormal (diffuse ST elevation), echocardiogram obtained which was stable. Patient began to improve over the next few hours and was discharged in stable condition on 11/9/2021. Covid test negative<br><br>Company comment: This regulatory case concerns a 26-year-old female patient, with a history of latent tuberculosis, who experienced the serious (hospitalization) expected AESIs of MYOCARDITIS and PERICARDITIS. The events occurred 3 days after receiving a third dose of mRNA-1273. The rechallenge is not applicable since no further dosing information has been disclosed at this time. Patient consulted to the ER due to multiple symptoms including chest pain, diarrhoea, chills, fatigue, hyperhidrosis |

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| | | and pyrexia. An abnormal electrocardiogram with diffuse ST elevation and increased troponin (up to 6266) and creatine phosphokinase (up to 221) were obtained. No treatment medications were reported. Patient was discharged stable on the next day. Patient0s history of latent tuberculosis remains as a confounder. The benefit-risk relationship of mRNA-1273 is not affected by this report |
| 4.1(b) | 4.1(b) | This case was received via 4.1(b) (Reference number: 4.1(b) on 30-Nov-2021 and was forwarded to Moderna on 30-Nov-2021.<br>This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCARDITIS (Myocarditis) in a 31-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 939903) for an unknown indication.<br><br>No Medical History information was reported.<br><br>On 28-Oct-2021, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 29-Oct-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criterion hospitalization). The patient was hospitalized for 2 days due to MYOCARDITIS. At the time of the report, MYOCARDITIS (Myocarditis) outcome was unknown.<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments.<br><br>Concomitant medications details were not reported by the reporter.<br>Treatment details was not reported by the reporter.<br>Patient was hospitalized for 2 days.<br><br>Company comment:<br>This case concerns a 31-year-old male patient with no medical history provided, who experienced the serious expected event of Myocarditis (AESI). The event occurred one day after the patient had received the third dose of the mRNA-1273 vaccine. The event required hospitalization and no further information regarding the clinical course of the event was provided. The outcome of the event was unknown. The re-challenge is not applicable as the patient experienced the event following the third dose of the vaccine and no additional doses are planned. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report.<br>Event seriousness assessed as per Regulatory Authority reporting. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 30-Nov-2021 and was forwarded to Moderna on 30-Nov-2021.<br>This regulatory authority case was reported by a pharmacist and describes the occurrence of MYOCARDITIS (Myocarditis) in a 33-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination.<br><br>The patient's past medical history included Chronic alcoholism and Obesity.<br>Concurrent medical conditions included Hypertension arterial. |

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| | | On 05-Aug-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) .5 milliliter. On 27-Aug-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criterion life threatening). At the time of the report, MYOCARDITIS (Myocarditis) was resolving.<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.<br><br>Concomitant medications details were not reported by the reporter. Treatment details was not reported by the reporter.<br><br>Company comment: This regulatory case concerns a 33-year-old, male patient with relevant medical history of Chronic alcoholism and Obesity, who experienced the expected, serious AESI of myocarditis. The event, which was life-threatening, occurred 22 days after administration of the second dose of the Moderna mRNA-1273 vaccine. No further details were provided. Treatment information was also not provided. However, the event was resolving at the time of the report. The rechallenge was not applicable as no additional dosing will be given. The medical history of Chronic alcoholism and Obesity, which creates an inflammatory environment, as well as the patient's gender remain as confounders. The benefit-risk relationship of Moderna COVID-19 Vaccine is not affected by this report. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 30-Nov-2021 and was forwarded to Moderna on 30-Nov-2021.<br>This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (Heart palpitations, chest pain 20/07/21, taken to hospital by ambulance, in hospital until 25/07/21. Diagnosis: acute perimyocarditis after vaccination, 01/11/21 MRI Heart muscle scar) in a 19-year-old male patient who received mRNA-1273 (COVID 19 Vaccine Moderna) (batch no. 3004217) for Prophylactic vaccination.<br><br>No Medical History information was reported.<br><br>On 18-Jul-2021, the patient received second dose of mRNA-1273 (COVID 19 Vaccine Moderna) (unknown route) 1 dosage form. On 20-Jul-2021, after starting mRNA-1273 (COVID 19 Vaccine Moderna), the patient experienced MYOCARDITIS (Heart palpitations, chest pain 20/07/21, taken to hospital by ambulance, in hospital until 25/07/21. Diagnosis: acute perimyocarditis after vaccination, 01/11/21 MRI Heart muscle scar) (seriousness criterion hospitalization). On 25-Jul-2021, MYOCARDITIS (Heart palpitations, chest pain 20/07/21, taken to hospital by ambulance, in hospital until 25/07/21. Diagnosis: acute perimyocarditis after vaccination, 01/11/21 MRI Heart muscle scar) had resolved with sequelae. |

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| | | For mRNA-1273 (COVID 19 Vaccine) (unknown route), the reporter did not provide any causality assessments.<br><br>No concomitant medications were reported<br>Nickel allergy, sun allergy. Information on risk factors or pre-existing conditions: Kawasaki syndrome as a 2 year old / Myocarditis and pericarditis, MRI, sono, blood values (CRP, troponin, CK, CK-MB), 3x daily 600 mg ibuprofen, 40 mg pantoprazole, 6 months of rest, max. strain of a sedentary activity, 01/11/2021 follow-up MRI: Heart muscle scar.<br><br>Company comment:<br>This case concerns a 19-year-old male patient with medical history of Kawasaki syndrome who experienced the expected serious event of Myocarditis. The event occurred two days after the administration of the second dose of mRNA-1273 vaccine. The patient initially developed Heart palpitations and chest pain, and after he was taken to hospital, the diagnosis of acute perimyocarditis was established. There were no provided results of laboratory investigations (CRP, troponin, CK, CK-MB). At the time of the report, the event had resolved with sequelae and the patient was advised to take 6 months of rest (with sedentary activity). Treatment medications included ibuprofen therapy. The re-challenge is not applicable as the event occurred following the second vaccination. It should be noted that this patient had Kawasaki syndrome in his past, therefore, he had increased susceptibility to myocardial inflammation. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report. Event seriousness assessed as per Regulatory Authority reporting.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 30-Nov-2021: Translation received on 01-Dec-2021 Suspect product dose number updated,Event verbatim updated, I narrative updated |
| 4.1(b) | 4.1(b) | This case was received via 4.1(b) (Reference number: 4.1(b) on 30-Nov-2021 and was forwarded to Moderna on 30-Nov-2021.<br>This regulatory authority case was reported by an other health care professional and describes the occurrence of CHEST PAIN (Chest pain), PAIN (Pain) and MYOCARDITIS (Myocarditis) in a 20-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 939909) for an unknown indication.<br><br>No Medical History information was reported.<br><br>On 15-Nov-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 15-Nov-2021, the patient experienced CHEST PAIN (Chest pain), PAIN (Pain) and MYOCARDITIS (Myocarditis). At the time of the report, CHEST PAIN (Chest pain), PAIN (Pain) and MYOCARDITIS (Myocarditis) had resolved.<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments.<br><br>Lab Data: Per patient, heart imaging. |

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| | | Symptom Text: Patient stated that she had new onset chest pain about 4 hours after the vaccine was administered. Pain then fluctuated throughout the night. She called pharmacy the next morning to seek advice. She advised that she should contact her primary care provider immediately to see if they could perform an evaluation, preferably including an EKG. Reported said if that was not an option, she should seek out an urgent care or emergency department for further evaluation. Reporter checked back in on her today, Thursday November the 18th, and she stated that her PCP could not see her that day but instructed her to go the ED if the pain worsened. She said that it did worsen about 2 hours later, so she presented to the medical facility. Per the patient, she stated that she was told she did have heart inflammation and was provided high dose steroids and was then observed for several hours before being discharged. The Dr said that it was inconclusive whether the vaccine was responsible for the inflammation. She said that she was now feeling better at this moment. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 30-Nov-2021 and was forwarded to Moderna on 30-Nov-2021.<br>This regulatory authority case was reported by a consumer and describes the occurrence of PERICARDITIS (Pericarditis) in a 23-year-old female patient who received mRNA-1273 (Spikevax) for Vaccination.<br><br>No Medical History information was reported.<br><br>On 03-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 05-Sep-2021, the patient experienced PERICARDITIS (Pericarditis) (seriousness criterion medically significant). At the time of the report, PERICARDITIS (Pericarditis) had not resolved.<br><br>Concomitant medication was not reported.<br><br>Company comment:<br>This case concerns a 23-year-old female patient with no medical history provided who experienced serious expected event of special interest Pericarditis. The event occurred approximately two days after the second dose of mRNA-1273. The rechallenge was not applicable as the event occurred following the second dose of the vaccine and as the event was still ongoing at the time of the report. Very limited information regarding clinical course of the event has been provided at this time. It was reported that the patient reported disability/permanent damage but that the report does not fulfill the criteria for this at reporting time. Furthermore, as per SD the patient reported that she got different medication (unspecified) that didn't work, and that, as stated, she now has chronic pericarditis and needs to take medication (unspecified) for more than 6 months to hopefully improve the condition. No further information was provided. The benefit-risk relationship of mRNA-1273 is not affected by this report.<br><br>The patient reported contact with nurse/physician. The patient reports that she got different medication that didn't work, and that she now has |

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| | | chronic PERICARDITIS and needs to take medication for more than 6 months to hopefully improve the condition.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 30-Nov-2021: Translation received on 02-Dec-2021 included no new information. |
| 4.1(b) | 4.1(b) | This case was received via 4.1(b) Reference number: 4.1(b) on 30-Nov-2021 and was forwarded to Moderna on 30-Nov-2021.<br>This regulatory authority case was reported by a consumer and describes the occurrence of FATIGUE (Fatigue/unusual tiredness), CHEST PAIN (Chest pain), PYREXIA (Fever), HYPERSENSITIVITY MYOCARDITIS (Myocarditis allergic), PALPITATIONS (Heart palpitations), PAIN IN EXTREMITY (Pain in arm), DYSPNOEA (Shortness of breath) and NECK PAIN (Neck pain) in a 36-year-old female patient who received mRNA-1273 (COVID 19 Vaccine Moderna) (batch no. 3004668) for an unknown indication.<br><br>Concomitant products included TOZINAMERAN (COVID-19 MRNA VACCINE BNT162B2) from 23-Feb-2021 to an unknown date for COVID-19 immunisation.<br><br>On 11-Nov-2021, the patient received third dose of mRNA-1273 (COVID 19 Vaccine Moderna) (unknown route) 1 dosage form. On 12-Nov-2021, after starting mRNA-1273 (COVID 19 Vaccine Moderna), the patient experienced HYPERSENSITIVITY MYOCARDITIS (Myocarditis allergic) (seriousness criterion medically significant). On an unknown date, the patient experienced FATIGUE (Fatigue/unusual tiredness) (seriousness criterion medically significant), CHEST PAIN (Chest pain) (seriousness criterion medically significant), PYREXIA (Fever) (seriousness criterion medically significant), PALPITATIONS (Heart palpitations) (seriousness criterion medically significant), PAIN IN EXTREMITY (Pain in arm) (seriousness criterion medically significant), DYSPNOEA (Shortness of breath) (seriousness criterion medically significant) and NECK PAIN (Neck pain) (seriousness criterion medically significant). At the time of the report, FATIGUE (Fatigue/unusual tiredness), CHEST PAIN (Chest pain), PYREXIA (Fever), PALPITATIONS (Heart palpitations), PAIN IN EXTREMITY (Pain in arm) and DYSPNOEA (Shortness of breath) outcome was unknown and HYPERSENSITIVITY MYOCARDITIS (Myocarditis allergic) and NECK PAIN (Neck pain) had not resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 09-Nov-2021, SARS-CoV-2 test: negative (Negative) No - Negative COVID-19 test.<br><br>The action taken with mRNA-1273 (COVID 19 Vaccine Moderna) (Unknown) was unknown.<br><br>On an unknown date, the patient underwent Chest X-ray and results were unknown. |

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| | | No treatment medications were reported.<br><br>Company comment:<br>This case concerns a 36-year-old female patient with no relevant medical history provided, who experienced the unexpected serious events of Fatigue, Chest pain, Pyrexia, Palpitations, Pain in extremity, Dyspnoea, Neck pain, as well as serious expected event of Hypersensitivity myocarditis. The event of Hypersensitivity myocarditis occurred one day after the administration of the mRNA-1273 vaccine, while the exact temporal relationship between the remaining reported events and exposure to the mRNA-1273 vaccine (reported as third vaccination) cannot be determined as the start date of these events was not provided. At the time of the report, the outcome of the events was unknown and no information regarding the clinical course of the events was provided. The action taken with the suspect product was retained as unknown as per Regulatory Authority, however, it should have been considered as not applicable as this vaccination was the third vaccination in this patient and no additional doses are expected to be administered at the moment. Therefore, the re-challenge is also assessed as not applicable. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 30-Nov-2021 and was forwarded to Moderna on 30-Nov-2021.<br>This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (cardiac muscle inflammation) in a 28-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 3005238) for COVID-19 vaccination.<br><br>Concurrent medical conditions included Asthma.<br>Concomitant products included BUDESONIDE (GIONA) for an unknown indication.<br><br>On 15-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 07-Oct-2021, the patient experienced MYOCARDITIS (cardiac muscle inflammation) (seriousness criterion hospitalization). At the time of the report, MYOCARDITIS (cardiac muscle inflammation) was resolving.<br><br>Treatment information was not provided.<br><br>Company comment:<br>This case concerns a 28-year-old female patient with no relevant medical history provided who experienced serious expected event of Myocarditis. The event occurred 22 days after the second dose of the mRNA-1273. The rechallenge was not applicable as the event occurred following the second dose of the vaccine. Very limited information regarding clinical course of the event has been provided at this time. The benefit-risk relationship of mRNA-1273 is not affected by this report. |

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| | | Most recent FOLLOW-UP information incorporated above includes:<br>On 30-Nov-2021: Translation document received on 02 Dec 2021 included event verbatim updated.<br>On 22-Dec-2021: Follow up received that contains Non Significant information includes Event verbatim updated, updated suspect product indication. |
| 4.1(b) | 4.1(b) | This case was initially received via European Medicines Agency (Reference number: 4.1(b) ) on 30-Nov-2021. The most recent information was received on 14-Dec-2021 and was forwarded to Moderna on 14-Dec-2021.<br>This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (CARDIAC MUSCLE INFLAMMATION) in a 16-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 3006273 and 3005238) for COVID-19 vaccination.<br><br>The patient's past medical history included Anxiety.<br>Concurrent medical conditions included Tonsillar hypertrophy.<br><br>On 19-Aug-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form.<br>On 16-Sep-2021, received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. On 08-Oct-2021, after starting mRNA-1273 (Spikevax), the patient experienced MYOCARDITIS (CARDIAC MUSCLE INFLAMMATION) (seriousness criterion medically significant). At the time of the report, MYOCARDITIS (CARDIAC MUSCLE INFLAMMATION) had not resolved.<br><br>No concomitant medication and treatment information was provided.<br><br>Company comment: This is a regulatory case concerning a 16-year-old male patient with no relavant medical history, who experienced the serious (due to medically important condition) expected AESI of Myocarditis. The event occurred approximately 22 days after the second dose of mRNA-1273 vaccine. The outcome of the event was reported as not recovered. The rechallenge was not applicable, as the event was reported exclusively after the second dose and no information on additional dosing is available. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 30-Nov-2021: Translated document received on 03-DEC-21, event verbatim and Pharmaceutical form(Dosage form)updated.<br>On 14-Dec-2021: Follow up contains significant information, Medical history (Tonsillar hypertrophy) added. |
| 4.1(b) | 4.1(b) | This case was received via 4.1(b) (Reference number: 4.1(b) ) on 30-Nov-2021 and was forwarded to Moderna on 30-Nov-2021.<br>This regulatory authority case was reported by a consumer and describes the occurrence of CHEST PAIN (Chest pain), CHEST DISCOMFORT (Chest pressure), HEART RATE INCREASED (Heart rate increased), NASOPHARYNGITIS (common cold), PALPITATIONS (Heart pounding), FATIGUE (Fatigue/unusual tiredness), ARTHRALGIA (Shoulder pain), |

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| | | PERICARDITIS (Pericarditis) and MYOCARDITIS (Myocarditis) in a 38-year-old male patient who received mRNA-1273 (COVID 19 Vaccine Moderna) (batch no. LOT3003651) for COVID-19 vaccination.<br><br>The patient's past medical history included Inflammation and Suspected COVID-19 from 19-Mar-2020 to 02-Apr-2020.<br><br>On 04-Aug-2021, the patient received second dose of mRNA-1273 (COVID 19 Vaccine Moderna) (unknown route) 1 dosage form. On 04-Aug-2021, the patient experienced HEART RATE INCREASED (Heart rate increased) (seriousness criterion medically significant), PALPITATIONS (Heart pounding) (seriousness criterion medically significant) and MYOCARDITIS (Myocarditis) (seriousness criterion medically significant). On 18-Nov-2021, the patient experienced PERICARDITIS (Pericarditis) (seriousness criterion medically significant). On an unknown date, the patient experienced CHEST PAIN (Chest pain) (seriousness criterion medically significant), CHEST DISCOMFORT (Chest pressure) (seriousness criterion medically significant), NASOPHARYNGITIS (common cold) (seriousness criterion medically significant), FATIGUE (Fatigue/unusual tiredness) (seriousness criterion medically significant) and ARTHRALGIA (Shoulder pain) (seriousness criterion medically significant). At the time of the report, CHEST PAIN (Chest pain), CHEST DISCOMFORT (Chest pressure), HEART RATE INCREASED (Heart rate increased), NASOPHARYNGITIS (common cold), ARTHRALGIA (Shoulder pain) and PERICARDITIS (Pericarditis) had resolved, PALPITATIONS (Heart pounding) and FATIGUE (Fatigue/unusual tiredness) outcome was unknown and MYOCARDITIS (Myocarditis) had resolved with sequelae.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 22-Dec-2020, SARS-CoV-2 test: positive (Positive) positive.<br>On 04-Aug-2021, Heart rate: 120-130 (High) 120-130 bpm and 104 (High) 104 bpm.<br>On 05-Aug-2021, Heart rate: 50-60 (Low) 50-60 bpm.<br><br>Concomitant drug details not provided.<br>Treatment details includes: He was prescribed a steroid injection, an anti-inflammatory, and a muscle relaxant.<br><br>It was reported that in the evening of second dose patient heart started really thumping. Within about 30 minutes heart rate had increased to 120 to 130BPM and was still 104 BPM 25 minutes. When patient woke heart rate was back to between 50 to 60BPM.Patient travelling in 4.1(b) a couple of week after suffering a brief common cold (had chest around lungs and heart and shoulder pains, including pressure when breathing, significant discomfort, not being able to lay on back or sides and elevated heart rate. After about 12 hours sought medical help non urgent and was diagnosed with some kind of inflammation around the heart. Within 1 day was significantly better and within 3 days had no symptoms at all. Patient |

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| | | had not tested positive for COVID-19 since having the vaccine. Patient was not enrolled in clinical trial<br>Company comment<br>This case concerns a 38-year-old male patient, with no reported relevant medical history, who experienced the unexpected serious events of CHEST PAIN, CHEST DISCOMFORT, HEART RATE INCREASED, NASOPHARYNGITIS, PALPITATIONS, FATIGUE, ARTHRALGIA and the expected serious events PERICARDITIS (AESI) and MYOCARDITIS (AESI). The events occurred after the administration of the second dose of mRNA-1273 vaccine. The rechallenge was unknown. In the evening of second dose patient heart started really thumping. Within about 30 minutes heart rate had increased. Then back to between 50 to 60BPM. Patient travelling in 4.1(b) a couple of weeks after suffering a brief common cold, and was diagnosed with some kind of inflammation around the heart. Within 3 days had no symptoms at all. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 02-Dec-2021: Followup received contains lab data information added, New events added, Treatment details in I narrative added. |
| 4.1(b) | 4.1(b) | This case was received via 4.1(b) (Reference number: 4.1(b) ) on 02-Dec-2021 and was forwarded to Moderna on 02-Dec-2021.<br>This regulatory authority case was reported by a consumer and describes the occurrence of ABNORMAL LOSS OF WEIGHT (Unintentional weight loss), HYPOGLYCAEMIA (Hypoglycemia), POOR QUALITY SLEEP (Poor sleep), FATIGUE (Fatigue extreme), NEUTROPENIA (Neutropenia), SLEEP DISORDER (Sleep disturbed), MUSCULOSKELETAL PAIN (Musculoskeletal pain), SYNCOPE (Fainting), LOSS OF CONSCIOUSNESS (Loss of consciousness), CHEST PAIN (Chest pain), PALPITATIONS (Heart palpitations), LYMPHADENOPATHY (Swollen glands), HEADACHE (Headache), VACCINATION SITE URTICARIA (Injection site hives), SOMNOLENCE (Sleepiness), PAIN IN EXTREMITY (Aches & pains in legs), RASH (Painful rash), MYALGIA (Muscular pains), VACCINATION SITE PAIN (Injection site pain) and MYOCARDITIS (Myocarditis) in a 39-year-old female patient who received mRNA-1273 (COVID 19 Vaccine Moderna) for COVID-19 vaccination.<br><br>Patient is not pregnant,Patient is not currently breastfeeding.<br>The patient's past medical history included Lyme disease from May 2016 to January 2020 and Suspected COVID-19 (Unsure when symptoms stopped) on 25-Mar-2020.<br><br>On 18-May-2021, the patient received first dose of mRNA-1273 (COVID 19 Vaccine Moderna) (unknown route) 1 dosage form.<br>On 07-Aug-2021, received second dose of mRNA-1273 (COVID 19 Vaccine Moderna) (unknown route) dosage was changed to 1 dosage form. On 18-May-2021, the patient experienced POOR QUALITY SLEEP (Poor sleep) (seriousness criteria disability and medically significant), FATIGUE (Fatigue extreme) (seriousness criteria disability and medically significant), MUSCULOSKELETAL PAIN (Musculoskeletal pain) (seriousness criteria disability and medically significant), SOMNOLENCE (Sleepiness) (seriousness criteria disability and medically significant) and VACCINATION SITE PAIN (Injection site pain) (seriousness criteria |

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| | | disability and medically significant). On 19-May-2021, the patient experienced LYMPHADENOPATHY (Swollen glands) (seriousness criteria disability and medically significant) and MYALGIA (Muscular pains) (seriousness criteria disability and medically significant). On 20-May-2021, the patient experienced HEADACHE (Headache) (seriousness criteria disability and medically significant) and PAIN IN EXTREMITY (Aches & pains in legs) (seriousness criteria disability and medically significant). On 25-May-2021, the patient experienced VACCINATION SITE URTICARIA (Injection site hives) (seriousness criteria disability and medically significant). On 26-May-2021, the patient experienced RASH (Painful rash) (seriousness criteria disability and medically significant). On 07-Aug-2021, after starting mRNA-1273 (COVID 19 Vaccine Moderna), the patient experienced NEUTROPENIA (Neutropenia) (seriousness criteria disability and medically significant) and MYOCARDITIS (Myocarditis) (seriousness criteria disability and medically significant). On 01-Sep-2021, the patient experienced ABNORMAL LOSS OF WEIGHT (Unintentional weight loss) (seriousness criteria disability and medically significant). On 07-Nov-2021, the patient experienced HYPOGLYCAEMIA (Hypoglycemia) (seriousness criteria disability and medically significant) and SLEEP DISORDER (Sleep disturbed) (seriousness criteria disability and medically significant). On an unknown date, the patient experienced SYNCOPE (Fainting) (seriousness criteria disability and medically significant), LOSS OF CONSCIOUSNESS (Loss of consciousness) (seriousness criteria disability and medically significant), CHEST PAIN (Chest pain) (seriousness criteria disability and medically significant) and PALPITATIONS (Heart palpitations) (seriousness criteria disability and medically significant). On 25-May-2021, VACCINATION SITE PAIN (Injection site pain) had resolved. On 27-May-2021, VACCINATION SITE URTICARIA (Injection site hives) had resolved. On 31-May-2021, RASH (Painful rash) had resolved. On 01-Jun-2021, SOMNOLENCE (Sleepiness) had resolved. On 09-Jun-2021, MYALGIA (Muscular pains) had resolved. On 10-Jun-2021, PAIN IN EXTREMITY (Aches & pains in legs) had resolved. At the time of the report, ABNORMAL LOSS OF WEIGHT (Unintentional weight loss), HYPOGLYCAEMIA (Hypoglycemia), POOR QUALITY SLEEP (Poor sleep), FATIGUE (Fatigue extreme), NEUTROPENIA (Neutropenia), SLEEP DISORDER (Sleep disturbed) and MUSCULOSKELETAL PAIN (Musculoskeletal pain) had not resolved, SYNCOPE (Fainting), LOSS OF CONSCIOUSNESS (Loss of consciousness), CHEST PAIN (Chest pain) and PALPITATIONS (Heart palpitations) outcome was unknown, LYMPHADENOPATHY (Swollen glands) had resolved with sequelae and HEADACHE (Headache) and MYOCARDITIS (Myocarditis) was resolving.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 29-Jul-2021, SARS-CoV-2 test: negative (Negative) No - Negative COVID-19 test.<br>On 03-Nov-2021, Lymphocyte count: abnormal (abnormal) below normal.<br>On 03-Nov-2021, Neutrophil count: abnormal (abnormal) below normal range.<br>On 03-Nov-2021, White blood cell count: abnormal (abnormal) below normal. |

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| | | Patient was not tested positive for COVID-19 since having the vaccine Spontaneous follow up received 18/06/2021.Patient stated that site did not permit her to put a date in for when she had suspected coronavirus in March 2020. she was diagnosed with Covid-19 by a general practitioner (GP) via the NHS Scotland Hub in March 2020 due to the symptoms and breathing problems she had. Patient was unable to work or go about daily routine for 7 weeks after first dose on 18 May 2021 and was mostly house bound. At week 8 Patient commenced a phased return to work but was still experiencing fatigue and managed this for 4 weeks until second dose of the vaccine was received on the 7th Aug 2021, whereby she have been house bound since then. Around 30 minutes after the vaccination was received, she started experiencing extreme stabbing pains in my muscles and deep within my bones across my entire body. she took paracetamol and ibuprofen at 4 hour intervals but this had no effect on reducing the pain. This severe reaction lasted for 1 week and then stopped after 3 full weeks. In the last three months have unintentionally lost over a stone and a half in weight. she was approx 10stone 7lbs before second dose and now weight 8 stone 12, which is alarming as she is unable to exercise or leave the house. Since 7th Nov 2021 patient been waking every night between 3-4am and awake for 2+ hours. This is very unusual. Finally, neutrophils have been consistently below normal range since getting the vaccine and now my lymphocytes and white blood cell count are now below normal as of bloods taken on the 03 Nov 2021. Patient was referred to haematology and endocrinology. Also experienced myocarditis in the first week. Have been experiencing extreme fatigue since vaccination and black outs for 8 weeks after vaccination date. As of now still experiencing fatigue and unable to work and go about general daily tasks.<br><br>Company comment: This case concerns a 39-year-old, female patient with medical history of Lyme disease, who experienced the unexpected events of Unintentional weight loss, Hypoglycemia, Poor quality sleep, Fatigue, Neutropenia, Sleep disorder, Musculoskeletal pain, Syncope, Loss of consciousness, Chest pain, Palpitations, Lymphadenopathy, Headache, Vaccination site urticaria, Somnolence, Pain in extremity, Rash, Myalgia, Vaccination site pain and expected event of Myocarditis. The events occurred on the same day or up to two days after the first dose of mRNA-1273, with exception of vaccination site rash and vaccination site urticaria which occurred 7 and 8 days after first dose, respectively, events of neutropenia and myocarditis which occurred on the same day after third dose of Moderna vaccine and events of abnormal loss of weight, hypoglycemia and sleep disorder which occurred a months after third dose. Events sleep disorder, syncope, loss of consciousness and chest pain occurred on unknown date. Patient's medical history of Lye disease is a confounder. The benefit-risk relationship of mRNA-1273 is n |
| 4.1(b) [redacted] | 4.1(b) [redacted] | This spontaneous case was reported by a consumer and describes the occurrence of PERICARDITIS (Cardiac pericarditis, Angina pectoris, chest pain,Pericarditis can disappear and reappear.) and MYOCARDITIS (Myocarditis) in a 19-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 3005687 and 214019) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below.<br><br>Concurrent medical conditions included Drug allergy. |

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| | | On 08-Aug-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form.<br>On 15-Sep-2021, received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. In 2021, the patient experienced CHEST PAIN (10 days from the vaccination patient found chest pains). On 15-Sep-2021, after starting mRNA-1273 (Spikevax), the patient experienced INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (Inappropriate schedule of vaccine administered) and VACCINATION SITE PAIN (Pain at the injection site/For a day the arm hurts). On 25-Sep-2021, the patient experienced PERICARDITIS (Cardiac pericarditis, Angina pectoris, chest pain,Pericarditis can disappear and reappear.) (seriousness criterion medically significant), MYOCARDITIS (Myocarditis) (seriousness criterion medically significant) and MUSCULOSKELETAL CHEST PAIN (Intercostal pains). On 15-Sep-2021, INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (Inappropriate schedule of vaccine administered) had resolved. At the time of the report, PERICARDITIS (Cardiac pericarditis, Angina pectoris, chest pain,Pericarditis can disappear and reappear.), MYOCARDITIS (Myocarditis) and MUSCULOSKELETAL CHEST PAIN (Intercostal pains) had not resolved, CHEST PAIN (10 days from the vaccination patient found chest pains) outcome was unknown and VACCINATION SITE PAIN (Pain at the injection site/For a day the arm hurts) had resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On an unknown date, Electrocardiogram: normal (normal) no effect the beats were normal, did not give any kind of sign..<br>On an unknown date, SARS-CoV-2 antibody test negative: negative (Negative) negative.<br>On an unknown date, Ultrasound Doppler: abnormal (abnormal) cardiac pericarditis with myocarditis with a part of the heart that bleeds blood on the ventricle valve.<br><br>No concomitant medication was reported.<br>The patient told his doctor and the doctor said he had nothing, he said you only have intercostal pains. The patient clarified that he never had heart problems, in the past he had competed in athletics. Patient had chest pains when he go up on the stairs. Patient discovered pericarditis with myocarditis last Thursday. Next Monday, the patient said that it will begin the treatment. He will start treatment with a private cardiologist. All these symptoms began on 25 Sep2021 and were still present when he takes the stairs or walk too much he feels that his heart starts to pinch and he has to stop. The patient clarified that he had never been positive to COVID-19. He never had a history of myocarditis / pericarditis nor personal neither in his family. Consent to follow up with Safety was given. After the second dose of vaccine, pericarditis was confirmed by the cardiologist. The pericarditis can disappear and reappear. Patient was still doing checking specific blood test. In last two months it was disappeared, but when patient had pain in the chest patient still had to identify more specific test. He confirmed that he had. After Eco-doppler test, |

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| | | Myocarditis was identified but it was not confirmed no track found by the cardiologist in the last check, pericarditis had been and he was still trying to understand. The next test will be able to better identify the problem.<br>10 days after the second dose of vaccine, patient had chest pain which seemed like intercostal pain but medical investigations found momentary pericarditis and further tests are needed.<br>No treatment information was provided.<br>Company comment: This case concerns a 19-year-old, male patient with no medical history reported, who experienced the expected serious AESI events of pericarditis and myocarditis (ECG was normal and ultrasound doppler evidenced pericarditis and myocarditis). The events occurred approximately 10 days after the second dose of mRNA-1273 vaccine and he had not recovered at the time of the report. Inappropriate schedule of vaccine administered was also noted in the case (window between doses was 38 days). The rechallenge was not applicable since the events happened after the second dose and no information on additional dosing is available, additionally events were ongoing. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Case was assessed as serious due to important medical event and medical judgement.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 13-Dec-2021: Translation received on 15-Dec-2021, which contains significant information: event description updated and allergy added. |
| 4.1(b) | 4.1(b) | This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) ) on 25-Nov-2021 and was forwarded to Moderna on 06-Dec-2021.<br>This case, initially reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref, 4.1(b)<br><br>Past medical history, allergies, treatments, drugs used in the past: penicillin allergy<br><br>On an unknown date, the patient received the 1st dose of this vaccine.<br><br>On 31-Jul-2021, at 14:45, the patient received the 2nd dose of this vaccine.<br><br>At 23:00, the patient experienced chest pain and pyrexia. Myocarditis developed.<br><br>On 03-Aug-2021, the patient visited the hospital and was diagnosed with myocarditis.<br><br>The patient was hospitalized for follow-up.<br><br>On 11-Aug-2021, the symptoms improved, and thus the patient was discharged from the hospital.<br><br>On 20-Aug-2021, the symptoms resolved.<br><br>The outcome of myocarditis was reported as resolved.<br><br>Follow-up investigation will be made. |

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| | | LP Company Comment:<br><br>The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.<br><br>Company comment: This case concerns a 31-year-old, male patient with no medical history, who experienced the expected event of myocarditis, which required hospitalization. The event occurred approximately 3 days after the second dose of mRNA-1273. The rechallenge was not applicable as events occurred after second dose and no further dosing was reported or planned, based on information provided. The reporter assessed the events as related to the product. The benefit-risk relationship of mRNA-1273 is not affected by this report. |
| 4.1(b) | 4.1(b) | This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 26-Nov-2021 and was forwarded to Moderna on 07-Dec-2021.<br>This case, initially reported to the 4.1(b) by a pharmacist, was received via the 4.1(b) (Ref, 4.1(b)<br><br>On an unknown date, the patient received the 1st dose of this vaccine. On 21-Nov-2021, the patient received the 2nd dose of this vaccine. On 22-Nov-2021, pyrexia of 38.5 degrees Celsius developed. On 23-Nov-2021, around 15:00, myocarditis developed. Chest pain developed, but the patient was just followed up. After 21:00, the symptoms did not improve, and the patient visited a nearby physician. The patient returned home without significant findings such as electrocardiogram changes. On 24-Nov-2021, the symptoms did not improve, and the patient returned to the hospital. Blood test showed increased cardiac enzymes, and echocardiography showed decreased cardiac function. The patient was raced to the reporting hospital. The patient was hospitalized. On 25-Nov-2021, the symptoms were resolving. The outcome of pyrexia and myocarditis was reported as resolving. Follow-up investigation will be made.<br><br>Company Comment: The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.<br><br>For mRNA-1273 (COVID-19 Vaccine Moderna Intramuscular Injection) (Intramuscular), the reporter considered PYREXIA (Pyrexia) and MYOCARDITIS (Myocarditis) to be possibly related.<br><br>This case concerns a 29-year-old, male subject with unknown medical history, who experienced the serious (seriousness criteria= caused hospitalization) unexpected event of Pyrexia and the serious (seriousness criteria= caused hospitalization; medically significant) expected event of Myocarditis(AESI). The event Pyrexia occurred 1 day after the second dose of mRNA 1273 VACCINE while event Myocarditis occurred 2 days after the second dose of mRNA 1273 VACCINE. Around 15:00 on the second day after the second dose vaccination, chest pain/myocarditis developed. Persistence of the symptom after 21:00 prompted consult with a physician but he was sent home after ECG showed no ECG changes. The next day, symptoms did not improve; hence, patient went to a |

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| | | hospital where blood test showed increased cardiac enzymes, and echocardiography showed decreased cardiac function, which prompted admission to the reporting hospital. At the time of the report, outcome of the events was Recovering/Resolving. The rechallenge was not applicable as no information regarding events after the first dose was available and, also, no information regarding an additional dose is given. The patient's age and gender remain as confounders. The benefit-risk relationship of mRNA 1273 VACCINE is not affected by this report. |
| 4.1(b) | 4.1(b) | This spontaneous case was reported by a consumer and describes the occurrence of MYOCARDITIS (Suspected condition of myocarditis) in a 27-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 3003603 and 3001944) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below.<br><br>No Medical History information was reported.<br><br>On 14-May-2021 at 8:15 PM, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form.<br>On 23-Jun-2021 at 1:30 PM, received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. On 23-Jun-2021, the patient experienced PAIN IN EXTREMITY (limb pain), PYREXIA (fever), HEADACHE (Headache), FATIGUE (Gets overworked superfast) and CHILLS (chills). On 01-Jul-2021, the patient experienced CHEST PAIN (Heart pain/ very severe pains in the chest), DYSPNOEA (Out of breath/ breathlessness), PALPITATIONS (Heart palpitations/ extreme racing heart out) and HYPOAESTHESIA (Numbness in the left arm). On 08-Jul-2021, the patient experienced DISORIENTATION (Disoriented at times), HEART RATE INCREASED (pulse jumps extremely high when standing up and moving , extreme fatigue (Chronic Fatigue)/ extremely high pulse rate (130-155)) and DIZZINESS (Dizziness). On 21-Jul-2021, the patient experienced ABDOMINAL PAIN UPPER (Digestive disorders (yellow stools, abdominal pain)/ Very severe pain in the upper abdomen). On 24-Sep-2021, the patient experienced BACK PAIN (back pain). On 26-Oct-2021, the patient experienced BURNING SENSATION (Sensation of burning nerves). On 15-Nov-2021, the patient experienced MYOCARDITIS (Suspected condition of myocarditis) (seriousness criterion medically significant). On an unknown date, the patient experienced ANGINA PECTORIS (Cardiac pain), DYSPEPSIA (Indigestion), DECREASED APPETITE (loss of appetite), MUSCLE TWITCHING (Sudden twitching in the muscles), RESTLESSNESS (restlessness in the body), ABNORMAL FAECES (Digestive disorders (yellow stools, abdominal pain)), ASTHENIA (Extreme fatigue / weakness / lack of energy (Chronic Fatigue)), CONDITION AGGRAVATED (Symptoms get worse) and LOSS OF PERSONAL INDEPENDENCE IN DAILY ACTIVITIES (daily life tasks accomplished with difficulty on one's own/ second vaccination no exercise is possible). On 27-Jun-2021, PAIN IN EXTREMITY (limb pain), PYREXIA (fever) and CHILLS (chills) had resolved. At the time of the report, MYOCARDITIS (Suspected condition of myocarditis), BURNING SENSATION (Sensation of burning nerves), LOSS OF PERSONAL INDEPENDENCE IN DAILY ACTIVITIES (daily life tasks accomplished with difficulty on one's own/ second vaccination no exercise is possible), DIZZINESS (Dizziness) and HYPOAESTHESIA (Numbness in the left arm) outcome was unknown and ANGINA PECTORIS (Cardiac pain), CHEST PAIN (Heart pain/ very severe pains in the chest), DYSPEPSIA |

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| | | (Indigestion), DECREASED APPETITE (loss of appetite), DYSPNOEA (Out of breath/ breathlessness), DISORIENTATION (Disoriented at times), HEART RATE INCREASED (pulse jumps extremely high when standing up and moving , extreme fatigue (Chronic Fatigue)/ extremely high pulse rate (130-155)), BACK PAIN (back pain), MUSCLE TWITCHING (Sudden twitching in the muscles), RESTLESSNESS (restlessness in the body), PALPITATIONS (Heart palpitations/ extreme racing heart out), ABNORMAL FAECES (Digestive disorders (yellow stools, abdominal pain)), ABDOMINAL PAIN UPPER (Digestive disorders (yellow stools, abdominal pain)/ Very severe pain in the upper abdomen), ASTHENIA (Extreme fatigue / weakness / lack of energy (Chronic Fatigue)), CONDITION AGGRAVATED (Symptoms get worse), HEADACHE (Headache) and FATIGUE (Gets overworked superfast) had not resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 23-Jun-2021, Blood pressure measurement: high (High) High.<br>On 23-Jun-2021, Heart rate: high (High) High.<br>On 08-Jul-2021, Blood pressure measurement: 138/85 (abnormal) 138/85.<br>On 08-Jul-2021, Body temperature: 36.3 (normal) 36.3 degree Celsius.<br>On 08-Jul-2021, Heart rate: 75 (normal) 75 per minute and 130-155 (High) 130-155.<br>On 21-Jul-2021, Blood pressure measurement: 137/87 (abnormal) 137/87.<br>On 21-Jul-2021, Body temperature: 37 (normal) 36.3 degree Celsius.<br>On 21-Jul-2021, Heart rate: 90 (normal) 90 per minute.<br>On 26-Oct-2021, Blood pressure measurement: 137/87 (abnormal) 137/87.<br>On 26-Oct-2021, Body temperature: 37.2 (normal) 36.3 degree Celsius.<br>On 26-Oct-2021, Heart rate: 90 (normal) 90 per minute.<br>On 11-Nov-2021, SARS-CoV-2 antibody test: more than 2500 u/ml (normal) antibodies more than 2500 U/ml..<br>On 15-Nov-2021, Magnetic resonance imaging: abnormal (abnormal) suspected condition of myocarditis.<br>In December 2021, Autoantibody test: positive (Positive) Beta 1 antibody positive.<br><br>01-Jul-2021 Patient experienced very severe pains in the chest, breathlessness.<br>08-Jul-2021: Patient was roused from sleep at night with an extremely high pulse rate (130-155).<br>He also had extremely severe chest pain, dizziness, and was disoriented at times. Patient went to the<br>emergency room. 21-July-2021: patient experienced very severe pain in the upper abdomen and pain in the chest region. The pain became so severe and unbearable that they went to the emergency room.The period August -September: the condition has not improved, symptoms persisted.<br>24-Sep-2021: Patient had very severe chest and back pain and patient again visited the emergency room. The period September - October 2021: |

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| | | All symptoms still persisted, no improvement in sight. Sudden twitching in the muscles.<br>26-Oct-2021: Patient had very severe pain, tightness in the chest and back. Sensation of burning nerves throughout the body and restlessness in the body. 15-Nov-2021: Cardio MRI was performed, and it was diagnosed suspected condition of myocarditis of LV posterior wall and postero-lateral segments.<br>Company Comment: This case concerns a 27-years-old male patient, with no medical history reported in this case, who experienced the serious expected AESI of Myocarditis. Additionally, other non-serious events were also reported. The event occurred approximately 4 months and 23 days after the administration of the second dose of the mRNA-1273 vaccine. The event was assessed with the seriousness criteria of Medically Significant. It was reported that the patient was diagnosed with a suspected condition of myocarditis of LV posterior wall and postero-lateral segments. No information on required treatment was disclosed. At the time of the report, the outcome of the event was Unknown. The rechallenge is not applicable since the event occurred after the second dose of the of the mRNA-1273 vaccine. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 14-Dec-2021: Translated document received on 17-DEC-2021 contains events, patient details, lab details and facility information added. Dosage regimen updated. |
| 4.1(b) | 4.1(b) | This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCARDITIS (Myocarditis) in a 34-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for an unknown indication.<br><br>No Medical History information was reported.<br><br>On 01-Nov-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 03-Nov-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criterion hospitalization). At the time of the report, MYOCARDITIS (Myocarditis) was resolving.<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments.<br><br>Age of the patient was reported as 34.4.<br><br>The patient had past history of mitral valve prolapse.<br><br>The patient took contraceptives and denied other medications used.<br><br>The patient visited LMD and cardiac echo at Doctor's clinic revealed moderate MR, PR, LVE, LAE, EF 43% (cardiomegaly with reduced EF). On 19-Nov-2021, the patient sought medical attention at the cardiology outpatient of hospital, due to short of breath for 2 weeks, episodes of palpitation (arrhythmia), DOE and orthopnea were noted in recent three days. The patient denied recent TOCC history, fever chest pain/tightness |

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| | | or extremities edema. Therefore, the patient was referred to ER, due to possible heart failure and/or myocarditis. At ER, her initial vital sign was T 36.6, P 70, R 20, BP 116/78 and GCS was E4V5M6. PE showed regular heart beat and no murmur was noted. Lab data was grossly normal. However EKG showed diffuse T wave inversion and LVH was noted, raising concern of myocarditis and heart failure. Heart echo was done and showed LVEF is 30.7%, DCM and regional wall motion abnormality, suspect coronary artery disease. Follow up cardiac enzyme was normal.<br><br>On 20-Nov-2021, under the impression of heart failure, DCM and myocarditis she was admitted to the hospital for further evaluation. After admission, the patient was prescribed with entresto, carvedilol, spironolactone, lasix for her HF. CTA was also arranged and the patient was prescribed aspirin for suspect CAD. In ward, hypokalemia was noted so follow up lab data was kept. The patient was prescribed colchicine for myocarditis and her symptoms subsided after medications used.<br><br>Three days later, the patient's symptom subside and electrolyte was corrected. CTA showed no evidence of CAD and Holter showed.<br><br>Under, relatively stable condition, on 24-Nov-2021, the patient was discharged from the hospital and the patient was advised to keep OPD follow up.<br><br>The patient was expected to come for a follow-up visit on 02-Dec-2021<br><br>Company Comment: This case concerns a 34-year-old female patient with no relevant medical history, who experienced the unexpected serious adverse event of special interest Myocarditis. The event, which caused hospitalization for the patient occurred 2 days after receiving the second dose of mRNA-1273 Vaccine. The rechallenge was not applicable since only information about the second dose was disclosed. The patient stayed at the hospital for 5 days and diagnostics revealed abnormalities in the EKG and echocardiogram, there was also noted hypokalemia. She was discharged improved and given with home medications. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report. |
| 4.1(b) | 4.1(b) | This case was received via an unknown source (no reference has been entered for a health authority or license partner) on 06-Dec-2021 and was forwarded to Moderna on 08-Dec-2021.<br>This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCARDITIS (Myocarditis) in a 30-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 072F21A_1101212-CDC) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 22-Nov-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 25-Nov-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criterion medically significant). At the time of the report, MYOCARDITIS (Myocarditis) was resolving. |

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| | | For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments.<br><br>No concomitant medication were reported<br>No treatment medication were reported<br><br>Patient received the second of moderna vaccine on 22-Nov-2021. After the vaccine patient experienced fever for 5 days, chest tightness (+) palpitation (+) dyspnea (+) N/V (-) abdominal pain (-) URI (-) dysuria (-). Patient stated consciousness E: 4 M: 6 V: 5. Laboratory data included Body temp 36.9°C, SpO2 100%, P: 95 (beats/min), R: 20 (breaths/min) BP 134/86 (mmHg), NT-proBNP 132.0 pg/m, hs-Troponin I: 71.1 pg/mL, Patient also stated Conscious clear, Chest: clear breathing sound. Abdomen: soft, no tenderness. Limb: no edema. NE: no specific finding, Myocarditis. Patient stated that due to body temperature maintained 40°C for two consecutive days since November 23. Patient went to the Emergency Department on November 25. The fever has subsided after treatment, and he returned to Cardiology Outpatient department on November 26.<br><br>This case concerns a 30-year-old male patient with no medical history, who experienced the unexpected serious adverse event of special interest Myocarditis. The event occurred 4 days after receiving the second dose of mRNA-1273 Vaccine. The rechallenge was not applicable since only information about the second dose was disclosed. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report. |
| 4.1(b) [redacted] | 4.1(b) [redacted] | This case was received via an unknown source (no reference has been entered for a health authority or license partner) on 06-Dec-2021 and was forwarded to Moderna on 08-Dec-2021.<br>This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCARDITIS (Myocarditis) in a 26-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for an unknown indication.<br><br>No Medical History information was reported.<br><br>On 15-Nov-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 18-Nov-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criterion medically significant). At the time of the report, MYOCARDITIS (Myocarditis) was resolving.<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments.<br><br>Patient was reported to be given second dose of Moderna vaccine on 25-Nov-2021 and also had second dose of Moderna vaccine in afternoon on 15-Nov-2021.<br><br>Patient started to have a fever of about 39 degrees, chills and general fatigue. The fever subsided the same night after the patient used antipyretics, and the symptoms of chills and general fatigue lasted for 1 day before recovery. |

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| | | On November 18, the patient suffered from chest tightness and wheezing after getting up in the morning and later the symptoms were improved. Patient also suffered from asthma and went to the clinic for X-ray and electrocardiographic examinations, where no abnormality was found.<br><br>On November 20, 2021, the patient started to suffer from chest tightness in addition to wheezing.<br><br>On November 25, 2021 patient went to hospital Abnormality was found in the electrocardiogram and a blood test was performed. Abnormal increase of myocardial enzymes were detected. The patient was diagnosed with vaccine-induced myocarditis and was hospitalized for treatment.<br><br>On November 29, 2021, the patient was taken daily blood tests during hospitalization. The myocardial enzymes decreased slightly but the improvement was not obvious and electrocardiogram was found to be normal, and the patient was discharged on the same day and arranged a return visit.<br><br>Relevant concomitant medications were not provided.<br>Treatment information was not provided.<br><br>This case concerns a 26-year-old male patient with no medical history, who experienced the unexpected serious adverse event of special interest Myocarditis. The event occurred 4 days after receiving the second dose of mRNA-1273 Vaccine. The rechallenge was not applicable since only information about the second dose was disclosed. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report. |
| 4.1(b) [redacted] | 4.1(b) [redacted] | This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCARDITIS (Myocarditis) in a 24-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for an unknown indication.<br><br>No Medical History information was reported.<br><br>On 21-Nov-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 24-Nov-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criterion hospitalization). At the time of the report, MYOCARDITIS (Myocarditis) was resolving.<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments.<br><br>No concomitant medications reported.<br>On 23-Sep-2021, the patient received the first dose of COVID-19 vaccine (AZ) and second shot of COVID-19 vaccine (Moderna) on 21-Nov-2021. At the night of 21-Nov-2021, and experienced chest tightness, chest pain and fever on 22-Nov-2021.<br>The patient visited the outpatient clinic of the Dept of Cardiology for follow-up on 24-Nov-2021 as he experienced symptoms of chest pain and |

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| | | shortness of breath. It was found that the complete EKG showed II, III, AVF, V1-V6 STE and elevation cardio [sic: cardiac] enzyme. The patient was diagnosed with myocarditis and was transferred to the ED for treatment. Vital signs: body temperature: 36.7 degree Celsius; BP: 122/77 mmHg; pulse: 103 beats/min; respiratory rate: 16 breaths/min. The CXR was no obvious acute lesion. Bed side Echo: well LV motion, no pericardiac effusion, no pleural effusion, no ascites, no AAA, no intimal flap. The patient was directly admitted to the ICU for 2 days for treatment subsequently. Cardiac enzymes & gt; 15000-17000. Cardiac enzymes 3800. The patient was transferred to the general ward on 26-Nov-2021 after the symptoms improved and was discharged on 29-Nov-2021 after the condition stabilized.<br>The patient has to take medication regularly now. The patient returned for visit on 06-Dec-2021. The patient has no symptoms of discomfort. The patient was instructed to avoid strenuous exercise at the moment and to seek medical attention as soon as possible in case of chest discomforts. Patient has no history of chronic illness.<br><br>Company Comment: This case concerns a 24 year old male patient with no reported medical history who experienced the serious, expected AESI event of myocarditis 3 days after the second dose of Covid-19 vaccine (mRNA 1273). Patient received AstraZeneca Covid-19 vaccine as first dose in the Covid-19 vaccine series. One day after the mRNA 1273 vaccine patient experienced chest tightness, then fever the following day. The patient went to the cardiology outpatient clinic 3 days after the mRNA 1273 vaccine due to dyspnea and chest pain. EKG showed II, III, AVF, V1-V6 STE and had elevated cardiac enzymes. The patient was diagnosed with myocarditis and referred to the emergency department. Bedside Echocardiogram showed good LV motion, no pericardial effusion, no pleural effusion, no ascites, no AAA, no intimal flap. Patient was admitted to the ICU for further management, two days after was transferred to general ward. Patient was discharged 6 days after admission. The benefit-risk relationship of mRNA 1273 vaccine is not affected by this report. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 09-Dec-2021 and was forwarded to Moderna on 09-Dec-2021.<br>This regulatory authority case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of TACHYCARDIA (Tachycardia, unspecified, Dehydratio II degree), VOLUME BLOOD DECREASED (Volume blood decreased), ANGINA PECTORIS (Angina pectoris, unspecified) and MYOCARDITIS (Myocarditis, unspecified) in a 33-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 3003185) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below.<br><br>No Medical History information was reported.<br><br>On 01-Jul-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 02-Jul-2021, the patient experienced ANGINA PECTORIS (Chest pain in heart area), HEART RATE INCREASED (Heart rate increased), WEIGHT DECREASED (Weight loss (7 kg)), DRY MOUTH (Dry mouth), ASTHENIA (Weakness), DECREASED APPETITE (Appetite lost), DYSPNOEA (Lack of air) and |

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| | | PYREXIA (Body temperature increased til 37.5 C). On 06-Jul-2021, the patient experienced TACHYCARDIA (Tachycardia, unspecified, Dehydratio II degree) (seriousness criterion hospitalization) and VOLUME BLOOD DECREASED (Volume blood decreased) (seriousness criteria hospitalization and medically significant). On 12-Jul-2021, the patient experienced ANGINA PECTORIS (Angina pectoris, unspecified) (seriousness criteria hospitalization and medically significant), MYOCARDITIS (Myocarditis, unspecified) (seriousness criteria hospitalization and medically significant) and ANGINA PECTORIS (Chest pain). In August 2021, the patient experienced POLYMENORRHOEA (Menstural cycle shortened). On 21-Sep-2021, the patient experienced SINUS TACHYCARDIA (Tachycardia sinuatrialis). On 12-Oct-2021, the patient experienced OVARIAN DISORDER (Ovarian dysfunction). On 04-Jul-2021, PYREXIA (Body temperature increased til 37.5 C) had resolved. On 06-Jul-2021, TACHYCARDIA (Tachycardia, unspecified, Dehydratio II degree) and VOLUME BLOOD DECREASED (Volume blood decreased) was resolving. On 12-Jul-2021, ANGINA PECTORIS (Angina pectoris, unspecified) and MYOCARDITIS (Myocarditis, unspecified) had resolved. On 01-Sep-2021, ANGINA PECTORIS (Chest pain in heart area), ANGINA PECTORIS (Chest pain), HEART RATE INCREASED (Heart rate increased), DRY MOUTH (Dry mouth), ASTHENIA (Weakness), DECREASED APPETITE (Appetite lost) and DYSPNOEA (Lack of air) had resolved. At the time of the report, OVARIAN DISORDER (Ovarian dysfunction), SINUS TACHYCARDIA (Tachycardia sinuatrialis), WEIGHT DECREASED (Weight loss (7 kg)) and POLYMENORRHOEA (Menstural cycle shortened) was resolving.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 06-Jul-2021, Blood pressure measurement: 114/81 (normal) Test result: 114/81 mmHg.<br>On 06-Jul-2021, Blood test: normal (normal) Test result: normal.<br>On 06-Jul-2021, Electrocardiogram: normal (normal) Test result: normal..<br>On 06-Jul-2021, Heart rate increased: 105 times/min (abnormal) Test result: 105 times/min.<br>On 12-Jul-2021, Electrocardiogram: normal (normal) Test result: normal.<br><br>Company comment: This case concerns a 33-year-old, female patient, with no medical history reported in this case, who experienced the serious (Hospitalization and Medically Significant) expected AESI of Myocarditis, the non-serious AESI of Sinus tachycardia and the serious unexpected events of Tachycardia, Volume blood decreased and Angina pectoris (reported as Angina pectoris, unspecified). Additionally, other non-serious events have been reported in this case. The event Myocarditis occurred approximately 12 days after the administration of the second dose of the mRNA-1273 vaccine and, at the time of the report, the outcome was reported as Recovered/Resolved. The event Sinus tachycardia occurred approximately 2 months and 21 days after the administration of the second dose of the mRNA-1273 vaccine and, at the time of the report, the outcome was reported as Recovering/Resolving. The event Tachycardia occurred approximately 6 days after the administration of the second dose of the mRNA-1273 vaccine, reported |

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| | | with the seriousness criteria of Hospitalization and, at the time of the report, the outcome was reported as Recovering/Resolving. The event Volume blood decreased occurred approximately 6 days after the administration of the second dose of the mRNA-1273 vaccine, reported with the seriousness criteria of Hospitalization and Medically Significant and, at the time of the report, the outcome was reported as, Recovering/Resolving. The event Angina pectoris (reported as: Angina pectoris, unspecified) occurred approximately 12 days after the administration of the second dose of the mRNA-1273 vaccine, reported with the seriousness criteria of Hospitalization and Medically Significant and, at the time of the report, the outcome was reported as, Recovered/Resolved. The rechallenge is not applicable since the events occurred after the second dose of the of the mRNA-1273 vaccine. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. |
| 4.1(b) | 4.1(b) | This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCARDITIS (Myocarditis) in a 35-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination.<br><br>Concurrent medical conditions included Mitral valve prolapse.<br><br>On 20-Nov-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 28-Nov-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criterion hospitalization prolonged). At the time of the report, MYOCARDITIS (Myocarditis) was resolving.<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments.<br><br>No concomitant medication were reported.<br>First dose of mrna1273 (AstraZeneca) on 05-AUG-2021. After second dose (Moderna) , she felt unwell in her whole body, lost her appetite, and noticed her muscles were twisted. On 25-NOV-2021 experienced intermittent chest tightness. On 28-NOV-2021 Chest tightness suddenly occurred during jogging in morning. She lost consciousness for a few minutes and was sent to emergency room for medical treatment. In emergency room, the fever was 38.9 and HR: 135 BPM, and the blood samples showed an increase in myocardial enzymes. Electrocardiogram showed sinus tachycardia with T wave inversion. Bedside echocardiography was normal. After about 10 seconds later, the whole body twitch was noticed, but no change of consciousness level was found, so antiepileptic drugs were given. Subsequent blood samples showed an increase in myocardial enzymes. On 28-NOV-2021 12:31, Troponin I was 1.13. Suspected of acute myocarditis, she was admitted to intensive care unit On 29-NOV-2021 She was transferred to general ward. On 30-nov-2021, patient complained of being unwell and suffering from asthma<br>Company Comment: This regulatory case concerns a 35-year-old female patient, with no relevant medical history reported, who experienced the serious (hospitalization) expected AESI of MYOCARDITIS. The event occurred 8 days after receiving the second dose of mRNA-1273. |

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| | | According to source narrative, patient experienced chest discomfort five days after being vaccinated. On the eighth day after vaccination, patient went to the ER were increase in myocardial enzymes and an abnormal electrocardiogram with T wave inversion were obtained. Echocardiogram was normal. Patient also experienced an episode of muscle twitching in the emergency room and was treated with antiepileptic drugs. She was admitted to the ICU for suspected myocarditis and the day after she was transferred to the general ward. The benefit-risk relationship of mRNA-1273 is not affected by this report |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 09-Dec-2021 and was forwarded to Moderna on 09-Dec-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of PERICARDITIS (PERICARDITIS) in a 16-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 3005697 and 3004670) for COVID-19 immunization.<br><br>No Medical History information was reported.<br><br>On 09-Aug-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form.<br>On 08-Sep-2021, received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. On 21-Nov-2021, after starting mRNA-1273 (Spikevax), the patient experienced PERICARDITIS (PERICARDITIS) (seriousness criterion medically significant). At the time of the report, PERICARDITIS (PERICARDITIS) had not resolved.<br><br>For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.<br><br>No concomitant medications were provided<br>Treatment Information was not provided.<br><br>Company comment: This is a regulatory case concerning a 16 year-old, male patient with no reported medical history, who experienced the serious (due to medically important condition) expected, according CCDS, AESI of Pericarditis. At the time of the report the event´s outcome was not recovered. The event occurred approximately 2 months 13 days after the second dose of mRNA-1273 vaccine. The rechallenge was not applicable, as the event was reported exclusively after the second dose and no information on additional dosing is available. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 07-Dec-2021 and was forwarded to Moderna on 07-Dec-2021.<br>This regulatory authority case was reported by a consumer and describes the occurrence of ARRHYTHMIA (Arrhythmia) and MYOCARDITIS (Suspected heart muscle inflammation (according to cardiologist on july 13)) in a 31-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3003183) for Prophylactic vaccination. The occurrence of additional non-serious events is detailed below.<br><br>No Medical History information was reported. |

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| | | On 20-Jun-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 20-Jun-2021, the patient experienced TACHYCARDIA (Tachycardia), INJECTION SITE ERYTHEMA (Injection site redness), INJECTION SITE PAIN (Injection site pain) and HEADACHE (Headache). On 21-Jun-2021, the patient experienced PYREXIA (Pyrexia). On 30-Jun-2021, the patient experienced ARRHYTHMIA (Arrhythmia) (seriousness criterion medically significant) and MYOCARDITIS (Suspected heart muscle inflammation (according to cardiologist on july 13)) (seriousness criterion medically significant). On an unknown date, the patient experienced MALAISE (Malaise) and FATIGUE (Fatigue). On 22-Jun-2021, PYREXIA (Pyrexia) had resolved. On 25-Jun-2021, INJECTION SITE ERYTHEMA (Injection site redness), INJECTION SITE PAIN (Injection site pain) and HEADACHE (Headache) had resolved. At the time of the report, ARRHYTHMIA (Arrhythmia), MYOCARDITIS (Suspected heart muscle inflammation (according to cardiologist on july 13)) and FATIGUE (Fatigue) had not resolved, TACHYCARDIA (Tachycardia) was resolving and MALAISE (Malaise) had resolved.<br><br>No concomitant medications were reported.<br>No treatment medications were reported .<br>Patient had allergies to hay fever (mild). After the first dose patient just experienced very typical vaccination reactions and only mild ones at that (exept for the not yet painful redness), and the only thing that made me unfit for work for a single day was the stomach ache. Patient would never have dreamed that it would be so bad after the Second vaccination. The pain at the injection site (treated with paracetamol).<br><br>Company Comment - This case concerns a 31 year old male patient with no relevant medical history, who experienced the serious expected event of myocarditis and the serious non-expected event of arrhythmia (both AESIs). The events occurred approximately 10 days after the second dose of mRNA-1273 vaccine. The rechallenge was unknown. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 07-Dec-2021: Translation received on 14 Dec 2021,contain significant info-with translated event verbatim and sender's comments . |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 09-Dec-2021 and was forwarded to Moderna on 09-Dec-2021.<br>This regulatory authority case was reported by a consumer and describes the occurrence of PYREXIA (Very strong chest pain, chest pressure, difficulty breathing. fever. Post-vaccine pericarditis), CHEST PAIN (Very strong chest pain, chest pressure, difficulty breathing. fever. Post-vaccine pericarditis) and PERICARDITIS (Very strong chest pain, chest pressure, difficulty breathing. fever. Post-vaccine pericarditis) in a 26-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 3005698) for COVID-19 vaccination. |

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| | | No Medical History information was reported.<br><br>On 27-Jul-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form.<br>On 29-Aug-2021, received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to 1 dosage form. On 29-Aug-2021, the patient experienced PYREXIA (Very strong chest pain, chest pressure, difficulty breathing. fever. Post-vaccine pericarditis) (seriousness criterion hospitalization), CHEST PAIN (Very strong chest pain, chest pressure, difficulty breathing. fever. Post-vaccine pericarditis) (seriousness criterion hospitalization) and PERICARDITIS (Very strong chest pain, chest pressure, difficulty breathing. fever. Post-vaccine pericarditis) (seriousness criterion hospitalization). At the time of the report, PYREXIA (Very strong chest pain, chest pressure, difficulty breathing. fever. Post-vaccine pericarditis), CHEST PAIN (Very strong chest pain, chest pressure, difficulty breathing. fever. Post-vaccine pericarditis) and PERICARDITIS (Very strong chest pain, chest pressure, difficulty breathing. fever. Post-vaccine pericarditis) had not resolved.<br><br>No concomitant medication details was reported.<br>No treatment medication details was reported.<br><br>Patient has dust mite allergy.<br><br>Company Comment:<br>This case concerns a 26-year-old, female patient with no medical history, who experienced the serious unexpected events of Pyrexia and Chest pain and the serious expected AESI of Pericarditis. The events occurred the same day after the second dose of mRNA-1273 vaccine. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 10-Dec-2021 and was forwarded to Moderna on 10-Dec-2021.<br>This regulatory authority case was reported by a consumer and describes the occurrence of PERICARDITIS (Pericarditis) in a 31-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 214016 and 3003660) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 14-Jul-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form.<br>On 11-Aug-2021, received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. On 13-Aug-2021, the patient experienced PERICARDITIS (Pericarditis) (seriousness criterion disability). At the time of the report, PERICARDITIS (Pericarditis) was resolving.<br><br>mRNA-1273 (Spikevax) (Unknown) dosing remained unchanged. |

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| | | Concomitant medications were not reported.<br>Treatment medications were not reported.<br><br>Company comment: This is a regulatory authority case concerning a 31-year-old male patient with no medical history reported, who experienced expected event of pericarditis. The event occurred 3 days after the second dose of mRNA-1273 vaccine. Clinical course, test results and treatment details were not provided. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 13-Dec-2021 and was forwarded to Moderna on 13-Dec-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of SEIZURE (CONVULSIONS), MYOCARDITIS (MYOCARDITIS) and WRONG PRODUCT ADMINISTERED (RECEIVED VACCINATION WITH MODERN ACCIDENTALLY INSTEAD OF PFIZER (BORN-93 IE AFTER -91 WHEN MODERN SHOULD NOT BE GIVEN). ) in a 28-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 214029) for COVID-19 vaccination.<br><br>Concurrent medical conditions included Epilepsy (Convulsive disease after OP tumor Cerebri) and Glioma (Cytostaticabeh for Glioma).<br><br>On 12-Nov-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 20-Nov-2021, the patient experienced SEIZURE (CONVULSIONS) (seriousness criteria medically significant and life threatening) and MYOCARDITIS (MYOCARDITIS) (seriousness criteria medically significant and life threatening). On an unknown date, the patient experienced WRONG PRODUCT ADMINISTERED (RECEIVED VACCINATION WITH MODERN ACCIDENTALLY INSTEAD OF PFIZER (BORN-93 IE AFTER -91 WHEN MODERN SHOULD NOT BE GIVEN). ) (seriousness criterion life threatening). At the time of the report, SEIZURE (CONVULSIONS), MYOCARDITIS (MYOCARDITIS) and WRONG PRODUCT ADMINISTERED (RECEIVED VACCINATION WITH MODERN ACCIDENTALLY INSTEAD OF PFIZER (BORN-93 IE AFTER -91 WHEN MODERN SHOULD NOT BE GIVEN). ) was resolving.<br><br>For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.<br><br>No concomitant medication was provided.<br>No treatment medication was provided. |
| 4.1(b) | 4.1(b) | This spontaneous case was reported by a consumer and describes the occurrence of PERICARDITIS (Pericarditis/Chest pain) in a 32-year-old female patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) (batch nos. 062H21A and 093D21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below.<br><br>No Medical History information was reported. |

| Case ID | WW Identifier | Narrative |
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| | | On 23-Sep-2021, the patient received first dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (Intramuscular) 1 dosage form.<br>On 29-Nov-2021 at 9:35 AM, received second dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 29-Nov-2021, the patient experienced EXPIRED PRODUCT ADMINISTERED (Expired vaccine adminstration) and INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (Vaccine was administered 67 days from first vaccination). 29-Nov-2021, the patient experienced CHEST DISCOMFORT (Tightness in the chest). On 30-Nov-2021, the patient experienced PERICARDITIS (Pericarditis/Chest pain) (seriousness criterion medically significant). On an unknown date, the patient experienced INSOMNIA (Had not slept in two weeks), TREMOR (Internal tremors (vibration on her body)), FEELING ABNORMAL (Adrenal dumps (feels like body is stuck flight or fight)) and VISION BLURRED (Blurred vision). On 29-Nov-2021, EXPIRED PRODUCT ADMINISTERED (Expired vaccine adminstration) and INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (Vaccine was administered 67 days from first vaccination) had resolved. At the time of the report, PERICARDITIS (Pericarditis/Chest pain), CHEST DISCOMFORT (Tightness in the chest) and INSOMNIA (Had not slept in two weeks) had not resolved and TREMOR (Internal tremors (vibration on her body)), FEELING ABNORMAL (Adrenal dumps (feels like body is stuck flight or fight)) and VISION BLURRED (Blurred vision) outcome was unknown.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 30-Nov-2021, Electrocardiogram: normal (normal) Normal.<br>On 03-Dec-2021, Electrocardiogram: normal (normal) Normal.<br>On an unknown date, Ultrasound scan: results not reported Results not reported.<br><br>Concomitant medications were not provided.<br>Date of birth of the patient was reported as 4.1(b) 1900.<br>Patient did not had had any symptoms after receiving the first dose.<br>It was reported that the next day after administration of second dose, she woke up with chest pain and tightness. She went to the emergency room and they told she had a mild case of pericarditis and had not slept in two weeks.<br>Patient stated she never experienced symptoms like this before receiving the Moderna COVID-19 vaccine. Patient stated she never had COVID-19 and never had a history of Myocarditis or pericarditis.<br>She stated that she had a doctor's appointment.<br>Patient started taking medication after receiving the second dose. HCP was aware of the side effects.<br>On 21-Dec-2021, Ultrasound scan: results not reported Results not reported.<br>This spontaneous case is concerning a 32 years old, female patient, with no medical history reported, who experienced the expected serious event of Pericarditis, which started one day after the second dose of mRNA-1273 vaccine. The patient experienced Chest discomfort two hours after vaccination and on the next day the patient went to ER and was |

| Case ID | WW Identifier | Narrative |
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| | | diagnosed with mild Pericarditis which was not resolved at the time of this report. Two ECGs have been performed with normal results and echocardiography was also scheduled, however result is not available at the time of this report. Additionally Inappropriate schedule of Vaccine administration (67 days between the first and the second dose) and Expired product administered (expiration date for the second dose March 2021 administered in November 2021) are also noted in this case. The benefit-risk relationship of mRNA-1273 in not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 22-Dec-2021: NNI case |
| 4.1(b) | 4.1(b) | This case was received via 4.1(b) (Reference number: 4.1(b) on 14-Dec-2021 and was forwarded to Moderna on 14-Dec-2021.<br>This regulatory authority case was reported by an other health care professional and describes the occurrence of ARTHRALGIA (Arthralgia), ECHOCARDIOGRAM ABNORMAL (Echocardiogram abnormal), PAIN (Pain), DYSPNOEA (Dyspnoea), CHEST PAIN (Chest pain), PERICARDIAL EFFUSION (Pericardial effusion) and PERICARDITIS (Pericarditis) in a 40-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 026B21A and 044B21A) for an unknown indication.<br><br>Concurrent medical conditions included Chronic kidney disease stage 5 (CKD Stage -V), High cholesterol, Hypertension, Gout and Mesangioproliferative glomerulonephritis.<br><br>On 09-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form.<br>On 09-Apr-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 10-May-2021, the patient experienced ARTHRALGIA (Arthralgia) (seriousness criterion hospitalization), ECHOCARDIOGRAM ABNORMAL (Echocardiogram abnormal) (seriousness criterion hospitalization), PAIN (Pain) (seriousness criterion hospitalization), DYSPNOEA (Dyspnoea) (seriousness criterion hospitalization), CHEST PAIN (Chest pain) (seriousness criterion hospitalization), PERICARDIAL EFFUSION (Pericardial effusion) (seriousness criterion hospitalization) and PERICARDITIS (Pericarditis) (seriousness criterion hospitalization). At the time of the report, ARTHRALGIA (Arthralgia), ECHOCARDIOGRAM ABNORMAL (Echocardiogram abnormal), PAIN (Pain), DYSPNOEA (Dyspnoea), CHEST PAIN (Chest pain), PERICARDIAL EFFUSION (Pericardial effusion) and PERICARDITIS (Pericarditis) had resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On an unknown date, Echocardiogram: abnormal (abnormal) small pericardial effusion.<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments.<br><br>No concomitant medication was reported.<br>No treatment information was reported. |

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| | | Other medications included furosemide 200 mg BID, verapamil 80, prednisone 10, lipitor 20, labetalol 300 BID and sodium and bicarb and flomax 4.<br>Within 1-2 days after vaccine, the patient did have chest pain that radiated to the shoulder and also experienced some dyspnea. After a few weeks the chest pain moved to the center chest and progressed. The patient went to ED 6/20/2021 and was diagnosed with pericarditis.<br><br>Company comment: This regulatory authority case concerns a 40-year-old male patient with no relevant medical history of mesangioproliferative glomerulonephritis, , who experienced the expected serious (hospitalization) event of Pericarditis after mRNA- 1273 Moderna vaccine. The onset of the event occurred approximately 1 to 2 days after the second dose of mRNA- 1273 vaccine. Clinical manifestations included chest pain and dyspnoea. Pericarditis was diagnosed 2 months and 11 days after vaccination. Additionally, Pericardial effusion was also reported and could be in connection with Pericarditis. Very limited information is available regarding clinical course and treatment. At the time of the report, the events had resolved. Additionally, very limited information is available regarding history of glomerulonephritis, which might be a confounder. The benefit-risk relationship of mRNA- 1273 vaccine is not affected by this report. |
| 4.1(b) | 4.1(b) | This case was received via 4.1(b) (Reference number: 4.1(b) on 13-Dec-2021 and was forwarded to Moderna on 13-Dec-2021.<br>This regulatory authority case was reported by an other health care professional and describes the occurrence of CHEST PAIN (Chest pain), C-REACTIVE PROTEIN INCREASED (C-reactive protein increased), CHEST X-RAY NORMAL (Chest X-ray normal), ELECTROCARDIOGRAM NORMAL (Electrocardiogram normal) and FULL BLOOD COUNT NORMAL (Full blood count normal) in a 24-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 27h21b) for an unknown indication. The occurrence of additional non-serious events is detailed below.<br><br>Concurrent medical conditions included Penicillin allergy.<br><br>On 05-Nov-2021, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 27-Nov-2021, the patient experienced CHEST PAIN (Chest pain), C-REACTIVE PROTEIN INCREASED (C-reactive protein increased), CHEST X-RAY NORMAL (Chest X-ray normal), ELECTROCARDIOGRAM NORMAL (Electrocardiogram normal), FULL BLOOD COUNT NORMAL (Full blood count normal), METABOLIC FUNCTION TEST (Metabolic function test), TROPONIN (Troponin) and PERICARDITIS (Pericarditis). At the time of the report, CHEST PAIN (Chest pain), C-REACTIVE PROTEIN INCREASED (C-reactive protein increased), CHEST X-RAY NORMAL (Chest X-ray normal), ELECTROCARDIOGRAM NORMAL (Electrocardiogram normal), FULL BLOOD COUNT NORMAL (Full blood count normal), METABOLIC FUNCTION TEST (Metabolic function test), TROPONIN (Troponin) and PERICARDITIS (Pericarditis) outcome was unknown. |

| Case ID | WW Identifier | Narrative |
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| | | DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On an unknown date, C-reactive protein: 13.4 (Inconclusive) 13.4mg/L.<br>On an unknown date, Chest X-ray: normal (normal) normal.<br>On an unknown date, Electrocardiogram: normal (normal) Normal sinus.<br>On an unknown date, Full blood count: normal (normal) Normal.<br>On an unknown date, Metabolic function test: normal (normal) Normal.<br>On an unknown date, Troponin: 0.01 (abnormal) abnormal.<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments.<br><br>Concomitant medications not provided by the reporter.<br>Treatment medications was not provided by the reporter.<br><br>Company comment: This regulatory authority case concerns a 24-year-old male patient with no relevant medical history who experienced the expected event of pericarditis. The event occurred approximately 22 days after the 3rd dose of the mRNA-1273 .No further details regarding clinical course were provided other than investigations performed (CRP increased, troponin abnormal, whereas ECG, chest X ray, full blood count, metabolic function test were normal ). The outcome of the event is unknown at the time of the report. The rechallenge was not applicable since the event occurred after the 3rd dose so, no rechallenge was done and recurrence was not applicable. The benefit-risk relationship of mRNA-1273 is not affected by this report. |
| 4.1(b) | 4.1(b) | This case was received via 4.1(b) Reference number: 4.1(b) on 14-Dec-2021 and was forwarded to Moderna on 14-Dec-2021.<br>This regulatory authority case was reported by an other health care professional and describes the occurrence of CHEST X-RAY (Chest X-ray), CHEST PAIN (Chest pain), HYPOAESTHESIA (Hypoaesthesia), MYOCARDITIS (Myocarditis) and PALPITATIONS (Palpitations) in a 39-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 013f21a) for an unknown indication.<br><br>No Medical History information was reported.<br><br>On 22-Nov-2021, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 23-Nov-2021, the patient experienced CHEST X-RAY (Chest X-ray), CHEST PAIN (Chest pain), HYPOAESTHESIA (Hypoaesthesia), MYOCARDITIS (Myocarditis) and PALPITATIONS (Palpitations). At the time of the report, CHEST X-RAY (Chest X-ray), CHEST PAIN (Chest pain), HYPOAESTHESIA (Hypoaesthesia), MYOCARDITIS (Myocarditis) and PALPITATIONS (Palpitations) had not resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On an unknown date, Chest X-ray: results not provided (Inconclusive) results not provided. |

| Case ID | WW Identifier | Narrative |
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| | | For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments.<br><br>Other medications not provided by the reporter<br>Treatment medications were not provided<br>Patient had a Left a numb, chest pain, heart palpitations and heart inflammation.<br><br>Company Comment: This case concerns a 39-year-old male subject, with no medical history reported, who experienced the non serious, expected, and AESI event of Myocarditis. The event occurred 1 day after the third dose of mRNA-1273 vaccine. The rechallenge is not applicable, as no additional dosing will be given. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. |
| 4.1(b) | 4.1(b) | This case was received via 4.1(b) (Reference number: 4.1(b) on 14-Dec-2021 and was forwarded to Moderna on 14-Dec-2021.<br>This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCARDITIS (Myocarditis), PERICARDITIS (Pericarditis), C-REACTIVE PROTEIN DECREASED (C-reactive protein decreased), CHEST PAIN (Chest pain) and DYSPNOEA (Dyspnoea) in a 21-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for an unknown indication. The occurrence of additional non-serious events is detailed below.<br><br>The patient's past medical history included Obesity.<br><br>On 23-Nov-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 24-Nov-2021, the patient experienced MYOCARDITIS (Myocarditis), PERICARDITIS (Pericarditis), C-REACTIVE PROTEIN DECREASED (C-reactive protein decreased), CHEST PAIN (Chest pain), DYSPNOEA (Dyspnoea), ECHOCARDIOGRAM ABNORMAL (Echocardiogram abnormal), ELECTROCARDIOGRAM ABNORMAL (Electrocardiogram abnormal), SINUS TACHYCARDIA (Sinus tachycardia), TROPONIN NORMAL (Troponin normal), FATIGUE (Fatigue), HEADACHE (Headache), NAUSEA (Nausea), PYREXIA (Pyrexia) and VOMITING (Vomiting). At the time of the report, MYOCARDITIS (Myocarditis), PERICARDITIS (Pericarditis), C-REACTIVE PROTEIN DECREASED (C-reactive protein decreased), CHEST PAIN (Chest pain), DYSPNOEA (Dyspnoea), ECHOCARDIOGRAM ABNORMAL (Echocardiogram abnormal), ELECTROCARDIOGRAM ABNORMAL (Electrocardiogram abnormal), SINUS TACHYCARDIA (Sinus tachycardia), TROPONIN NORMAL (Troponin normal), FATIGUE (Fatigue), HEADACHE (Headache), NAUSEA (Nausea), PYREXIA (Pyrexia) and VOMITING (Vomiting) had resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On an unknown date, C-reactive protein: 2.85 and asymptomatic (abnormal) 1 day after vaccine on admission .7, the next day 2.85 and asymptomatic.. |

| Case ID | WW Identifier | Narrative |
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| | | On an unknown date, Echocardiogram: showed to clear evidence of myocarditis/pericardit (abnormal) showed to clear evidence of myocarditis/pericarditis..<br>On an unknown date, Electrocardiogram: showed to clear evidence of myocarditis/pericardit (abnormal) showed to clear evidence of myocarditis/pericarditis..<br>On an unknown date, Troponin: negative (Negative) Negative.<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments.<br><br>No concomitant medications were reported.<br><br>It was reported that patient went to ER with cheats pain, shortness of breath, fatigue, nausea, vomiting and headache, was found to have sinus tachycardia in the 130s-140sand was admitted to rule out myocarditis. Patient developed fever later that day.<br><br>Treatment medications were not reported.<br><br>Company comment: This is a regulatory authority case concerning a 21-year-old female patient with no relevant medical history, who experienced myocarditis and pericarditis. The events occurred 1 day after the second dose of mRNA-1273 vaccine. Patient presented to ER with chest pain, shortness of breath, fatigue, nausea, vomiting and head ache. Found to have sinus tachycardia in the 130s-140s. She was admitted to rule out myocarditis. Later that day developed fever. Diagnostic test included Echocardiogram and Electrocardiogram: both showed to clear evidence of myocarditis/pericarditis; Troponin: negative; C-reactive protein: 1 day after vaccine on admission .7, the next day 2.85 Treatment details were not provided. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. |
| 4.1(b) | 4.1(b) | This case was received via 4.1(b) (Reference number: 4.1(b) on 14-Dec-2021 and was forwarded to Moderna on 14-Dec-2021.<br>This regulatory authority case was reported by an other health care professional and describes the occurrence of ELECTROCARDIOGRAM ST SEGMENT ELEVATION (Electrocardiogram ST segment elevation), CHEST PAIN (Chest pain), DYSPNOEA EXERTIONAL (Dyspnoea exertional), ELECTROCARDIOGRAM ABNORMAL (Electrocardiogram abnormal), PYREXIA (Pyrexia), TROPONIN INCREASED (Troponin increased) and MYOCARDITIS (Myocarditis) in a 30-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for an unknown indication.<br><br>No Medical History information was reported.<br><br>On 27-Nov-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 28-Nov-2021, the patient experienced ELECTROCARDIOGRAM ST SEGMENT ELEVATION (Electrocardiogram ST segment elevation) (seriousness criterion hospitalization), CHEST PAIN (Chest pain) (seriousness criterion hospitalization), DYSPNOEA EXERTIONAL (Dyspnoea exertional) |

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| | | (seriousness criterion hospitalization), ELECTROCARDIOGRAM ABNORMAL (Electrocardiogram abnormal) (seriousness criterion hospitalization), PYREXIA (Pyrexia) (seriousness criterion hospitalization), TROPONIN INCREASED (Troponin increased) (seriousness criterion hospitalization) and MYOCARDITIS (Myocarditis) (seriousness criterion hospitalization). At the time of the report, ELECTROCARDIOGRAM ST SEGMENT ELEVATION (Electrocardiogram ST segment elevation), CHEST PAIN (Chest pain), DYSPNOEA EXERTIONAL (Dyspnoea exertional), ELECTROCARDIOGRAM ABNORMAL (Electrocardiogram abnormal), PYREXIA (Pyrexia), TROPONIN INCREASED (Troponin increased) and MYOCARDITIS (Myocarditis) outcome was unknown.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On an unknown date, Electrocardiogram: abnormal (abnormal) Electrocardiogram with diffuse STE.<br>On an unknown date, Troponin: 440 (Inconclusive) 440, 447 (Inconclusive) 447 and 800 (Inconclusive) 800.<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments.<br><br>No concomitant product use was provided by the reporter.<br><br>The patient was presented with subjective fevers, chest pain, and progressive DOE for 3 days before presenting to Emergency department on 30-Nov-2021. Electrocardiogram and troponin positive, likely perimyocarditis.<br>Treatment medication included NSAIDs and colchicine and was improved with treatment.<br><br>Company comment:<br>This case concerns a 30-year-old male patient, with no medical history reported, who experienced the serious (due to hospitalization) expected AESI of myocarditis and the serious (due to hospitalization) unexpected events of chest pain, dyspnoea exertional, electrocardiogram ST segment elevation and troponin increased after second dose of mRNA-1273. The events could be in association with each other. The events occurred the next day after second dose of mRNA-123. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. |
| 4.1(b) | 4.1(b) | This case was received via 4.1(b) (Reference number: 4.1(b) on 14-Dec-2021 and was forwarded to Moderna on 14-Dec-2021.<br>This regulatory authority case was reported by an other health care professional and describes the occurrence of BLOOD TEST (Blood test), ELECTROCARDIOGRAM (Electrocardiogram), MYOCARDITIS (Myocarditis) and X-RAY (X-ray) in a 24-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for an unknown indication.<br><br>The patient's past medical history included Measles.<br>Concurrent medical conditions included Gilbert's syndrome. |

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| | | On 22-Apr-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 25-Jun-2021, the patient experienced BLOOD TEST (Blood test), ELECTROCARDIOGRAM (Electrocardiogram), MYOCARDITIS (Myocarditis) and X-RAY (X-ray). At the time of the report, BLOOD TEST (Blood test), ELECTROCARDIOGRAM (Electrocardiogram), MYOCARDITIS (Myocarditis) and X-RAY (X-ray) outcome was unknown.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On an unknown date, Blood test: results not provided (Inconclusive) Results not provided.<br>On an unknown date, Electrocardiogram: results not provided (Inconclusive) Results not provided.<br>On an unknown date, X-ray: results not provided (Inconclusive) Results not provided.<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments.<br><br>No concomitant medications were provided.<br>No treatment medications were provided.<br><br>Company comment. This regulatory authority case concerns a 24-year-old, male patient with no reported relevant medical history, who experienced the expected non-serious AESI event of myocarditis. The event occurred 2 months after the second dose of mRNA-1273. No information about previous vaccination schedule was provided. Electrocardiogram, blood tests, and X-ray were performed, but the results are not provided. No details on clinical course and / or treatment were provided in the source document. At the time of the report the outcome of the event was unknown. The benefit-risk relationship of mRNA-1273 is not affected by this report. |
| 4.1(b) | 4.1(b) | This regulatory authority case was reported by an other health care professional and describes the occurrence of PERICARDITIS (Pericarditis) in a 20-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for an unknown indication.<br><br>No Medical History information was reported.<br><br>On 21-Nov-2021, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 22-Nov-2021, the patient experienced PERICARDITIS (Pericarditis). At the time of the report, PERICARDITIS (Pericarditis) had resolved.<br><br>The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown) was unknown.<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. |

| Case ID | WW Identifier | Narrative |
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| | | No concomitant medication was reported.<br><br>Patient developed pericarditis after moderna booster shot.<br><br>No treatment medication use was reported.<br><br>This is a regulatory authority case concerning a 20-year-old, male patient with no relevant medical history, who experienced the expected non-serious event of Pericarditis. The events occurred approximately 1 day after the third dose of mRNA-1273 COVID 19 Vaccine. The rechallenge was unknown since no information about the first dose was disclosed. The benefit-risk relationship of mRNA-1273 COVID 19 Vaccine, is not affected by this report. |
| 4.1(b) | 4.1(b) | This case was received via 4.1(b) (Reference number: 4.1(b) ) on 05-Dec-2021 and was forwarded to Moderna on 05-Dec-2021.<br>This regulatory authority case was reported by a consumer and describes the occurrence of CHEST PAIN (Chest pain), INFLAMMATION (inflammation), FATIGUE (Fatigue/unusual tiredness) and MYOCARDITIS (Myocarditis) in a 19-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) (batch no. 3004732) for an unknown indication.<br><br>Concomitant products included ELASOMERAN (COVID-19 VACCINE MODERNA) from 21-Sep-2021 to an unknown date for Vaccination.<br><br>On 30-Nov-2021, the patient received second dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 01-Dec-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criterion medically significant). On an unknown date, the patient experienced CHEST PAIN (Chest pain) (seriousness criterion medically significant), INFLAMMATION (inflammation) (seriousness criterion medically significant) and FATIGUE (Fatigue/unusual tiredness) (seriousness criterion medically significant). At the time of the report, CHEST PAIN (Chest pain), INFLAMMATION (inflammation) and FATIGUE (Fatigue/unusual tiredness) outcome was unknown and MYOCARDITIS (Myocarditis) was resolving.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On an unknown date, SARS-CoV-2 test: negative (Negative) No - Negative COVID-19 test.<br>On an unknown date, X-ray: abnormal (abnormal) mild inflammation around the heart.<br><br>Patient had Fatigue/unusual tiredness. Chest pain, phoned 111, referred patient to Hospital for further tests. Took an X-ray and said there was mild inflammation around the heart and to manage with ibuprofen and paracetamol.<br>Patient had not tested positive for COVID-19 since having the vaccine.<br>Patient was not enrolled in clinical trial. |

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| | | Company comment: This case concerns a 19-year-old, female patient with no medical history, who experienced the unexpected events of chest pain, inflammation and fatigue and expected event of myocarditis. The event of myocarditis occurred approximately 1 day after the third dose of mRNA-1273, while the rest of the events occurred on unspecified date. As reported, the patient had fatigue/unusual tiredness, chest pain and was referred to Hospital for further tests. An X-ray showed there was mild inflammation around the heart and it was recommended to patient to manage it with ibuprofen and paracetamol. The benefit-risk relationship of mRNA-1273 is not affected by this report. Event seriousness assessed as per Regulatory Authority reporting.<br><br>Most recent FOLLOW-UP information incorporated above includes: On 07-Dec-2021: Follow up report contains lab data, action taken of suspect drug and outcome of event were updated. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 14-Dec-2021 and was forwarded to Moderna on 14-Dec-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myocarditis) in a 29-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination.<br><br>Previously administered products included for COVID-19 vaccination: COVID-19 Vaccine Moderna dispersion for injection COVID-19 mRNA Vaccine (nucleoside modified)SpykeVax on 05-Oct-2021.<br>Past adverse reactions to the above products included No adverse event with COVID-19 Vaccine Moderna dispersion for injection COVID-19 mRNA Vaccine (nucleoside modified)SpykeVax.<br><br>On 03-Nov-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 04-Nov-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criterion medically significant). At the time of the report, MYOCARDITIS (Myocarditis) had not resolved.<br><br>For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.<br><br>Concomitant medication was not provided<br><br>Treatment information was not provided<br><br>Company Comment: This case concerns a 29-year-old female subject, with unknown relevant medical history, who experienced the serious expected event of Myocarditis. The event occurred 1 day after the second dose of mRNA1273 vaccine and 30 days after the first dose of mRNA vaccine. No information regarding any diagnostic test done or medication taken was available. At the time of the report, myocarditis was not resolved. Rechallenge was not applicable as there was no information regarding the presence/absence of adverse event after the first dose and, also, no information regarding an additional dose is available. The benefit-risk relationship of mRNA 1273 Vaccine is not affected by this report. |

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| 4.1(b) | 4.1(b) | This case was initially received via 4.1(b) (Reference number: 4.1(b) ) on 05-Dec-2021. The most recent information was received on 15-Dec-2021 and was forwarded to Moderna on 15-Dec-2021.<br>This regulatory authority case was reported by an other health care professional and describes the occurrence of FATIGUE (Fatigue), CHEST PAIN (Chest Pain), TACHYCARDIA (Tachycardia), DYSPNOEA (Dyspnoea), HOSPITALISATION (Hospitalisation) and MYOCARDITIS (Myocarditis) in an 18-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) (batch no. 3004737) for COVID-19 vaccination.<br><br>Previously administered products included for COVID-19 vaccination: SARS-COV-2 VIRUS and SARS-COV-2 VIRUS.<br>Past adverse reactions to the above products included No adverse event with SARS-COV-2 VIRUS and SARS-COV-2 VIRUS.<br>Concurrent medical conditions included Asthma (on inhalers.).<br>Concomitant products included SALBUTAMOL for Asthma.<br><br>On 27-Nov-2021, the patient received third dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 01-Dec-2021, the patient experienced FATIGUE (Fatigue) (seriousness criterion hospitalization), CHEST PAIN (Chest Pain) (seriousness criterion hospitalization), DYSPNOEA (Dyspnoea) (seriousness criterion hospitalization), HOSPITALISATION (Hospitalisation) (seriousness criterion hospitalization) and MYOCARDITIS (Myocarditis) (seriousness criterion hospitalization). On an unknown date, the patient experienced TACHYCARDIA (Tachycardia) (seriousness criterion hospitalization). On 08-Dec-2021, HOSPITALISATION (Hospitalisation) had resolved. At the time of the report, FATIGUE (Fatigue), CHEST PAIN (Chest Pain), TACHYCARDIA (Tachycardia) and DYSPNOEA (Dyspnoea) outcome was unknown and MYOCARDITIS (Myocarditis) was resolving.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 01-Dec-2021, Blood creatine: 73 (abnormal) abnormal.<br>On 01-Dec-2021, Blood potassium: 4.6 (abnormal) abnormal.<br>On 01-Dec-2021, Blood sodium: 136 (abnormal) abnormal.<br>On 01-Dec-2021, Blood urea: 3.0 (abnormal) abnormal.<br>On 01-Dec-2021, C-reactive protein: 17 (abnormal) abnormal.<br>On 01-Dec-2021, Chest X-ray: normal (normal) Normal.<br>On 01-Dec-2021, Echocardiogram: results not provided Results not provided.<br>On 01-Dec-2021, Electrocardiogram: results not provided Results not provided.<br>On 01-Dec-2021, Full blood count: hb 160, wc 10.3 (abnormal) Hb 160, WC 10.3.<br>On 01-Dec-2021, SARS-CoV-2 test: negative (Negative) No - Negative COVID-19 test.<br>On 01-Dec-2021, Troponin: 759 (abnormal) abnormal.<br>On 03-Dec-2021, Troponin: 6023 (abnormal) abnormal.<br>On 06-Dec-2021, C-reactive protein: 3 (abnormal) abnormal.<br>On 07-Dec-2021, Magnetic resonance imaging heart: epicardial oedema (abnormal) Epicardial oedema. |

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| | | For mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown), the reporter did not provide any causality assessments.<br><br>Patient was admitted to hospital on the 1st of December with chest pain. Treated as myocarditis / peri-myocarditis likely secondary to covid vaccine. The patient was treated with prednisolone, colchicine, ibuprofen. On 1-DEC-2021, cardiac troponin was raised with peak troponin value of 759, and serial values of 672/759. ECG showed ST depression in V1-V2. Echocardiogram result was preserved left ventricular disfunction. Patient has not tested positive for COVID-19 since having the vaccine. Patient is not enrolled in clinical trial.<br><br>Concomitant medication included INHALERS.<br><br>Company comment: This regulatory authority case concerns an 18-year-old, male subject with a medical history of asthma and medication with inhalers, who experienced the serious expected event of Myopericarditis (AESI) and the serious unexpected events of fatigue, chest pain, tachycardia and hospitalization. The event occurred 4 days after the third dose of mRNA vaccine. 4 days after the vaccination, patient was admitted to hospital with chest pain and treated as myocarditis/peri-myocarditis likely secondary to mRNA-1273 vaccine. At the time of the report, event myocarditis was resolving while all the other events had unknown outcome. Rechallenge was not applicable as no additional dose is expected to be given. The patient's age and gender remain as confounders for the event myocarditis, while his medical history of asthma and medication with inhalers remain as confounders for events fatigue, chest pain, and tachycardia. The benefit-risk relationship of mRNA 1273 vaccine is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes: On 15-Dec-2021: Follow-up received included Events updated, Concomitant medication and Lab data updated. |
| 4.1(b) | 4.1(b) | This case was received via 4.1(b) (Reference number: 4.1(b) on 14-Dec-2021 and was forwarded to Moderna on 14-Dec-2021.<br>This regulatory authority case was reported by an other health care professional and describes the occurrence of PERICARDITIS (Pericarditis) and CHEST DISCOMFORT (Chest discomfort) in a 28-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 035C21A and 053C21A) for an unknown indication.<br><br>No Medical History information was reported.<br><br>On 29-Sep-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form.<br>On 29-Sep-2021, received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 03-Oct-2021, the patient experienced PERICARDITIS (Pericarditis) and CHEST DISCOMFORT (Chest discomfort). At the time of the report, PERICARDITIS (Pericarditis) and CHEST DISCOMFORT (Chest discomfort) had not resolved. |

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| | | For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments.<br><br>Concomitant product use was not provided by the reporter.<br><br>The patient reported that in a week after his second dose he developed a weird sensation on his chest near his heart that he thought was his lungs. After about a month it got a bit worse and went to an urgent care where they said he had pericarditis. He was on anti inflammatory medications for past 3 weeks and it's just now finally starting to get better but symptoms still persist.<br><br>Company comment:<br>This case concerns a 28-year-old male patient with no medical history, who experienced the expected event of Pericarditis (AESI) and unexpected event of Chest discomfort. The events occurred four days after the patient had received the second dose of the mRNA-1273 vaccine (as per provided dates). Reportedly, in a week after the second dose, the patient developed a weird sensation on his chest near his heart, as reported. After about a month, this sensation got a bit worse and the patient went to an urgent care where it was found that the patient had pericarditis. He was on anti inflammatory medications for past 3 weeks. The patient started to to get better, but symptoms still persisted at the time of the report. The rechallenge was not applicable as the events were still ongoing at the time of the report. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report. The event of Pericarditis (which is on IME list) was assessed as non-serious as per Regulatory Authority reporting and was retained as such. As per source document, the patient received t first and second dose of the vaccine on the same date. This information was kept as such, however, the provided date of vaccination most likely refers to the second dose. |
| 4.1(b) | 4.1(b) | This case was received via 4.1(b) (Reference number: 4.1(b) on 14-Dec-2021 and was forwarded to Moderna on 14-Dec-2021.<br>This regulatory authority case was reported by an other health care professional and describes the occurrence of PERICARDITIS (Pericarditis) in an 18-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for an unknown indication. The occurrence of additional non-serious events is detailed below.<br><br>No Medical History information was reported.<br><br>On 24-Nov-2021, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 26-Nov-2021, the patient experienced PERICARDITIS (Pericarditis) (seriousness criterion medically significant), CHEST PAIN (Chest pain), ELECTROCARDIOGRAM NORMAL (Electrocardiogram normal) and INFLAMMATION (Inflammation). At the time of the report, PERICARDITIS (Pericarditis), CHEST PAIN (Chest pain), ELECTROCARDIOGRAM NORMAL (Electrocardiogram normal) and INFLAMMATION (Inflammation) had not resolved. |

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| | | DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 27-Nov-2021, Electrocardiogram: normal (normal) NORMAL EKG scan.<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments.<br><br>Other medications included Aleve.<br><br>Patient reported chest pains, leading to a visit to an urgent care clinic, where he was told to see a cardiologist. They took EKG and his heart was looked fine, patient stated that however they believe he was in pain due to pericarditis. Patient was prescribed with Prednisolone and Colchicine to reduce the pain and inflammation. |
| 4.1(b) | 4.1(b) | This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 08-Dec-2021 and was forwarded to Moderna on 14-Dec-2021.<br>This case, initially reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref, 4.1(b) On an unknown date, the patient received the 1st dose of this vaccine. On 07-Nov-2021, the patient received the 2nd dose of this vaccine. On 10-Nov-2021, at 14:12, the patient was aware of chest pain and visited a nearby hospital. Electrocardiogram showed a diffuse ST-segment elevation, and the patient was referred to the reporting hospital. Blood tests showed elevated troponin I, CK, and CK-MB, and the patient was hospitalized with a diagnosis of acute myocarditis. On an unknown date, monitor management and echo follow were performed, and symptoms tended to improve with analgesics. On 15-Nov-2021, the symptoms were resolving, and the patient was discharged from the hospital. The outcome of acute myocarditis was reported as resolving. Follow-up investigation will be made. Company Comment: The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. |
| 4.1(b) | 4.1(b) | This case was initially received via 4.1(b) (Reference number: 4.1(b) ) on 14-Dec-2021. The most recent information was received on 19-Dec-2021 and was forwarded to Moderna on 19-Dec-2021.<br>This regulatory authority case was reported by a consumer and describes the occurrence of FATIGUE (Fatigue/unusual tiredness), CHEST PAIN (Chest pain), DYSPNOEA (Shortness of breath), PALPITATIONS (Heart palpitations), FLANK PAIN (side), PERIPHERAL SWELLING (hand), GASTRIC ULCER (Stomach ulcer) and PERICARDITIS (Pericarditis) in a 38-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) (batch no. 3004223) for an unknown indication.<br><br>The patient's past medical history included Ramsay-Hunt syndrome (Suffered with Ramsay Hunt Syndrome approx 8 weeks after first Moderna dose. Reported via 4.1(b) .) in 2021.<br>Previously administered products included for Product used for unknown indication: 152686.04.003 on 15-May-2021.<br>Past adverse reactions to the above products included Ramsay-Hunt syndrome with 152686.04.003. |

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| | | Concomitant products included ELASOMERAN (COVID-19 VACCINE MODERNA) for COVID-19 vaccination.<br><br>On 21-Sep-2021, the patient received second dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 01-Dec-2021, after starting mRNA-1273 (Moderna CoviD-19 Vaccine), the patient experienced PERICARDITIS (Pericarditis) (seriousness criterion medically significant). On an unknown date, the patient experienced FATIGUE (Fatigue/unusual tiredness) (seriousness criterion medically significant), CHEST PAIN (Chest pain) (seriousness criterion medically significant), DYSPNOEA (Shortness of breath) (seriousness criterion medically significant), PALPITATIONS (Heart palpitations) (seriousness criterion medically significant), FLANK PAIN (side) (seriousness criterion medically significant), PERIPHERAL SWELLING (hand) (seriousness criterion medically significant) and GASTRIC ULCER (Stomach ulcer) (seriousness criterion medically significant). At the time of the report, FATIGUE (Fatigue/unusual tiredness), CHEST PAIN (Chest pain), DYSPNOEA (Shortness of breath), PALPITATIONS (Heart palpitations) and GASTRIC ULCER (Stomach ulcer) outcome was unknown, FLANK PAIN (side) and PERIPHERAL SWELLING (hand) was resolving and PERICARDITIS (Pericarditis) had not resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On an unknown date, Electrocardiogram: result not reported No information.<br>On an unknown date, X-ray: result not reported No information.<br><br>Patient has not had symptoms associated with COVID-19 not had a COVID-19 test not tested positive for COVID-19 since vaccine.<br>Patient had chest pain on left hand side, radiating across neck and behind collarbone and down left arm. Attended A&E - ECG and X Ray taken - acute pericarditis diagnosed. The symptoms did not lead to a hospital stay. Diagnosis was made by a medical professional. A&E Doctor - acute pericarditis.<br>Treatment given for symptoms with following medication prescribed: 600mg Ibuprofen. One to be taken three times per day.Unspecified blood tests for certain proteins were done and Doctor advised all bloods were normal.Patient was received Moderna. 1st (3002332) was 15/05/21 and 2nd (3004223) was 21/09/21.He was reluctant to getting the booster as he was very unwell<br><br>Company comment: This regulatory authority case concerns a 38-year-old male patient with relevant medical history of Ramsay Hunt syndrome after the first dose of mRNA-1273, who experienced serious unexpected events of fatigue, chest pain, shortness of breath, palpitations, flank pain, peripheral swelling and gastric ulcer and expected event of pericarditis. Additionally, time between the first and the second dose of mRNA-1273 was more than 35 days. The events occurred approximately 2 months and 10 days after the second dose of the mRNA-1273 . Reportedly, the patient presented to the AE with chest pain on the left side that radiated |

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| | | across neck and behind the collarbone down to the left arm. ECG and X ray were performed and the patient was diagnosed with acute pericarditis. The patient was not hospitalized due to the events and ibuprofen 600mg 3 times/day was prescribed as a corrective treatment for the event. The rechallenge was not applicable since the event/s occurred after the 2nd dose so, no rechallenge was done and recurrence was not applicable. The regulatory authority assessed the rechallenge as unknown. The benefit-risk relationship of mRNA-1273 is not affected by this report. Event seriousness assessed as per Regulatory Authority reporting.<br><br>Most recent FOLLOW-UP information incorporated above includes: On 19-Dec-2021: significant follow up added includes Concomitant medication updated, Event added, I narrative updated |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 14-Dec-2021 and was forwarded to Moderna on 14-Dec-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of CHEST PAIN (Chest pain in the front and back exacerbated by the inspiration. The day before treated with 2 doses of Moderna COVID vaccine. Clinical diagnosis of suspected pericarditis.), PAIN (Chest pain in the front and back exacerbated by the inspiration. The day before treated with 2 doses of Moderna COVID vaccine. Clinical diagnosis of suspected pericarditis.) and PERICARDITIS (Chest pain in the front and back exacerbated by the inspiration. The day before treated with 2 doses of Moderna COVID vaccine. Clinical diagnosis of suspected pericarditis.) in a 28-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3005294) for COVID-19 immunisation.<br><br>No Medical History information was reported.<br><br>On 19-Nov-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 20-Nov-2021, the patient experienced CHEST PAIN (Chest pain in the front and back exacerbated by the inspiration. The day before treated with 2 doses of Moderna COVID vaccine. Clinical diagnosis of suspected pericarditis.) (seriousness criterion medically significant), PAIN (Chest pain in the front and back exacerbated by the inspiration. The day before treated with 2 doses of Moderna COVID vaccine. Clinical diagnosis of suspected pericarditis.) (seriousness criterion medically significant) and PERICARDITIS (Chest pain in the front and back exacerbated by the inspiration. The day before treated with 2 doses of Moderna COVID vaccine. Clinical diagnosis of suspected pericarditis.) (seriousness criterion medically significant). At the time of the report, CHEST PAIN (Chest pain in the front and back exacerbated by the inspiration. The day before treated with 2 doses of Moderna COVID vaccine. Clinical diagnosis of suspected pericarditis.), PAIN (Chest pain in the front and back exacerbated by the inspiration. The day before treated with 2 doses of Moderna COVID vaccine. Clinical diagnosis of suspected pericarditis.) and PERICARDITIS (Chest pain in the front and back exacerbated by the inspiration. The day before treated with 2 doses of Moderna COVID vaccine. Clinical diagnosis of suspected pericarditis.) was resolving. |

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| | | For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.<br><br>Concomitant medication was not provided<br>Treatment information was not provided |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) on 14-Dec-2021 and was forwarded to Moderna on 14-Dec-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myocardite) in a 25-year-old male patient who received mRNA-1273 (Spikevax) (batch no. J07BX03) for COVID-19 vaccination.<br><br>Concurrent medical conditions included Tobacco user (Tobacco: 10 cigarettes/day).<br><br>On 23-Nov-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 27-Nov-2021, after starting mRNA-1273 (Spikevax), the patient experienced MYOCARDITIS (Myocardite) (seriousness criterion hospitalization). At the time of the report, MYOCARDITIS (Myocardite) was resolving.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 27-Nov-2021, SARS-CoV-2 test: negative (Negative) Negative.<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.<br><br>No relevant concomitant medications were reported.<br>Treatment drug information was not provided.<br><br>Company comment:<br>This case concerns a 25-year-old male patient with no relevant medical history provided who experienced serious expected event of special interest Myocarditis which required hospitalization. The event occurred four days after the second dose of mRNA-1273. The rechallenge was not applicable as the event occurred following the second dose of the vaccine. At the time of the report, Myocarditis was resolving and no further information regarding clinical course of the event, hospitalization details, laboratory results or diagnostic tests was provided. The benefit-risk relationship of mRNA-1273 is not affected by this report. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 14-Dec-2021 and was forwarded to Moderna on 14-Dec-2021.<br>This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (Heart muscle inflammation, extreme menstrual period), HEAVY MENSTRUAL BLEEDING (Heart muscle inflammation, extreme menstrual period) and TACHYCARDIA (Tachycardia) in a 39-year-old female patient who received mRNA-1273 (Spikevax) for Prophylactic vaccination.<br><br>No Medical History information was reported. |

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| | | On 15-Jul-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 01-Aug-2021, the patient experienced MYOCARDITIS (Heart muscle inflammation, extreme menstrual period) (seriousness criterion medically significant), HEAVY MENSTRUAL BLEEDING (Heart muscle inflammation, extreme menstrual period) (seriousness criterion medically significant) and TACHYCARDIA (Tachycardia) (seriousness criterion medically significant). At the time of the report, MYOCARDITIS (Heart muscle inflammation, extreme menstrual period) and HEAVY MENSTRUAL BLEEDING (Heart muscle inflammation, extreme menstrual period) had not resolved and TACHYCARDIA (Tachycardia) outcome was unknown.<br><br>Concomitant medications were not reported .<br>Treatment information was not provided.<br><br>Patient had Foods only: cashew & cross allergies.<br><br>Company comment:<br>This case concerns a 39-year-old female patient, with no medical history reported, who experienced the serious expected AESI of myocarditis and the serious unexpected events of tachycardia and heavy menstrual bleeding after second dose of mRNA-1273. The events occurred 18 days after second dose. No information regarding complementary studies was provided. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. |
| 4.1(b) | 4.1(b) | This regulatory authority case was reported by a physician and describes the occurrence of DYSPNOEA (Intermittent dyspnoea), PYREXIA (Intermittent fever), MALAISE (Intermittent malaise), CHEST DISCOMFORT (Intermittent chest pressure sometimes located centrally), MYALGIA (Muscle pain) and MYOCARDITIS (Myocarditis) in a 28-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 immunisation.<br><br>The patient's past medical history included Substance user (Previous monthly user of cocaine but nothing since summer 2021) in 2021.<br>Previously administered products included for COVID-19 immunisation: SPIKEVAX in 2021.<br>Past adverse reactions to the above products included No adverse event with SPIKEVAX.<br>Concurrent medical conditions included Cigarette smoker (Smokes 5 cigarettes per week).<br><br>On 15-Nov-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 16-Nov-2021, the patient experienced PYREXIA (Intermittent fever) (seriousness criterion hospitalization), MYALGIA (Muscle pain) (seriousness criterion hospitalization) and MYOCARDITIS (Myocarditis) (seriousness criterion hospitalization). On 17-Nov-2021, the patient experienced DYSPNOEA (Intermittent dyspnoea) (seriousness criterion hospitalization) and CHEST |

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| | | DISCOMFORT (Intermittent chest pressure sometimes located centrally) (seriousness criterion hospitalization). On 18-Nov-2021, the patient experienced MALAISE (Intermittent malaise) (seriousness criterion hospitalization). At the time of the report, DYSPNOEA (Intermittent dyspnoea), PYREXIA (Intermittent fever), MALAISE (Intermittent malaise), CHEST DISCOMFORT (Intermittent chest pressure sometimes located centrally), MYALGIA (Muscle pain) and MYOCARDITIS (Myocarditis) was resolving.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>In November 2021, Cardiac telemetry: no arrhythmias No arrhythmias.<br>In November 2021, Echocardiogram: nothing abnormal, no pericardial accumulation Nothing abnormal, no pericardial accumulation.<br>In November 2021, Electrocardiogram: sinus rhythm, normal conduction Sinus rhythm, normal conduction, flattening of t-waves in v4 to v6 Flattening of T-waves in V4 to V6, normalised, nothing abnormal (At cardiology unit) Normalised, nothing abnormal, borderline significant q-waves in v4 to v6 Borderline significant q-waves in V4 to V6 and narrow complexes Narrow complexes.<br>On 20-Nov-2021, C-reactive protein: 68 (At hospitalisation) 68 Unit not specified.<br>On 20-Nov-2021, Troponin T: 139 (At hospitalisation) 139 Unit not specified.<br>On 21-Nov-2021, C-reactive protein: 31 (At discharge) 31 Unit not specified.<br>On 21-Nov-2021, Investigation: perimyocarditis without pericardial effusion (abnormal) Perimyocarditis without pericardial effusion and slight enzyme emission Slight enzyme emission.<br>On 21-Nov-2021, Physical examination: feeling well and without pain Feeling well and without pain.<br>On 21-Nov-2021, Troponin T: 83 (At discharge) 83 Unit not specified.<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.<br><br>No concomitant medication were reported.<br>No treatment medication were reported.<br><br>This is a regulatory authority case concerning a 28-year-old, male patient with past medical history of substance Abuse (cocaine), who experienced the unexpected serious events of Dyspnoea, Pyrexia, Malaise, Chest discomfort, Myalgia and expected serious event of myocarditis. The events occurred approximately 1 day after the second dose of mRNA-1273 COVID 19 Vaccine. The events were reported as resolving. The rechallenge was unknown since no information about the first dose was disclosed. The medical history, of substance Abuse (cocaine) remains a confounder. The benefit-risk relationship of mRNA-1273 COVID 19 Vaccine, is not affected by this report. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 14-Dec-2021 and was forwarded to Moderna on 14-Dec-2021.<br>This regulatory authority case was reported by a consumer and describes the occurrence of PERICARDITIS (Pericarditis sicca) in an 18-year-old |

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| | | male patient who received mRNA-1273 (Spikevax) (batch no. 3003610) for COVID-19 vaccination.<br><br>The patient's past medical history included COVID-19 and Viral syndrome on 09-Aug-2021.<br>Concurrent medical conditions included Allergy.<br><br>On 02-Jul-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 29-Aug-2021, after starting mRNA-1273 (Spikevax), the patient experienced PERICARDITIS (Pericarditis sicca) (seriousness criterion medically significant). At the time of the report, PERICARDITIS (Pericarditis sicca) had resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 03-Sep-2021, Blood pressure measurement: 150/90 mmhg (High) 150/90 mmHg.<br>On 03-Sep-2021, Chest X-ray: normal (normal) Normal.<br>On 03-Sep-2021, Echocardiogram: normal (normal) Left ventricle 46mm. Homogeneous overall and segmental kinetics. FEVG= 70%, cardiac flow = 7L/min. Left pressures: normal, E/A: 1.5, E/E': 4 OG measured at 30 ml/m2. Aortic valve: fine no reworked without leakage or stenosis. Undilated VD, systolic function of right ventricle: TAPSE=30 mm Wave S=13cm/s. Paps estimated at 15 mmHg - IT VCI compliant. Aorta ascending measured at 30 mm..<br>On 03-Sep-2021, Electrocardiogram: normal (normal) Normal.<br>On 03-Sep-2021, Fibrin D dimer: negative (Negative) negative.<br>On 03-Sep-2021, SARS-CoV-2 test: negative (Negative) negative.<br>On 03-Sep-2021, Troponin I: negative (Negative) Negative.<br>On 09-Sep-2021, Blood pressure measurement: 140/70 mmhg (High) 140/70 mmHg.<br>On 09-Sep-2021, Echocardiogram: normal (normal) Normal, no pericardial effusion..<br>On 09-Sep-2021, Electrocardiogram: sinus rhythm 75/min, fine qrs, no repolarization d (abnormal) Sinus rhythm 75/min, fine QRS, no repolarization disorders, no sequelae..<br><br>Concomitant product usage were not provided.<br>Treatment details were not provided.<br><br>Company comment. This regulatory authority case concerns a 18 -year-old, male patient with previous relevant medical history of viral syndrome on August 09, 2021, who experienced the expected serious event of pericarditis. The event occurred 58 days after the second dose of mRNA-1273. No information about previous vaccination schedule was provided. The rechallenge was done with unknown outcome.<br>On September 03, 2021, a Chest X-ray and an electrocardiogram were performed with normal result. On the same date, his Blood pressure measurement was 150/90 mmHg, and an Echocardiogram was performed where the patient had preserved left ventricular function with normal diastolic function and filling pressures with no significant |

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| | | valvopathies. Preserved segmental motility. Normal right cavities. PSAP 15 mmHg. Fibrin D dimer, troponin I and SARS-CoV-2 test were reported as negative. On September 09, an Electrocardiogram was performed without pathological value, and the echocardiogram was normal, without pericardial effusion. His Blood pressure measurement was 140/70 mmHg. Patient´s medical history of previous viral syndrome could be confounder for the event. At the time of the report the outcome of the event was recovered. The case was assessed as serious as per Regulatory Authority´s report due to important medical event. The benefit-risk relationship of mRNA-1273 is not affected by this report. |
| 4.1(b) | 4.1(b) | This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) ) on 13-Dec-2021 and was forwarded to Moderna on 17-Dec-2021.<br><br>This case, initially reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref, 4.1(b) Myocarditis was assessed as serious by the MAH.<br><br>On 07-Sep-2021, at 11:00, the patient received the 1st dose of this vaccine. On 05-Oct-2021, at 11:00, the patient received the 2nd dose of this vaccine. On an unknown date, the patient experienced physical deconditioning.<br><br>On 08-Oct-2021, myocarditis developed. The patient made the initial visit to the reporting hospital. Echocardiography was performed to show decreased left ventricular ejection fraction (EF) of 67.3%. On 25-Nov-2021, the patient revisited the hospital. Echocardiography was performed to show a recovery of EF of 80.2%. The symptoms were resolving.<br><br>The outcome of myocarditis was reported as resolving. Follow-up investigation will be made.<br><br>Company Comment: The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. |
| 4.1(b) | 4.1(b) | This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) ) on 16-Dec-2021 and was forwarded to Moderna on 20-Dec-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Acute myocarditis) in an 18-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna Intramuscular Injection) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 30-Oct-2021, the patient received second dose of mRNA-1273 (COVID-19 Vaccine Moderna Intramuscular Injection) (Intramuscular) dosage was changed to 1 dosage form.<br>On an unknown date, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna Intramuscular Injection) (Intramuscular) 1 dosage form. On 01-Nov-2021, after starting mRNA-1273 (COVID-19 Vaccine Moderna Intramuscular Injection), the patient experienced MYOCARDITIS (Acute myocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Acute myocarditis) was resolving. |

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| | | DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 31-Oct-2021, Blood test: normal (normal) No abnormalities.<br>On 31-Oct-2021, Electrocardiogram: normal (normal) No abnormalities.<br>On 01-Nov-2021, Blood test: abnormal (abnormal) Diagnosed with acute myocarditis.<br>On 01-Nov-2021, Echocardiogram: abnormal (abnormal) Diagnosed with acute myocarditis.<br>On 01-Nov-2021, Electrocardiogram: abnormal (abnormal) Diagnosed with acute myocarditis.<br>On an unknown date, Body temperature: 36.6 (normal) 36.6 degree Celsius.<br><br>For mRNA-1273 (COVID-19 Vaccine Moderna Intramuscular Injection) (Intramuscular), the reporter considered MYOCARDITIS (Acute myocarditis) to be possibly related.<br><br>Company comment: This case concerns an 18-year-old male patient, with no medical history reported in this case, who experienced the serious expected AESI of Myocarditis. The event occurred approximately 3 days after the administration of the second dose of the mRNA-1273 vaccine and the outcome was reported as Recovering/Resolving. The event was assessed with the seriousness criteria of Hospitalization and Medically Significant by the reporter. It was reported that, as diagnostic tests, a blood test, an electrocardiogram and an echocardiogram were performed. No further information on performed treatment was disclosed. The rechallenge is not applicable since the event occurred after the second dose of the of the mRNA-1273 vaccine. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. |
| 4.1(b) | 4.1(b) | This case was received via 4.1(b) (Reference number: 4.1(b) ) on 17-Dec-2021 and was forwarded to Moderna on 17-Dec-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of PERICARDIAL EFFUSION (Pericardial effusion), DYSPNOEA (Shortness of breath), DYSPNOEA (Breath shortness), DYSPNOEA (Dyspnoea), the second episode of CHEST PAIN (Chest pain), CHEST PAIN (Chest Pain), the first episode of CHEST PAIN (Chest pain), FATIGUE (Fatigue), TACHYCARDIA (Tachycardia), PAIN (Generalised aching), MYOCARDITIS (Myocarditis) and PERICARDITIS (Pericarditis) in a 39-year-old female patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for COVID-19 vaccination.<br><br>Co-suspect product included non-company product COLCHICINE for an unknown indication.<br><br>Concomitant products included COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (COVID-19 VACCINE ASTRAZENECA) from 04-Mar-2021 to an unknown date for COVID-19 vaccination.<br><br>On 08-Dec-2021, the patient received third dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form.<br>On an unknown date, the patient started COLCHICINE (unknown route) at an unspecified dose. On 08-Dec-2021, the patient experienced the first |

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| | | episode of CHEST PAIN (Chest pain) (seriousness criteria hospitalization, disability, medically significant and life threatening). On 09-Dec-2021, the patient experienced DYSPNOEA (Breath shortness) (seriousness criteria hospitalization, disability, medically significant and life threatening), the second episode of CHEST PAIN (Chest pain) (seriousness criteria hospitalization, disability, medically significant and life threatening), MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization, disability, medically significant and life threatening) and PERICARDITIS (Pericarditis) (seriousness criteria hospitalization, disability, medically significant and life threatening). On an unknown date, the patient experienced PERICARDIAL EFFUSION (Pericardial effusion) (seriousness criteria hospitalization, disability, medically significant and life threatening), DYSPNOEA (Shortness of breath) (seriousness criteria hospitalization, disability, medically significant and life threatening), DYSPNOEA (Dyspnoea) (seriousness criteria hospitalization, disability, medically significant and life threatening), CHEST PAIN (Chest Pain) (seriousness criteria hospitalization, disability, medically significant and life threatening), FATIGUE (Fatigue) (seriousness criteria hospitalization, disability, medically significant and life threatening), TACHYCARDIA (Tachycardia) (seriousness criteria hospitalization, disability, medically significant and life threatening) and PAIN (Generalised aching) (seriousness criteria hospitalization, disability, medically significant and life threatening). At the time of the report, PERICARDIAL EFFUSION (Pericardial effusion) and DYSPNOEA (Shortness of breath) was resolving, DYSPNOEA (Breath shortness), the last episode of CHEST PAIN (Chest pain), MYOCARDITIS (Myocarditis) and PERICARDITIS (Pericarditis) had not resolved and DYSPNOEA (Dyspnoea), CHEST PAIN (Chest Pain), FATIGUE (Fatigue), TACHYCARDIA (Tachycardia) and PAIN (Generalised aching) outcome was unknown.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 13-Dec-2021, Chest X-ray: abnormal (abnormal) Slightly enlarged heart.<br>On 13-Dec-2021, Computerised tomogram thorax: abnormal (abnormal) Small pericardial effusion.<br>On 13-Dec-2021, SARS-CoV-2 test: negative (Negative) No - Negative COVID-19 test.<br>On 13-Dec-2021, Troponin: elevated (High) Elevated.<br>On 14-Dec-2021, Echocardiogram: abnormal (abnormal) Pericardial effusion.<br>On an unknown date, Blood test: result not provided (Inconclusive) Result not provided.<br>On an unknown date, C-reactive protein: 345 345.<br>On an unknown date, Ejection fraction: 40 40%.<br><br>For mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown), the reporter did not provide any causality assessments.<br><br>No medical history was provided by the reporter.<br><br>It was reported that patient took the vaccine and 5 hours later she felt mild chest pain. On next day that chest pain became much more intense and severe, associated with shortness of breath, aching and tearing. |

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| | | Work up showed high inflammatory markers with raised C-reactive protein (CRP) 345, elevated Troponin, echocardiogram (ECHO) showed pericardial effusion, ejection fraction (EF) of 40%. She took treatment for myo-pericarditis.<br><br>Patient not tested positive for COVID-19 since she had the vaccine and not had symptoms associated with COVID-19.<br>It was reported that the event was relate to possible myocarditis or pericarditis.<br><br>Patient did few tests like ECHO, Troponin, Basic blood test. Patient had Myocarditis and pericarditis.<br><br>Patient was admitted to the hospital since 13-Dec-2021 and not discharged at the time of report. She consulted one cardiologist and diagnosed with Myo-pericarditis. Colchicine, ACE-I, B. Blocker was given as treatment drugs. Troponin, chest x-ray was checked on 13-Dec-2021. Troponin was raised and the chest x-ray result was slightly enlarged heart. On 14 Dec 2021 echocardiogram done and the results were overall impression of impaired left ventricle (LV) systolic function. Visually estimated left ventricle ejection fraction (LVEF) 40-45%. Regional wall abnormalities present. Small collection of pericardial fluid seen, measuring maximum in diastole 0.6cm. On 13-Dec-2021 chest computed tomography was carried out and the results were scan negative for pulmonary embolism (PE). Small pericardial effusion with some mediastinal fat stranding. The findings were non-specific and in the context of very raised CRP and mildly raised troponin include pericarditis or myocarditis.<br><br>Company Comment : This regulatory case concerns a 39-year-old, female patient with history of co-administration of Colchicine and concomitant administration of the AstraZeneca COVID-19 vaccines, who experienced the expected, serious AESI of myocarditis and pericarditis, and the unexpected, serious events of pericardial effusion, dyspnoea (LLT: shortness of breath), dyspnoea (LLT: breath shortness), dyspnoea (LLT: dyspnoea), chest pain (first episode), chest pain (second episode), chest pain (third episode), fatigue, tachycardia and pain. These events were reported as life-threatening, resulted in hospitalization, disabling and medically significant. The event chest pain (first episode) occurred on the same day after administration of the third dose of the Moderna mRNA-1273 vaccine. The events dyspnoea (LLT: breath shortness), chest pain (second episode), myocarditis and pericarditis occurred 1 day after administration of the third dose of the Moderna mRNA-1273 vaccine. The start dates of the other events were not provided. Laboratory tests done on 13Dec2021 showed Troponin-elevated, Chest CT-small pericardial effusion and Chest X-ray-slightly enlarged heart. Echocardiogram done on 14Dec2021 showed 'impaired left ventricle systolic function. Visually estimated left ventricle ejection fraction (LVEF) 40-45%. Regional wall abnormalities present. Small collection of pericardial fluid seen, measuring maximum in diastole 0.6 cm'. Chest CT showed 'no pulmonary embolism; small pericardial effusion with some mediastinal fat stranding'. The findings were non-specific and in the context of a very raised CRP (345) and mildly raised Troponin, the patient was diagnosed with Pericarditis or Myocarditis. The patient was seen by a Cardiologist and |

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| | | was prescribed with Colchicine, ACE-inhibitor and Beta-blocker. The events pericardial effusion and dyspnoea (LLT: shortness of breath) were resolving at the time of the report. The events myocarditis, pericarditis, dyspnoea (LLT: breath shortness), chest pain (first episode) and chest pain (second episode) had not resolved at the time of the report. The outcomes of the other events were unknown at the time of the report. The history of co-administration of Colchicine and concomitant administration of the AstraZeneca COVID-19 vaccines remains a confounder. The benefit-risk relationship of the Moderna mRNA-1273 vaccine is not affected by |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 20-Dec-2021 and was forwarded to Moderna on 20-Dec-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myocarditis) in a 31-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3004951) for COVID-19 vaccination.<br><br>Previously administered products included for COVID-19 vaccination: SPIKEVAX on 23-Sep-2021.<br>Past adverse reactions to the above products included No adverse event with SPIKEVAX.<br><br>On 31-Oct-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 18-Nov-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criterion hospitalization). At the time of the report, MYOCARDITIS (Myocarditis) had not resolved.<br><br>For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.<br><br>No concomitant medications were provided.<br>No treatment information was provided.<br><br>Company comment:<br>This case concerns a 31-year-old male patient with no medical history provided who experienced serious expected event of special interest Myocarditis. The event occurred 18 days after the second dose of mRNA-1273. At the time of the report, the event was still ongoing and no further information regarding clinical course of the event was provided at this time. The benefit-risk relationship of mRNA-1273 is not affected by this report. It should be noted that the patient received second dose of the vaccine 38 days after the first dose which is outside of the correct window. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 21-Dec-2021 and was forwarded to Moderna on 21-Dec-2021.<br>This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (Myopericarditis) in a 40-year-old male patient who received mRNA-1273 (Spikevax) (batch no. J07BX03) for COVID-19 vaccination. |

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| | | No Medical History information was reported.<br><br>On 29-Jun-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 04-Jul-2021, the patient experienced MYOCARDITIS (Myopericarditis) (seriousness criterion hospitalization). At the time of the report, MYOCARDITIS (Myopericarditis) had resolved.<br><br>Treatment information not provided.<br>Concomitant medication not provided.<br><br>Company comment:<br>This case concerns a 40-year-old male patient with no medical history provided who experienced serious expected event of special interest Myocarditis. The event occurred five days after the second dose of mRNA-1273. At the time of the report, the event resolved and no further information regarding clinical course of the event was provided. No information regarding laboratory nor diagnostic tests was provided. As per SD, no rechallenge was done and, therefore, recurrence is not applicable. The benefit-risk relationship of mRNA-1273 is not affected by this report. |
| 4.1(b) | 4.1(b) | This case was received via 4.1(b) (Reference number: 4.1(b) on 21-Dec-2021 and was forwarded to Moderna on 21-Dec-2021.<br>This regulatory authority case was reported by an other health care professional and describes the occurrence of C-REACTIVE PROTEIN INCREASED (C-reactive protein increased), CHEST PAIN (Chest pain), MYOCARDITIS (Myocarditis) and TROPONIN (Troponin) in a 25-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 045321A) for an unknown indication.<br><br>No Medical History information was reported.<br><br>On 03-Dec-2021, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 04-Dec-2021, the patient experienced C-REACTIVE PROTEIN INCREASED (C-reactive protein increased) (seriousness criterion hospitalization), CHEST PAIN (Chest pain) (seriousness criterion hospitalization), MYOCARDITIS (Myocarditis) (seriousness criterion hospitalization) and TROPONIN (Troponin) (seriousness criterion hospitalization). At the time of the report, C-REACTIVE PROTEIN INCREASED (C-reactive protein increased), CHEST PAIN (Chest pain), MYOCARDITIS (Myocarditis) and TROPONIN (Troponin) had not resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On an unknown date, C-reactive protein: elevated (High) Elevated C-reactive protein.<br>On an unknown date, Troponin: 12 (High) 12. |

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| | | For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments.<br><br>Symptom Text: Myocarditis Troponin = 12 Required hospital admission Sxs = severe, worsening chest pain beginning approximately 24hrs following booster dose.<br><br>Company Comment: This case concerns a 25-year-old male subject, with no medical history reported, who experienced the unexpected and serious events of C-Reactive protein increased, Chest pain, and Troponin, and the serious, expected, and AESI event of Myocarditis. The events occurred 1 day after the third dose of mRNA-1273 vaccine. The rechallenge is not applicable, as no additional dosing will be given. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. |
| 4.1(b) | 4.1(b) | This case was received via 4.1(b) (Reference number: 4.1(b) on 21-Dec-2021 and was forwarded to Moderna on 21-Dec-2021.<br>This regulatory authority case was reported by an other health care professional and describes the occurrence of C-REACTIVE PROTEIN INCREASED (C-reactive protein increased), CHEST X-RAY NORMAL (Chest X-ray normal), CHEST PAIN (Chest pain), COMPUTERISED TOMOGRAM THORAX NORMAL (Computerised tomogram thorax normal), ECHOCARDIOGRAM ABNORMAL (Echocardiogram abnormal), EFFUSION (Effusion), ELECTROCARDIOGRAM ABNORMAL (Electrocardiogram abnormal), FATIGUE (Fatigue), FIBRIN D DIMER INCREASED (Fibrin D dimer increased), MAGNETIC RESONANCE IMAGING ABNORMAL (Magnetic resonance imaging abnormal), MYOCARDITIS (Myocarditis), NAUSEA (Nausea), TACHYCARDIA (Tachycardia) and TROPONIN INCREASED (Troponin increased) in a 23-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for an unknown indication.<br><br>Concurrent medical conditions included Schizophrenia.<br><br>On 27-Nov-2021, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 01-Dec-2021, the patient experienced C-REACTIVE PROTEIN INCREASED (C-reactive protein increased) (seriousness criterion hospitalization), CHEST PAIN (Chest pain) (seriousness criterion hospitalization), ECHOCARDIOGRAM ABNORMAL (Echocardiogram abnormal) (seriousness criterion hospitalization), EFFUSION (Effusion) (seriousness criterion hospitalization), ELECTROCARDIOGRAM ABNORMAL (Electrocardiogram abnormal) (seriousness criterion hospitalization), FATIGUE (Fatigue) (seriousness criterion hospitalization), FIBRIN D DIMER INCREASED (Fibrin D dimer increased) (seriousness criterion hospitalization), MAGNETIC RESONANCE IMAGING ABNORMAL (Magnetic resonance imaging abnormal) (seriousness criterion hospitalization), MYOCARDITIS (Myocarditis) (seriousness criterion hospitalization), NAUSEA (Nausea) (seriousness criterion hospitalization), TACHYCARDIA (Tachycardia) (seriousness criterion hospitalization) and TROPONIN INCREASED (Troponin increased) (seriousness criterion hospitalization). 01-Dec-2021, the patient experienced CHEST X-RAY NORMAL (Chest X-ray normal) (seriousness criterion hospitalization) and |

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| | | COMPUTERISED TOMOGRAM THORAX NORMAL (Computerised tomogram thorax normal) (seriousness criterion hospitalization). At the time of the report, C-REACTIVE PROTEIN INCREASED (C-reactive protein increased), CHEST X-RAY NORMAL (Chest X-ray normal), CHEST PAIN (Chest pain), COMPUTERISED TOMOGRAM THORAX NORMAL (Computerised tomogram thorax normal), ECHOCARDIOGRAM ABNORMAL (Echocardiogram abnormal), EFFUSION (Effusion), ELECTROCARDIOGRAM ABNORMAL (Electrocardiogram abnormal), FATIGUE (Fatigue), FIBRIN D DIMER INCREASED (Fibrin D dimer increased), MAGNETIC RESONANCE IMAGING ABNORMAL (Magnetic resonance imaging abnormal), MYOCARDITIS (Myocarditis), NAUSEA (Nausea), TACHYCARDIA (Tachycardia) and TROPONIN INCREASED (Troponin increased) had not resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 01-Dec-2021, C-reactive protein: high (High) high.<br>On 01-Dec-2021, Chest X-ray: normal (normal) normal.<br>On 01-Dec-2021, Computerised tomogram: normal (normal) no pulmonary embolism.<br>On 01-Dec-2021, Echocardiogram: abnormal (abnormal) myocarditis.<br>On 01-Dec-2021, Electrocardiogram: abnormal (abnormal) abnormal.<br>On 01-Dec-2021, Fibrin D dimer: elevated (High) elevated.<br>On 01-Dec-2021, Magnetic resonance imaging: abnormal (abnormal) myocarditis.<br>On 01-Dec-2021, Tachycardia: 120 (High) 120bp.<br>On 01-Dec-2021, Troponin: 7.9 (High) Blood drawn troponin 7.9.<br>On 01-Dec-2021, Ultrasound scan: abnormal (abnormal) mild effusion.<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments.<br><br>No treatment medications were provided<br>Other Medication provided 300 mg, clozapine 20 mg, Lexapro 200 mg, Minocycline 750 mg, metformin 1000 mg, omega 3<br>Patient experienced myocarditis 4 days after vaccination<br>Patient was experienced Exhaustion<br>patient went to ER and admitted in hospital on 01 Dec 2021 to 02 Dec 2021<br><br>Company Comment: This case concerns a 23-year-old male subject, with no relevant medical history, who experienced the unexpected and serious events of Troponin increased, Effusion, Tachycardia, Chest pain, among others, and the expected, serious, and AESI event of Myocarditis. Patient was hospitalized 2 days, and myocarditis was confirmed by imaging studies. The events occurred 4 days after the third dose of mRNA-1273 vaccine. The rechallenge is not applicable, as no additional dosing will be given. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. |
| 4.1(b) | 4.1(b) | This case was received via 4.1(b) (Reference number: 4.1(b) on 21-Dec-2021 and was forwarded to Moderna on 21-Dec-2021. |

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| | | This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCARDITIS (Myocarditis) in a 27-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 012H21B) for an unknown indication.<br><br>No Medical History information was reported.<br><br>On 24-Nov-2021, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 27-Nov-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Myocarditis) had resolved.<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments.<br><br>Other Medication use information was not provided by reporter.<br>Patient was treated in hospital. Treatment medication use information was not provided by reporter.<br><br>Company Comment: This case refers to a 27-year-old female patient with no known medical history who experienced the serious but expected event of Myocarditis approximately 3 days after receiving a dose of the mRNA-1273 vaccine. No causality assessment was provided by the reporter. The benefit-risk relationship of mRNA-1273 is not affected by this report. Events seriousness assessed as per Regulatory Authority reporting. |
| 4.1(b) | 4.1(b) | This case was received via 4.1(b) (Reference number: 4.1(b) on 21-Dec-2021 and was forwarded to Moderna on 21-Dec-2021.<br>This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCARDITIS (Myocarditis), ELECTROCARDIOGRAM ST SEGMENT ELEVATION (Electrocardiogram ST segment elevation), C-REACTIVE PROTEIN INCREASED (C-reactive protein increased), ECHOCARDIOGRAM NORMAL (Echocardiogram normal) and TROPONIN INCREASED (Troponin increased) in a 24-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 065F21A) for an unknown indication.<br><br>Concurrent medical conditions included Chiari malformation, Scoliosis, Anxiety and Depression.<br><br>On 19-Nov-2021, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 22-Nov-2021, the patient experienced MYOCARDITIS (Myocarditis), ELECTROCARDIOGRAM ST SEGMENT ELEVATION (Electrocardiogram ST segment elevation), C-REACTIVE PROTEIN INCREASED (C-reactive protein increased), ECHOCARDIOGRAM NORMAL (Echocardiogram normal) and TROPONIN INCREASED (Troponin increased). At the time of the report, MYOCARDITIS |

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| | | (Myocarditis), ELECTROCARDIOGRAM ST SEGMENT ELEVATION (Electrocardiogram ST segment elevation), C-REACTIVE PROTEIN INCREASED (C-reactive protein increased), ECHOCARDIOGRAM NORMAL (Echocardiogram normal) and TROPONIN INCREASED (Troponin increased) had not resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 22-Nov-2021, C-reactive protein: 5.0 (High) C Reactive protein - 5.0mg/dL (elevated).<br>On 22-Nov-2021, Electrocardiogram ST segment: elevation (High) EKG - with mild ST segment elevation.<br>On 22-Nov-2021, Troponin: 0.53 (High) Troponin serum - elevated (0.53ng/mL) with no increase over time and 0.46 (High) 0.46ng/mL - 3 hour repeat.<br>On 29-Nov-2021, Echocardiogram: normal (normal) normal LV size and systolic function, no pericardial effusion.<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments.<br><br>Other medications include Duloxetine, Trazadone, hydroxyzine.<br>Patient experienced myopericarditis (mild) managed as outpatient with colchicine, ibuprofen. Patient ongoing symptoms with slight improvement at follow up doctor's visit on 02-DEC-2021.<br><br>Company comment: This is a regulatory authority case concerning a 24-year-old male patient with no relevant medical history who experienced expected event of myocarditis (AESI). The event occurred 3 days after the third dose of mRNA-1273 vaccine. Diagnostic test results performed on 22-Nov-2021 showed C Reactive protein - 5.0mg/dL (elevated), Troponin serum - elevated (0.53ng/mL) with no increase over time (0.46ng/mL - 3 hour repeat) and EKG - with mild ST segment elevation. On 29-Nov-2021 Echocardiogram showed normal LV size and systolic function, no pericardial effusion. The event was managed as outpatient with colchicine and ibuprofen. It was reported a slight improvement of the symptoms at follow up doctor's visit on 02-DEC-2021. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. |
| 4.1(b) | 4.1(b) | This spontaneous case was reported by an other health care professional and describes the occurrence of PERICARDIAL EFFUSION (pericardial effusion), MYOCARDITIS (pericarditis with suspected myocarditis) and PERICARDITIS (pericarditis with suspected myocarditis) in a 39-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 3005888) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below.<br><br>The patient's past medical history included COVID-19 on 10-Nov-2020.<br><br>On 02-Nov-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form.<br>On 01-Dec-2021, received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to 1 dosage form. On 01-Dec-2021, the patient experienced FATIGUE (total fatigue). On 04-Dec-2021, the patient experienced PALPITATIONS (Palpitation/irregular). On 08-Dec- |

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| | | 2021, the patient experienced PERICARDIAL EFFUSION (pericardial effusion) (seriousness criteria hospitalization and medically significant), MYOCARDITIS (pericarditis with suspected myocarditis) (seriousness criteria hospitalization and medically significant) and PERICARDITIS (pericarditis with suspected myocarditis) (seriousness criteria hospitalization and medically significant). In December 2021, the patient experienced PRESYNCOPE (Presyncope symptoms) and DIZZINESS (dizziness). On an unknown date, the patient experienced BACK PAIN (Shoulder/upper back pain). The patient was hospitalized from 09-Dec-2021 to 10-Dec-2021 due to MYOCARDITIS, PERICARDIAL EFFUSION and PERICARDITIS. The patient was treated with COLCHICINE (oral) from 09-Dec-2021 to 30-Dec-2021 for Pericarditis and Myocarditis, at a dose of 0.5 milligram,2x1; ESOMEPRAZOLE MAGNESIUM, NAPROXEN (VIMOVO) (oral) from 09-Dec-2021 to 12-Dec-2021 for Myocarditis and Pericarditis, at a dose of 500/20mg, 2x1 and SODIUM CHLORIDE at a dose of 0.9 % 500 ML. In December 2021, FATIGUE (total fatigue) had resolved. At the time of the report, PERICARDIAL EFFUSION (pericardial effusion), PALPITATIONS (Palpitation/irregular), PRESYNCOPE (Presyncope symptoms), BACK PAIN (Shoulder/upper back pain) and DIZZINESS (dizziness) outcome was unknown and MYOCARDITIS (pericarditis with suspected myocarditis) and PERICARDITIS (pericarditis with suspected myocarditis) had not resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 10-Nov-2020, SARS-CoV-1 test: positive (Positive) Positive.<br>On 08-Dec-2021, Echocardiogram: abnormal (abnormal) a pericardial effusion was found..<br>On 10-Dec-2021, Heart rate: 60 (normal) rhythmic heartbeat, 60 beats per min, vesicular breathing.<br>On 30-Dec-2021, Echocardiogram: abnormal (abnormal) a pericardial effusion remained unchanged..<br>On an unknown date, Activated partial thromboplastin time: 43.9 (High) 43.9 Seconds, slightly high.<br>On an unknown date, Basophil count: 0.0 (normal) 0.0 10^9/l.<br>On an unknown date, Basophil percentage: 0.6 (normal) 0.6 percentage.<br>On an unknown date, Blood chloride: result not reported Result not Reported.<br>On an unknown date, Blood cholesterol: 5.32 (High) 5.32 mmol/l, borderline high.<br>On an unknown date, Blood creatine phosphokinase: 121.0 u/l (High) 121.0 U/l, slightly high.<br>On an unknown date, Blood creatine phosphokinase MB: 12.3 (normal) 12.3 U/l.<br>On an unknown date, Blood creatinine: 78.0 (normal) 78.0 µmol/L.<br>On an unknown date, Blood fibrinogen: 2.22 (normal) 2.22 g/l.<br>On an unknown date, Blood glucose: 5.82 (normal) 5.82 mmol/l.<br>On an unknown date, Blood potassium: 4.3 (normal) 4.3 mmol/l.<br>On an unknown date, Blood pressure measurement: 120/80 (normal) 120/80 mmHg.<br>On an unknown date, Blood sodium: 137.0 (normal) 137.0 mmol/l.<br>On an unknown date, Blood thyroid stimulating hormone: 1.87 (normal) 1.87 mIU/ml.<br>On an unknown date, Blood triglycerides: 0.75 (normal) 0.75 mmol/l.<br>On an unknown date, Blood urea: 5.6 (normal) 5.6 mmol/l. |

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| | | On an unknown date, C-reactive protein: 2.6 (normal) 2.6 mg/l.<br>On an unknown date, Chest X-ray: results not reported Results not reported.<br>On an unknown date, Echocardiogram: small pericardial effusion (abnormal) Aorta asc.-29mm. Left atrium-32mm, apical-47 / 41mm. Left chamber - IVS/RWLV-8/8mm. Telesystolic Volume/Telediastolic Volume - 32/123ml. EF 75%. No disturbances in segment kinetics. Preserved diastolic function. Mitral valve - prolapse of AMC. Minimum MI. Aortic valve - tricuspid, intact. Right atrium - 42/40mm. Right chamber - 36mm. TAPSE- 32mm. Minimum TI. Pericardium - minimal exfoliation behind RWLV, 180 ml in front of the right cavities, mainly in front of the RA with initial compression of the RA. Preserved respiratory mobility of VCI. Conclusion: Preserved systolic function of the LV. Preserved diastolic function. Minimum MI. Small pericardial effusion - hemodynamically insignificant.<br>On an unknown date, Electrocardiogram: sinus rhythm, indifferent position (abnormal) sinus rhythm, indifferent position, no rhythm-conduction disorders..<br>On an unknown date, Eosinophil count: 0.0 (normal) 0.0 10^9/l.<br>On an unknown date, Eosinophil percentage: 0.1 (normal) 0.1 percentage.<br>On an unknown date, Erythroblast count: 0.0 (normal) 0.0 10^9/l, 0 percentage.<br>On an unknown date, Fibrin D dimer: 116.0 (normal) 116.0 ng/ml.<br>On an unknown date, Haematocrit: 41.9 (normal) 41.9 percentage.<br>On an unknown date, Haemoglobin: 141.0 (normal) 141.0 g/l.<br>On an unknown date, Heart rate: 88 (normal) 88 beats/min.<br>On an unknown date, High density lipoprotein: 1.95 (normal) 1.95 mmol/l.<br>On an unknown date, Low density lipoprotein: 3.03 (normal) 3.03 mmol/l.<br>On an unknown date, Lymphocyte count: 1.3 (normal) 1.3 10^9/l.<br>On an unknown date, Lymphocyte percentage: 23.2 (normal) 23.2 percentage.<br>On an unknown date, Mean cell haemoglobin: 28.9 (normal) 28.9 pg.<br>On an unknown date, Mean cell haemoglobin concentration: 337.0 (normal) 337.0 g/l.<br>On an unknown date, Mean cell volume: 85.6 (normal) 85.6 fL.<br>On an unknown date, Mean platelet volume: 8.4 (normal) 8.4 fL.<br>On an unknown date, Monocyte count: 0.2 (normal) 0.2 10^9/l.<br>On an unknown date, Monocyte percentage: 4.4 (normal) 4.4 percentage.<br>On an unknown date, Neutrophil count: 4.0 (High) 4.0 10^9/l.<br>On an unknown date, Neutrophil percentage: 71.7 (High) 71.7 percentage.<br>On an unknown date, Platelet count: 305.0 (normal) 305.0 10^9/l.<br>On an unknown date, Red blood cell count: 4.9 (normal) 4.9 10^12/l.<br>On an unknown date, Red blood cell sedimentation rate: 5 (normal) 5 mm/h.<br>On an unknown date, Red cell distribution width: 13.2 (normal) 13.2 percentage and 39.4 (normal) 39.4 fL.<br>On an unknown date, Troponin I: 0.0014 (normal) 0.0014 ng/ml.<br>On an unknown date, Very low density lipoprotein: 0.34 (normal) 0.34 mmol/l.<br>On an unknown date, White blood cell count: 5.6 (normal) 5.6 10^9/l. |

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| | | For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered MYOCARDITIS (pericarditis with suspected myocarditis) and PERICARDITIS (pericarditis with suspected myocarditis) to be related. No further causality assessments were provided for PERICARDIAL EFFUSION (pericardial effusion), PALPITATIONS (Palpitation/irregular), PRESYNCOPE (Presyncope symptoms), BACK PAIN (Shoulder/upper back pain), DIZZINESS (dizziness) and FATIGUE (total fatigue).<br><br>No concomitant medications were reported.<br>Patient had no known allergies.<br><br>This is a 39-year-old patient with a complaint of presyncopal symptoms, no syncope and palpitations after a second dose of the Moderna vaccine. A few hours after the second dose of the vaccine, she had total fatigue for three days. On day 4 after the administered second dose, she began experiencing palpitations in the evening after bedtime and during night sleep. On 08-Dec-2021 she consulted with a cardiologist and after an echocardiography a pericardial effusion was found. The next day she was hospitalized. Control echocardiography were performed weekly after the hospitalization and the pericardial effusion remained unchanged as of 30-Dec-2021. During the clinical stay, she was without recurrence of symptoms. No rhythm-conducting disturbances were registered on the ECG monitor. She was discharged without complaints and on stable hemodynamics, on an outpatient basis, wi |
| 4.1(b) | 4.1(b) | This case was received via 4.1(b) (Reference number: 4.1(b) on 21-Dec-2021 and was forwarded to Moderna on 21-Dec-2021.<br>This regulatory authority case was reported by an other health care professional and describes the occurrence of CHEST PAIN (Chest pain) and MYOCARDITIS (Myocarditis) in a 22-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 064HZIA) for an unknown indication.<br><br>No Medical History information was reported.<br><br>On 28-Nov-2021, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 01-Dec-2021, the patient experienced CHEST PAIN (Chest pain) and MYOCARDITIS (Myocarditis). At the time of the report, CHEST PAIN (Chest pain) and MYOCARDITIS (Myocarditis) outcome was unknown.<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments.<br><br>Concomitant and treatment medication was not provided.<br><br>Patient had treated in ER for chest pain and diagnosed with myocarditis.<br><br>company comment:<br>This regulatory case concerns a 22-year-old male patient, with no medical history reported, who experienced the non-serious unexpected AESI of MYOCARDITIS. The event occurred approximately 3 days after receiving a third dose of mRNA-1273. No information about previous vaccination |

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| | | was provided. The outcome of the event is unknown at the time of this report. The benefit-risk relationship is not affected by this report. Chest pain was also reported as an event but it can be considered as a symptom of myocarditis. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 20-Dec-2021 and was forwarded to Moderna on 20-Dec-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of CHEST PAIN (Chest pain without radiation), MALAISE (Not feeling well and a sensation of something sharp), FEELING COLD (Had a feeling of very cold) and MYOCARDITIS (Myocarditis) in a 33-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3004954) for COVID-19 vaccination.<br><br>Previously administered products included for COVID-19 immunisation: SPIKEVAX on 04-Sep-2021.<br>Past adverse reactions to the above products included No adverse event with SPIKEVAX.<br><br>On 02-Oct-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 03-Oct-2021, after starting mRNA-1273 (Spikevax), the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). In October 2021, the patient experienced CHEST PAIN (Chest pain without radiation) (seriousness criterion hospitalization), MALAISE (Not feeling well and a sensation of something sharp) (seriousness criterion hospitalization) and FEELING COLD (Had a feeling of very cold) (seriousness criterion hospitalization). At the time of the report, CHEST PAIN (Chest pain without radiation), MALAISE (Not feeling well and a sensation of something sharp) and FEELING COLD (Had a feeling of very cold) outcome was unknown and MYOCARDITIS (Myocarditis) was resolving.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>In October 2021, Electrocardiogram: normal (normal) Normal sinus rhythm.<br>In October 2021, Troponin I: low (Low) Decreased from 210 to 40 in one day.<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.<br><br>No concomitant medications reported.<br>Treatment details were not provided.<br><br>This is a regulatory case concerning a 33-year-old male patient with no reported relevant medical history, who experienced the serious expected AESI event of myocarditis and serious unexpected events of chest pain, malaise and feeling cold. The event of myocarditis occurred on the next day after the second dose of mRNA-1273 vaccine administration and the events of chest pain, malaise, feeling cold occurred on unknow day of the same month. The events were assessed as related, per temporal |

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| | | association with the product administration. The rechallenge was not applicable, since the events occurred after the second dose and no further dosing is expected. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. |
| 4.1(b) | 4.1(b) | This case was received via 4.1(b) (Reference number: 4.1(b) on 21-Dec-2021 and was forwarded to Moderna on 21-Dec-2021.<br>This regulatory authority case was reported by an other health care professional and describes the occurrence of ADENOVIRUS TEST (Adenovirus test), CARDIAC TELEMETRY NORMAL (Cardiac telemetry normal), CHEST PAIN (Chest pain), ECHOCARDIOGRAM (Echocardiogram), ELECTROCARDIOGRAM NORMAL (Electrocardiogram normal), HIV TEST NEGATIVE (HIV test negative), HUMAN METAPNEUMOVIRUS TEST (Human metapneumovirus test), HUMAN RHINOVIRUS TEST (Human rhinovirus test), INFLUENZA A VIRUS TEST NEGATIVE (Influenza A virus test negative), INFLUENZA B VIRUS TEST (Influenza B virus test), INFLUENZA VIRUS TEST NEGATIVE (Influenza virus test negative), MYOCARDITIS (Myocarditis), RESPIRATORY SYNCYTIAL VIRUS TEST NEGATIVE (Respiratory syncytial virus test negative), SARS-COV-2 TEST NEGATIVE (SARS-CoV-2 test negative) and TROPONIN INCREASED (Troponin increased) in a 25-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for an unknown indication.<br><br>No Medical History information was reported.<br><br>On 03-Dec-2021, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 04-Dec-2021, the patient experienced ADENOVIRUS TEST (Adenovirus test) (seriousness criterion hospitalization), CARDIAC TELEMETRY NORMAL (Cardiac telemetry normal) (seriousness criterion hospitalization), CHEST PAIN (Chest pain) (seriousness criterion hospitalization), ECHOCARDIOGRAM (Echocardiogram) (seriousness criterion hospitalization), ELECTROCARDIOGRAM NORMAL (Electrocardiogram normal) (seriousness criterion hospitalization), HIV TEST NEGATIVE (HIV test negative) (seriousness criterion hospitalization), HUMAN METAPNEUMOVIRUS TEST (Human metapneumovirus test) (seriousness criterion hospitalization), HUMAN RHINOVIRUS TEST (Human rhinovirus test) (seriousness criterion hospitalization), INFLUENZA A VIRUS TEST NEGATIVE (Influenza A virus test negative) (seriousness criterion hospitalization), INFLUENZA B VIRUS TEST (Influenza B virus test) (seriousness criterion hospitalization), INFLUENZA VIRUS TEST NEGATIVE (Influenza virus test negative) (seriousness criterion hospitalization), MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant), RESPIRATORY SYNCYTIAL VIRUS TEST NEGATIVE (Respiratory syncytial virus test negative) (seriousness criterion hospitalization), SARS-COV-2 TEST NEGATIVE (SARS-CoV-2 test negative) (seriousness criterion hospitalization) and TROPONIN INCREASED (Troponin increased) (seriousness criterion hospitalization). At the time of the report, ADENOVIRUS TEST (Adenovirus test), CARDIAC TELEMETRY NORMAL (Cardiac telemetry normal), CHEST PAIN (Chest pain), ECHOCARDIOGRAM (Echocardiogram), ELECTROCARDIOGRAM NORMAL (Electrocardiogram normal), HIV |

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| | | TEST NEGATIVE (HIV test negative), HUMAN METAPNEUMOVIRUS TEST (Human metapneumovirus test), HUMAN RHINOVIRUS TEST (Human rhinovirus test), INFLUENZA A VIRUS TEST NEGATIVE (Influenza A virus test negative), INFLUENZA B VIRUS TEST (Influenza B virus test), INFLUENZA VIRUS TEST NEGATIVE (Influenza virus test negative), MYOCARDITIS (Myocarditis), RESPIRATORY SYNCYTIAL VIRUS TEST NEGATIVE (Respiratory syncytial virus test negative), SARS-COV-2 TEST NEGATIVE (SARS-CoV-2 test negative) and TROPONIN INCREASED (Troponin increased) had not resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 06-Dec-2021, Adenovirus test: negative (Negative) Negative.<br>On 06-Dec-2021, Influenza B virus test: negative (Negative) Negative.<br>On 06-Dec-2021, Metapneumovirus infection: negative (Negative) Negative.<br>On 06-Dec-2021, Parainfluenzae virus infection: negative (Negative) Negative.<br>On 06-Dec-2021, Pneumonia influenzal: negative (Negative) Negative.<br>On 06-Dec-2021, Polymerase chain reaction: negative (Negative) Negative.<br>On 06-Dec-2021, Rhinovirus infection: negative (Negative) Negative.<br>On 06-Dec-2021, Troponin: elevated troponin (High) elevated troponin.<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments.<br><br>Diagonostics test included RNA PCR negative for Influenza A H3, Influenza B, RSV A, RSVB, Parainfluenza 1, Parainfluenza 2, Parainfluenza 3, and on &th Dec 2021 Telemetry and TTE completed, results were pending.<br>No concomitant medications provided.<br>No treatment medications provided.<br>Patient presented with chest pain that started the day after his Covid booster vaccine. He was found to have elevated troponin (EKG non-ischemic, no arrhythmia; BP and HR normal) and was diagnosed with myocarditis. No other possible cause of myocarditis was found. Specifically, he had no illness or sick contacts in the preceding weeks, a viral RNA PCR panel was negative (including Covid, Influenza A H1, Influenza A H3, Influenza B, RSV A, RSVB, Parainfluenza 1, Parainfluenza 2, Parainfluenza 3, Rhinovirus, Metapneumovirus, Adenovirus), HIV was negative, and he had no signs/symptoms/history of rheumatologic disease. His pain is improving without treatment. He has no s/sx of heart failure. A TTE was completed, result pending.<br><br>Company comment: This is a regulatory case concerning a 25 year-old, male patient with no reported medical history, who experienced the serious (due to hospitalization) expected, according CCDS, AESI of myocarditis and the serious (due to hospitalization) unexpected, according CCDS, event of chest pain. Additionally, troponin increased alongside multiple laboratory tests and imaging were reported. The events occurred approximately 1 day after the booster dose of mRNA-1273 vaccine. The outcome of the events was reported as not recovered. The rechallenge was not applicable, as the events were reported |

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| | | exclusively after the booster dose. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. |
| 4.1(b) | 4.1(b) | This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 16-Dec-2021 and was forwarded to Moderna on 22-Dec-2021.<br>This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 16-Dec-2021 and was forwarded to Moderna on 22-Dec-2021.<br><br>This case, initially reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref, 4.1(b) On an unknown date, the patient received the 1st dose of this vaccine. On an unknown date, body temperature before the vaccination: 36.8 degrees Celsius. On 22-Nov-2021, at 16:00, the patient received the 2nd dose of this vaccine. Pyrexia developed. The patient took an antipyretic. On 23-Nov-2021, pyrexia improved. On 25-Nov-2021, at 07:30, the patient was urgently transported to the hospital as he was aware of left chest pain. Blood test showed elevated troponin I of 325 pg/mL. Acute myocarditis was suspected, so the patient was referred to the reporting hospital. Electrocardiogram and echocardiogram test showed no significant abnormalities, but troponin I was further elevated to 1,560.2 pg/mL; thus, the patient was hospitalized for follow-up. On 27-Nov-2021, the patient was discharged from the hospital as the symptoms were resolving. The outcome of pyrexia and suspected acute myocarditis was reported as resolving. Follow-up investigation will be made.<br>Company Comment: The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. |
| 4.1(b) | 4.1(b) | This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 21-Dec-2021 and was forwarded to Moderna on 23-Dec-2021.<br>This case, reported to the 4.1(b) (4.1(b) by a corporation, was received via the 4.1(b) (Ref, 4.1(b) Myocarditis was assessed as serious by the MAH. On 16-Oct-2021, at 13:00, the patient received the 1st dose of the vaccine. On an unknown date, body temperature before the vaccination: 36.0 degrees Celsius. On 13-Nov-2021, at 13:00, the patient received the 2nd dose of the vaccine. On 14-Nov-2021, pyrexia and chest pain developed. On 16-Nov-2021, at 14:30, the patient visited a nearby hospital because the symptoms were not improved. Since elevated CPK was observed, the patient was referred to the reporting hospital. Cardiac ultrasonography showed decreased cardiac function. A myocardial biopsy performed at the time of cardiac catheterization revealed infiltration of inflammatory cells intramyocardially, and the patient was diagnosed with myocarditis. On an unknown date, cardiac function improved to the normal range by follow-up. On 24-Nov-2021, the symptoms were resolving. The outcome of myocarditis was reported as resolving. Follow-up investigation will be made. Company Comment: The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. |
| 4.1(b) | 4.1(b) | This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 22-Dec-2021 and was forwarded to Moderna on 23-Dec-2021.<br>This case, initially reported to the 4.1(b) by a (physician), was received via the 4.1(b) (Ref, |

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| | | 4.1(b) On an unknown date, the patient received the 1st dose of this vaccine. On 13-Nov-2021, the patient received the 2nd dose of this vaccine. On 14-Nov-2021 to 16-Nov-2021, the patient had chest pain. On 16-Nov-2021, the patient was hospitalized with a myocarditis. On 20-Nov-2021, as the symptom was resolving, the patient was discharged from the hospital. The outcome of myocarditis was reported as resolving. Follow-up investigation will be made.<br>LP Company Comment: The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.<br><br>Company comment:<br>This case concerns a 17-year-old male patient with no medical history provided who experienced serious expected event of special interest Myocarditis. The event occurred three days after the second dose of mRNA-1273. It was reported that one day following vaccination the patient experienced chest pain and that three days following vaccination the patient was hospitalized with myocarditis. It was further reported that the patient was discharged four days later as the symptoms were resolving. At the time of the report the outcome of the event Myocarditis was reported as resolving. No further information regarding clinical course of the event was provided at this time. No information regarding laboratory nor diagnostic tests was provided at this time. As per SD, no rechallenge was done and, therefore, recurrence is not applicable. The Reporter assessed the event as possibly related to the suspect product. The benefit-risk relationship of mRNA-1273 is not affected by this report. |
| 4.1(b) | 4.1(b) | This case was received via an unknown source (no reference has been entered for a health authority or license partner) on 20-Dec-2021 and was forwarded to Moderna on 22-Dec-2021.<br>This regulatory authority case was reported by an other health care professional and describes the occurrence of CHEST DISCOMFORT (Chest tightness, chest pain), CHEST PAIN (Chest tightness, chest pain) and MYOCARDITIS (Myocarditis) in a 35-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 24-Nov-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 28-Nov-2021, the patient experienced CHEST DISCOMFORT (Chest tightness, chest pain) (seriousness criterion hospitalization), CHEST PAIN (Chest tightness, chest pain) (seriousness criterion hospitalization) and MYOCARDITIS (Myocarditis) (seriousness criterion hospitalization). At the time of the report, CHEST DISCOMFORT (Chest tightness, chest pain), CHEST PAIN (Chest tightness, chest pain) and MYOCARDITIS (Myocarditis) was resolving.<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. |

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| | | Patient received Moderna vaccine on 24-NOV-2021 and on November 26, the patient developed fever, and was admitted to the emergency room for chest pain and breathing difficulties TOCC (-)<br>Patient medical history included on November 26, the patient had a fever in the early morning, and the patient had stabbing chest pain, which occurred once breathing, with a painful look cold sweating.<br>Follow up info included on 08-DEC-2021. Patient said he felt chest distress when sleeping on his side. The physician knew his condition. The patient had taken anticoagulants and hypertension medications now. The health center told him not to do too much activities to cause cardiac stress, and provided VICP information. The patient accepted and understood. The medical abstract was uploaded.<br>Company comment: This regulatory case concerns a 35-years-old male patient, with no medical history reported in this case, who experienced the serious expected AESI of Myocarditis and the serious unexpected events of Chest discomfort and Chest pain. The events occurred 5 days after the administration of the second dose of the mRNA-1273 vaccine. The events were assessed by the reporter with the seriousness criteria of Hospitalization, and, at the time of the report, the outcome of the events was Recovering/Resolving. No further information on clinical course and diagnostic tests performed was disclosed. The rechallenge is not applicable since the events occurred after the second dose of the of the mRNA-1273 vaccine. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. |
| 4.1(b) | 4.1(b) | This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCARDITIS (Myocarditis) in a 28-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for an unknown indication.<br><br>No Medical History information was reported.<br><br>On 06-Dec-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 09-Dec-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criterion hospitalization). At the time of the report, MYOCARDITIS (Myocarditis) was resolving.<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments.<br><br>No concomitant medications were reported.<br>On 08-Oct-2021, patient received first dose of AstraZeneca vaccine.<br>On 06-Dec-2021, patient received second dose of Moderna vaccine and began to develop fever, headache, dizziness, joint pain (finger dip) and chest tightness the next day. Later the symptoms changed to palpitation and chest pain.<br>On 08-Dec-2021 22:20, patient went to ER. Emergency examination showed troponin-I elevation and ECG ST elevation.The patient had a shock in the emergency department, so norepinephrine was given briefly. It was reported that no obvious embolism was found during cardiac catheterization. Patient was stable after catherization, then norepinephrine was removed. Blood pressure SBP was about 80-90 |

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| | | mmHg. The patient was under MICU2 observation and cardiac ultrasound examinations and ECG were done.<br>On 09-Dec-2021, it was reported that patient had finished cardiac catheterization and no embolism was found. Patient's condition was stable, the patient was under MICU observation and conscious. SBP was increased (about 100).After that, it was planned to arrange cardiac ultrasound and other examinations.<br>Company comment: This regulatory case concerns a 28-years-old male patient, with no medical history reported in this case, who experienced the serious expected AESI of Myocarditis. The event occurred approximately 4 days after the administration of the second dose of the mRNA-1273 vaccine. The events were assessed by the reporter with the seriousness criteria of Hospitalization. It was reported that the patient had troponin-I elevation and a ST elevation in the electrocardiogram performed and that went into shock for what he required norepinephrine. At the time of the report, the outcome of the event was Recovering/Resolving. The rechallenge is not applicable since the event occurred after the second dose of the of the mRNA-1273 vaccine. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. |
| 4.1(b) | 4.1(b) | This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 21-Dec-2021 and was forwarded to Moderna on 23-Dec-2021.<br>This case, initially reported to the 4.1(b) by a (physician), was received via the 4.1(b) (Ref, 4.1(b)<br><br>On an unknown date, the patient received the 1st dose of this vaccine. On 01-Oct-2021, at 17:00, the patient received the 2nd dose of this vaccine. On 02-Oct-2021, low-grade fever, queasy, and headache developed. On 03-Oct-2021, low-grade fever went down, and the symptoms were resolving. On 04-Oct-2021, at 07:00, myocarditis developed. The patient complained of chest pain and visited another hospital. No obvious abnormalities were found, and the patient returned home. In the afternoon, chest pain was exacerbated, and the patient visited another hospital again. The electrocardiogram showed ST elevation, and the patient was referred to a previous physician. Based on elevated troponin T, CK, and CK-MB in blood test and electrocardiogram, myocarditis was suspected, and the patient was raced the reporting hospital. The cardiac ultrasonography showed good cardiac function. The patient was hospitalized for follow-up under management in the monitor. On 05-Oct-2021, chest pain tended to improve, but there was no change in the electrocardiogram. On 06-Oct-2021, cardiac MRI was performed. Delayed images showed enhancing effect of the lateral wall. On 12-Oct-2021, the symptoms were not exacerbated, and the patient was discharged from the hospital. On 10-Dec-2021, the symptoms were resolving. The outcome of myocarditis was reported as resolving. Follow-up investigation will be made. Company Comment: The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.<br><br>This is a regulatory case concerning a 14-year-old male patient with no relevant medical history, who experienced the serious expected AESI event of myocarditis. The event occurred 4 days after the second dose of mRNA-1273 vaccine administration. The events were assessed as related, per temporal association with the product administration. The |

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| | | rechallenge was not applicable since the events occurred after the second dose and no further dosing is expected. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. |
| 4.1(b) | 4.1(b) | This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) ) on 22-Dec-2021 and was forwarded to Moderna on 24-Dec-2021. The license partner had received the report from 4.1(b) Reference number: 4.1(b)<br>This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) ) on 22-Dec-2021 and was forwarded to Moderna on 24-Dec-2021. The license partner had received the report from 4.1(b) (Reference number: 4.1(b)<br>This regulatory authority case was reported by a pharmacist and describes the occurrence of MYOCARDITIS (Myocarditis) in a 20-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna Intramuscular Injection) for COVID-19 vaccination.<br><br>Previously administered products included for Product used for unknown indication: Loratadine and Oseltamivir phosphate.<br>Past adverse reactions to the above products included Allergy with Loratadine and Oseltamivir phosphate.<br>Concurrent medical conditions included Diabetes mellitus (Visiting the hospital regularly), Heart disorder (Visiting the hospital regularly) and Pollinosis.<br><br>On 08-Sep-2021, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna Intramuscular Injection) (Intramuscular) 1 dosage form.<br>On 21-Oct-2021, received second dose of mRNA-1273 (COVID-19 Vaccine Moderna Intramuscular Injection) (Intramuscular) dosage was changed to 1 dosage form. On 23-Oct-2021, after starting mRNA-1273 (COVID-19 Vaccine Moderna Intramuscular Injection), the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Myocarditis) was resolving.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 23-Oct-2021, Heart rate: 90-100 90-100 /min.<br>On 28-Oct-2021, Electrocardiogram: normal (normal) No abnormalities.<br>On 28-Oct-2021, Myocardial necrosis marker: no major changes No major changes..<br>On an unknown date, Body temperature: 36.5 36.6 Degree Celsius.<br><br>For mRNA-1273 (COVID-19 Vaccine Moderna Intramuscular Injection) (Intramuscular), the reporter considered MYOCARDITIS (Myocarditis) to be possibly related.<br><br>Reporter's comments: Myocarditis is strongly suspected based on the symptom.<br>Sender's comments: The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.<br><br>Company comment |

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| | | This is a regulatory case concerning a 20-year-old male patient with medical history of Diabetes mellitus and Heart disorder, who experienced the serious expected AESI event of MYOCARDITIS. The event occurred approximately 2 days after the third dose of mRNA-1273. The rechallenge was not applicable. The medical history of Diabetes mellitus and Heart disorder remains a confounder. The benefit-risk relationship of mRNA-1273 is not affected by this report. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 24-Dec-2021 and was forwarded to Moderna on 24-Dec-2021.<br>This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (CARDIAC MUSCLE INFLAMMATION) in an 18-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 3005697) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 15-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 30-Oct-2021, after starting mRNA-1273 (Spikevax), the patient experienced MYOCARDITIS (CARDIAC MUSCLE INFLAMMATION) (seriousness criterion hospitalization). At the time of the report, MYOCARDITIS (CARDIAC MUSCLE INFLAMMATION) was resolving.<br><br>Concomitant medication was not reported.<br>Treatment details were not reported.<br><br>This is a regulatory case concerning an 18-year-old female patient with no relevant medical history, who experienced the serious expected AESI event of myocarditis. The event occurred approximately 1 month 16 days after the second dose of mRNA-1273 vaccine administration. The event was assessed as related to the product administration. The rechallenge was not applicable since the events occurred after the second dose and no further dosing is expected. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. |
| 4.1(b) | 4.1(b) | This case was received via European Medicines Agency (Reference number: 4.1(b) ) on 27-Dec-2021 and was forwarded to Moderna on 27-Dec-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myopericarditis) in a 34-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 3005885 and 3005696) for COVID-19 vaccination.<br><br>Concurrent medical conditions included Smoker.<br><br>On 08-Sep-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form.<br>On 04-Oct-2021, received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to 1 dosage form. On 18-Nov-2021, the patient experienced MYOCARDITIS (Myopericarditis) (seriousness |

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| | | criterion hospitalization). At the time of the report, MYOCARDITIS (Myopericarditis) was resolving.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 25-Nov-2021, N-terminal prohormone brain natriuretic peptide: 130 pg/ml iu international unit(s) (High) 130 pg/ml Iu international unit(s).<br>On 25-Nov-2021, Troponin T: 461 ng/l iu international unit(s) (High) 461 ng/L Iu international unit(s).<br><br>For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.<br><br>Concomitant Elements: Healthy<br>Concomitant product use was not provided by the reporter.<br>No treatment information was provided.<br><br>This case concerns a 34-year-old male patient with no relevant medical history, who experienced the unexpected serious adverse event of special interest, Myocarditis, the event caused hospitalization for the patient as reported by the regulatory authority. The event of Myocarditis occurred approximately 1 month after receiving the second dose of mRNA-1273 Vaccine. The rechallenge was reported as not applicable by the regulatory authority. N-terminal prohormone brain natriuretic peptide and Troponin T labs showed high results. No clinical or treatment details were given. It is reported that the event was resolving. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report. |
| 4.1(b) | 4.1(b) | This case was initially received via 4.1(b) (Reference number: 4.1(b) ) on 23-Dec-2021. The most recent information was received on 07-Jan-2022 and was forwarded to Moderna on 07-Jan-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (Myocarditis) in a 32-year-old female patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below.<br><br>Undiagnosed lupus<br>Patient has not had symptoms associated with COVID-19<br>Patient is not pregnant,Patient is not currently breastfeeding.<br>Concurrent medical conditions included Lupus erythematosus (Undiagnosed lupus) and Immunodeficiency (Has an illness or condition, not listed above, which reduces the immune response (e.g. immunodef...).<br>Concomitant products included COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (COVID-19 VACCINE ASTRAZENECA) from 13-Apr-2021 to 20-Jun-2021 and COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (COVID-19 VACCINE ASTRAZENECA) for COVID-19 vaccination, CURCUMIN for Inflammation.<br><br>On 21-Dec-2021, the patient received third dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 21-Dec-2021, the patient experienced MYOCARDITIS (Myocarditis) |

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| | | (seriousness criterion medically significant). On an unknown date, the patient experienced TACHYCARDIA (Racing heart (tachycardia)) and CHEST PAIN (Chest pain). At the time of the report, MYOCARDITIS (Myocarditis) had not resolved and TACHYCARDIA (Racing heart (tachycardia)) and CHEST PAIN (Chest pain) outcome was unknown.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On an unknown date, SARS-CoV-2 test: negative (Negative) No - Negative COVID-19 test.<br><br>Patient has not had symptoms associated with COVID-19. Patient is not currently breastfeeding. Fom the moment patient received the vaccine patient's heart started beating fast and continued to felt the pain around it.<br><br>No treatment medication was provided.<br><br>Company comment: This is a regulatory case concerning a 32-year-old female patient with the medical history of Immunodeficiency, who experienced the expected serious event of Myocarditis (seriousness criterion medically significant), with the unexpected events of Tachycardia, Chest pain, and Pain. These events occurred on the same day the patient received the third dose of mRNA-1273 (Moderna CoviD-19 Vaccine). The medical history of Immunodeficiency may be a cofounder. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report.<br><br>This is a regulatory case concerning a 32-year-old female patient with the medical history of Immunodeficiency and lupus erythematosus, who experienced the expected serious event of Myocarditis with the unexpected events of Tachycardia, and Chest pain. These events occurred on the same day the patient received the third dose of mRNA-1273 (Moderna CoviD-19 Vaccine). The medical history of Immunodeficiency may be a cofounder. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 07-Jan-2022: Follow-up received included information regarding concomitant medications, action taken with suspect product updated and narrative updated. |
| 4.1(b) | 4.1(b) | This case was initially received via 4.1(b) (Reference number: 4.1(b) ) on 27-Dec-2021. The most recent information was received on 30-Dec-2021 and was forwarded to Moderna on 30-Dec-2021.<br>This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (Myocarditis), EPISTAXIS (Nose bleed), HEADACHE (Headache), MYALGIA (Muscle soreness) and CHEST PAIN (Chest pain) in a 32-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) (batch no. 3006325) for COVID-19 immunisation. The occurrence of additional non-serious events is detailed below. |

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| | | No Medical History information was reported.<br><br>On 23-Dec-2021, the patient received third dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 23-Dec-2021, the patient experienced MYALGIA (Muscle soreness). On 24-Dec-2021, after starting mRNA-1273 (Moderna CoviD-19 Vaccine), the patient experienced HEADACHE (Headache). On 25-Dec-2021, the patient experienced MYOCARDITIS (Myocarditis). On 26-Dec-2021, the patient experienced EPISTAXIS (Nose bleed). On an unknown date, the patient experienced CHEST PAIN (Chest pain) and DYSPNOEA (Shortness of breath). On 25-Dec-2021, HEADACHE (Headache) had resolved. On 26-Dec-2021, MYOCARDITIS (Myocarditis) and EPISTAXIS (Nose bleed) had resolved. At the time of the report, MYALGIA (Muscle soreness) was resolving and CHEST PAIN (Chest pain) and DYSPNOEA (Shortness of breath) outcome was unknown.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On an unknown date, SARS-CoV-2 test: negative (Negative) No - Negative COVID-19 test.<br><br>No concomitant medications were provided by reporter.<br>No treatment medications were provided<br>Patient not had symptoms associated with COVID-19. Patient not tested positive for COVID-19 since having the vaccine<br><br>Company comment: This Regulatory Authority case concerns a 32-year-old, male patient, with no reported medical history, who experienced the expected, non-serious and AESI of Myocarditis, among others. The event occurred 2 days after receiving a dose of mRNA-1273 vaccine, considered as the third dose of the patient's COVID-19 vaccination schedule. It was not reported if the previous two doses of his COVID-19 vaccination schedule were mRNA-1273 vaccines as well. Regulatory Authority captured the rechallenge as unknown. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Seriousness criteria of non-serious was maintained for the event for consistency with the RA report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 30-Dec-2021: significant follow-up Included action taken of suspect drug |
| 4.1(b) | 4.1(b) | This case was initially received via 4.1(b) (Reference number: 4.1(b) ) on 21-Dec-2021. The most recent information was received on 04-Jan-2022 and was forwarded to Moderna on 04-Jan-2022.<br>This regulatory authority case was reported by a pharmacist and describes the occurrence of MYOCARDITIS (Myocarditis), CHEST PAIN (Chest pain) and PYREXIA (Fever) in a 19-year-old female patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for COVID-19 vaccination. |

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| | | The patient's past medical history included 4.1(b) (late 10/2021) in October 2021.<br>Concurrent medical conditions included Irritable bowel syndrome.<br>Concomitant products included DOXYCYCLINE from 28-Oct-2021 to 04-Nov-2021 for Infection, COLCHICINE, MEBEVERINE, SUMATRIPTAN and INTRAUTERINE CONTRACEPTIVE DEVICE for an unknown indication.<br><br>On 30-Jun-2021, the patient received first dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form.<br>On 16-Dec-2021, received second dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 18-Dec-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). 18-Dec-2021, the patient experienced CHEST PAIN (Chest pain) (seriousness criteria hospitalization and medically significant). On an unknown date, the patient experienced PYREXIA (Fever) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Myocarditis) and CHEST PAIN (Chest pain) had not resolved and PYREXIA (Fever) outcome was unknown.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>In December 2021, Blood bicarbonate: 30 30.<br>In December 2021, Blood chloride: 106 106.<br>In December 2021, Blood creatinine: 77 77.<br>In December 2021, Blood potassium: 4.5 4.5.<br>In December 2021, Blood sodium: 141 141.<br>In December 2021, Blood urea: 3.7 3.7.<br>In December 2021, C-reactive protein: 9 9.<br>On 18-Dec-2021, Basophil count: 0.03 0.03.<br>On 18-Dec-2021, Blood bicarbonate: 28 28.<br>On 18-Dec-2021, Blood chloride: 104 104.<br>On 18-Dec-2021, Blood creatinine: 71 71.<br>On 18-Dec-2021, Blood culture negative: negative (Negative) negative.<br>On 18-Dec-2021, Blood magnesium: 0.89 0.89.<br>On 18-Dec-2021, Blood potassium: 4.0 4.0.<br>On 18-Dec-2021, Blood sodium: 139 139.<br>On 18-Dec-2021, Blood urea: 3.3 3.3.<br>On 18-Dec-2021, C-reactive protein: 52 52.<br>On 18-Dec-2021, Chest X-ray: nothing abnormal detected (normal) nothing abnormal detected.<br>On 18-Dec-2021, Echocardiogram: normal (normal) normal.<br>On 18-Dec-2021, Electrocardiogram: sinus rhythm with inferolateral st elevation (abnormal) sinus rhythm with inferolateral ST elevation with PR depression inferior leads T wave inversion anterior leads.<br>On 18-Dec-2021, Eosinophil count: 0.09 0.09.<br>On 18-Dec-2021, Haematocrit: 0.365 0.365.<br>On 18-Dec-2021, Haemoglobin: 122 122.<br>On 18-Dec-2021, Lymphocyte count: 0.89 0.89.<br>On 18-Dec-2021, Mean cell haemoglobin: 29.5 29.5.<br>On 18-Dec-2021, Mean cell haemoglobin concentration: 334 334.<br>On 18-Dec-2021, Mean cell volume: 88.2 88.2.<br>On 18-Dec-2021, Monocyte count: 0.95 0.95.<br>On 18-Dec-2021, Neutrophil count: 9.25 9.25. |

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| | | On 18-Dec-2021, Nucleated red cells: 0.00 0.00.<br>On 18-Dec-2021, Platelet count: 196 196.<br>On 18-Dec-2021, Red blood cell count: 4.14 4.14.<br>On 18-Dec-2021, Troponin: 6,931 6,931.<br>On 18-Dec-2021, White blood cell count: 11.2 11.2.<br>On 19-Dec-2021, Electrocardiogram: slight st elevation (abnormal) slight ST elevation most leads inferior/anterior.<br>On 19-Dec-2021, Troponin: 15,197 15,197.<br>On 20-Dec-2021, Basophil count: 0.04 0.04.<br>On 20-Dec-2021, Blood bicarbonate: 28 28.<br>On 20-Dec-2021, Blood chloride: 106 106.<br>On 20-Dec-2021, Blood creatinine: 74 74.<br>On 20-Dec-2021, Blood potassium: 4.8 4.8.<br>On 20-Dec-2021, Blood sodium: 140 140.<br>On 20-Dec-2021, Blood urea: 3.6 3.6.<br>On 20-Dec-2021, Echocardiogram: normal (normal) normal.<br>On 20-Dec-2021, Eosinophil count: 0.24 0.24.<br>On 20-Dec-2021, Haematocrit: 0.371 0.371.<br>On 20-Dec-2021, Haemoglobin: 125 125.<br>On 20-Dec-2021, Lymphocyte count: 1.19 1.19.<br>On 20-Dec-2021, Mean cell haemoglobin: 29.6 29.6.<br>On 20-Dec-2021, Mean cell haemoglobin concentration: 337 337.<br>On 20-Dec-2021, Mean cell volume: 87.7 87.7.<br>On 20-Dec-2021, Monocyte count: 0.44 0.44.<br>On 20-Dec-2021, Neutrophil count: 4.32 4.32.<br>On 20-Dec-2021, Nucleated red cells: 0.00 0.00.<br>On 20-Dec-2021, Platelet count: 206 206.<br>On 20-Dec-2021, Red blood cell count: 4.23 4.23.<br>On 20-Dec-2021, Troponin: 17,057 17,057.<br>On 20-Dec-2021, White blood cell count: 6.2 6.2.<br><br>For mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown), the reporter did not provide any causality assessments.<br><br>Patient was not pregnant and was not currently breastfeeding.<br>Patient did not had symptoms associated with COVID-19. Not had a COVID-19 test.<br>Patient was not tested positive for COVID-19 since having the vaccine.<br>Myocarditis and pericarditis were reported.<br>The patient was admitted to hospital and still an inpatient. Patient was seen by cardiologist.<br>Treatment was provided to the patient which included NSAIDS and colchicine.<br>Cardiac biopsy was not performed. Coronary angiography was not carried out.<br>Patient reported chest pain, fever, myocarditis.<br><br>Patient had not tested positive for COVID-19 since having the vaccine.<br><br>Patient was not enrolled in clinical trial.<br><br>Company Comment: This case concerns a 19-year-old female patient, with no relevant medical history reported in this case, who experience the serious AESI expected event of Myocarditis and the serious unexpected |

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| | | events Chest Pain and Pyrexia. The events Myocarditis and Chest Pain occurred approximately 4 days after the administration of the Second dose of the mRNA-1273 vaccine and the outcome at the time of the report was Not Recovered/Not Resolved. The event Pyrexia occurred in an unknown date after the administration of the Second dose of the mRNA-1273 vaccine and the outcome at the time of the report was Unknown. The rechallenge could be considered not applicable since the events occurred after the 2nd dose and no additional dosing will be given. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 23-Dec-2021: Follow-up document received on 23-Dec-2021 contains significant information lab data updated and event coding updated.<br>On 04-Jan-2022: Follow-up contains significant information: Reporter updated from other HCP to pharmacist. Medical history added. Lab data added. Event (myocarditis) coding updated. Outcome of event (chest pain) was changed from unknown to not recovered. Indication of suspect added. Suspect start date (dose 2) updated and dose 1 details added. Concomitant product (Intrauterine Contraceptive device) added. I-narrative updated. |
| 4.1(b) | 4.1(b) | This case was received via 4.1(b) (Reference number: 4.1(b) ) on 23-Dec-2021 and was forwarded to Moderna on 23-Dec-2021.<br>This regulatory authority case was reported by a consumer and describes the occurrence of FATIGUE (Fatigue/unusual tiredness), CHEST PAIN (Chest pain) and PERICARDITIS (Pericarditis) in a 22-year-old male patient who received mRNA-1273 (COVID 19 Vaccine Moderna) (batch no. 000014A) for an unknown indication.<br><br>Concomitant products included ELASOMERAN (COVID-19 VACCINE MODERNA) and ELASOMERAN (COVID-19 VACCINE MODERNA) for an unknown indication.<br><br>On 20-Dec-2021, the patient received third dose of mRNA-1273 (COVID 19 Vaccine Moderna) (unknown route) 1 dosage form. On 21-Dec-2021, the patient experienced CHEST PAIN (Chest pain) (seriousness criterion medically significant) and PERICARDITIS (Pericarditis) (seriousness criterion medically significant). On an unknown date, the patient experienced FATIGUE (Fatigue/unusual tiredness) (seriousness criterion medically significant). At the time of the report, FATIGUE (Fatigue/unusual tiredness) and CHEST PAIN (Chest pain) outcome was unknown and PERICARDITIS (Pericarditis) was resolving.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On an unknown date, Blood test: crp 11 CRP 11.<br>On an unknown date, Electrocardiogram: indicated pericarditis indicated pericarditis.<br>On an unknown date, Troponin: raised 11 raised 11. |

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| | | other treatment medications- Ibuprofen and omeprazole<br>Patient has not had symptoms associated with COVID-19 Not had a COVID-19 test<br>Patient has not tested positive for COVID-19 since having the vaccine<br>Patient is not enrolled in clinical trial<br>Did the symptoms lead to a hospital stay?: "No"<br>Was a diagnosis made by a medical professional?: "Yes"<br>If yes, please confirm the type of healthcare professional (cardiologist, GP etc) that provided this diagnosis and any specific details of the diagnosis given.: "On call A&E doctor"<br>FU msg received 24.12.2021:<br>I've been put on a course of 600mg ibuprofen 3 times a day for 2 weeks, reducing the dose by 200mg each week thereafter.<br>Shortly after the booster I went for a brief walk and the following day I went out to visit a friend.<br>I don't have any history of long term medical conditions or regular medication. I've never experienced physical trauma, heart surgery, heart attack, infection, cancer involving radiation therapy, or chemotherapy, and do not drink or take recreational drugs or steroids.<br>I've never had a similar reaction to another vaccine or medication and have not had covid before.<br>Company comment<br>This case concerns a 22-year-old male patient, with no medical history, who experienced the unexpected serious events of FATIGUE and CHEST PAIN, and the expected serious event of PERICARDITIS (AESI). The events occurred on the following day after the administration of the third dose of mRNA-1273 vaccine. At the time of the report, PERICARDITIS was resolving. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 23-Dec-2021: Initial and Follow-up processed together. Concomitant medications, Lot number and results for lab data were updated. |
| 4.1(b) | 4.1(b) | This case was initially received via 4.1(b) (Reference number: 4.1(b) ) on 27-Dec-2021. The most recent information was received on 03-Jan-2022 and was forwarded to Moderna on 03-Jan-2022.<br>This regulatory authority case was reported by a consumer and describes the occurrence of FATIGUE (Fatigue/unusual tiredness), CHEST PAIN (Chest pain), DYSPNOEA (Shortness of breath), PALPITATIONS (Heart palpitations), HYPERTENSION (Blood pressure high), TROPONIN INCREASED (Troponin increased) and MYOCARDITIS (Myocarditis) in a 34-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) (batch no. 00014A) for COVID-19 vaccination.<br><br>No Medical History information was reported.<br><br>On 22-Dec-2021, the patient received third dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 24-Dec-2021, after starting mRNA-1273 (Moderna CoviD-19 Vaccine), the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). On an unknown date, the patient experienced FATIGUE (Fatigue/unusual tiredness) (seriousness criteria hospitalization and medically significant), CHEST PAIN (Chest |

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| | | pain) (seriousness criteria hospitalization and medically significant), DYSPNOEA (Shortness of breath) (seriousness criteria hospitalization and medically significant), PALPITATIONS (Heart palpitations) (seriousness criteria hospitalization and medically significant), HYPERTENSION (Blood pressure high) (seriousness criteria hospitalization and medically significant) and TROPONIN INCREASED (Troponin increased) (seriousness criteria hospitalization and medically significant). At the time of the report, FATIGUE (Fatigue/unusual tiredness), CHEST PAIN (Chest pain), DYSPNOEA (Shortness of breath), PALPITATIONS (Heart palpitations), HYPERTENSION (Blood pressure high) and TROPONIN INCREASED (Troponin increased) had not resolved and MYOCARDITIS (Myocarditis) was resolving.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 25-Dec-2021, SARS-CoV-2 test: no - negative covid-19 test (Negative) No - Negative COVID-19 test.<br>On an unknown date, Blood pressure measurement: 178/110 178/110.<br>On an unknown date, Troponin: raised (High) Raised.<br><br>No concomitant medications were reported.<br>Reported that Patient doesn't drink, doesn't take drugs and has never taken anabolic steroids. Patient has not had symptoms associated with COVID-19.<br>Patient reported fatigue/unusual tiredness, myocarditis and shortness of breath. Post vaccine, heart palpitation, sore chest, high blood pressure, raised troponin levels and chest pain. Electrocardiogram (ECG), Blood Pressure - 178/110 (No history of high blood pressure) and X-ray and Bloods tests was done and confirmed troponin levels and Blood Pressure spiked. The report was related to possible inflammation of the heart (myocarditis or pericarditis).<br>symptoms doesn't lead to a hospital stay. The diagnosis was made by a general practitioner (GP). Events were still ongoing, seeing cardiologist. Patient has not tested positive for COVID-19 since having the vaccine. Patient was not enrolled in clinical trial. Patient had no ongoing illness, no history of long-term medical conditions. Patient had previously diagnosed suspected COVID-19 infection in March 2020.<br><br>Company comment:This regulatory case concerns a 34-year-old, male patient with no medical history of High blood pressure, who experienced the expected, serious AESI of myocarditis and the unexpected, serious events of fatigue, chest pain, dyspnea, palpitations, hypertension and troponin increased. The event myocarditis occurred 2 days after administration of the third dose of the Moderna mRNA-1273 vaccine. The start dates of the other events were not provided. Troponin levels were found to be increased. However, the results of the Electrocardiogram and X-ray done were not provided. The patient was prescribed with amlodipine (unspecified dosage, frequency and duration). The event myocarditis was resolving at the time of the report. The outcomes of the other events were unknown at the time of the report.. The benefit-risk relationship of the Moderna mRNA-1273 vaccine is not affected by this report. |

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| | | Most recent FOLLOW-UP information incorporated above includes:<br>On 03-Jan-2022: Follow-up received included lab test, suspect product indication, event outcome and narrative updated. |
| 4.1(b) | 4.1(b) | This case was received via 4.1(b) (Reference number: 4.1(b) ) on 26-Dec-2021 and was forwarded to Moderna on 26-Dec-2021.<br>This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (Myocarditis), FATIGUE (Fatigue/unusual tiredness), DYSPNOEA (Shortness of breath), ANGINA PECTORIS (Cardiac pain) and CHEST DISCOMFORT (Chest discomfort) in a 35-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) (batch no. 3005287) for an unknown indication. The occurrence of additional non-serious events is detailed below.<br><br>Family history included Family history of cardiovascular disorder (There is heart disease on my maternal side of the family.).<br><br>On 16-Dec-2021, the patient received third dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 16-Dec-2021, the patient experienced MYOCARDITIS (Myocarditis) and PALPITATIONS (Heart palpitations). On 17-Dec-2021, after starting mRNA-1273 (Moderna CoviD-19 Vaccine), the patient experienced CHEST DISCOMFORT (Chest discomfort). On an unknown date, the patient experienced FATIGUE (Fatigue/unusual tiredness), DYSPNOEA (Shortness of breath), ANGINA PECTORIS (Cardiac pain) and TACHYCARDIA (Racing heart (tachycardia)). At the time of the report, MYOCARDITIS (Myocarditis) had not resolved, FATIGUE (Fatigue/unusual tiredness), DYSPNOEA (Shortness of breath), ANGINA PECTORIS (Cardiac pain), PALPITATIONS (Heart palpitations) and TACHYCARDIA (Racing heart (tachycardia)) outcome was unknown and CHEST DISCOMFORT (Chest discomfort) was resolving.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 21-Dec-2021, SARS-CoV-2 test: negative (Negative) No - Negative COVID-19 test.<br>On an unknown date, Cardiovascular examination: normal (normal) Found that my heart rate had returned to normal.<br><br>Concomitant medications were not reported.<br>No treatment medication reported.<br><br>Patient had Fatigue/unusual tiredness, chest pain, myocarditis, heart palpitations, shortness of breath and (racing heart) tachycardia.<br>At first the patient experienced heart palpitations that would not subside on the night of the 16th. The next morning patient woke up with tightness and discomfort in the chest. Patient called the general practitioner (GP) and they requested to see me the patient at clinic. They examined the |

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| | | patient and found that patient's heart rate had returned to normal, and they prescribed ibuprofen to reduce the inflammation of the heart. They wanted the patient to do an electrocardiogram (ECG), however the walk in clinic nearby was not accepting any walk ins due to COVID. Patient went home and rested with ibuprofen. It has been a week and patient left feeling fatigued and his heart feels tender and sore. Patient became out of breath after going out walking, and do experience some chest tightness still. Patient needs to do an ECG and get proper<br>This RA case concerns a male patient of 35 years old with medical Family history of cardiovascular disorder, experienced the expected AESI event of Myocarditis and unexpected nonserious events of Angina Pectoris, Dyspnea, Palpitations, chest discomfort and Fatigue. The event Myocarditis occurred one day after third dose of mRNA1273 vaccine. However, on unknown date events Angina pectoris, Dyspnea, Tachycardia and Fatigue occurred after third dose of mRNA-1273 vaccine. The outcome of Myocarditis was reported not recovered and other events outcome was unknown. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes:<br>On 30-Dec-2021: Follow-up received on 30-Dec-2021 with Events Chest discomfort and Palpitations added, Action taken was updated. |
| 4.1(b) | 4.1(b) | This case was initially received via 4.1(b) (Reference number: 4.1(b) ) on 26-Dec-2021. The most recent information was received on 30-Dec-2021 and was forwarded to Moderna on 30-Dec-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of CHEST PAIN (Chest Pain), CHEST DISCOMFORT (Chest tightness) and MYOCARDITIS (Myocarditis) in a 35-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) (batch no. 000040A) for COVID-19 immunisation.<br><br>The patient's past medical history included Polycystic ovaries. Concurrent medical conditions included Kidney polycystic (adult polycystic kidney disease).<br>Concomitant products included COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (COVID-19 VACCINE ASTRAZENECA) from 01-Apr-2021 to an unknown date and COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (COVID-19 VACCINE ASTRAZENECA) for COVID-19 immunisation.<br><br>On 20-Dec-2021, the patient received third dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 24-Dec-2021, after starting mRNA-1273 (Moderna CoviD-19 Vaccine), the patient experienced MYOCARDITIS (Myocarditis) (seriousness criterion hospitalization). On an unknown date, the patient experienced CHEST PAIN (Chest Pain) (seriousness criterion hospitalization) and CHEST DISCOMFORT (Chest tightness) (seriousness criterion hospitalization). At the time of the report, CHEST PAIN (Chest Pain) and CHEST DISCOMFORT (Chest tightness) outcome was unknown and MYOCARDITIS (Myocarditis) had not resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): |

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| | | On 24-Dec-2021, SARS-CoV-2 test: no - negative covid-19 test (Negative) Negative.<br>On 24-Dec-2021, Troponin: level 2944 high.<br>On an unknown date, Angiocardiogram: results not reported (Inconclusive) Inconclusive.<br>On an unknown date, Chest X-ray: nil acute (Negative) Negative.<br>On an unknown date, Echocardiogram: bedside echo- no effusion (normal) Normal..<br>On an unknown date, Electrocardiogram: st elevation in all leads, worse inferiorly (abnormal) ST elevation in all leads, worse inferiorly.<br>On an unknown date, Magnetic resonance imaging heart: inconclusive (Inconclusive) Inconclusive.<br>On an unknown date, Troponin: raised -highest 4915 (High) High.<br><br>For mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown), the reporter did not provide any causality assessments.<br><br>Patient experienced Chest pain and Myocarditis. He was admitted on 24Dec2021 with chest tightness. ECG changes were indicative of pericarditis; cardiac troponin was raised on admission (3,000), on 24Dec2021 at 07:30 shows 2944, and peak troponin value shows 4,915.<br><br>Lab data investigations shows ECG with ST elevation in all leads, worse inferiorly; Chest X-ray is clear and nil acute; Echocardiogram shows no effusion. Awaiting results of Cardiac MRI and CTCA.<br><br>Patient was treated for myo-pericarditis with analgesia at present. Patient well otherwise.<br><br>Company Comment: This regulatory case concerns a 35-year-old, male patient with history of concomitant administration of the AstraZeneca COVID-19 vaccines, who experienced the expected, serious AESI of myocarditis and the unexpected, serious events of chest pain and chest discomfort. The event myocarditis occurred 4 days after administration of the booster dose of the Moderna mRNA-1273 vaccine. The start dates of the other events were not provided. The patient was admitted with symptoms of chest tightness. Troponin levels were increased, with highest at 4,915. Electrocardiogram showed 'ST elevation in all leads, worse inferiorly'. Echocardiogram and Chest X-ray were unremarkable. The results of the other diagnostic tests were not provided. The patient was treated for myopericarditis with unspecified analgesic. The event myocarditis had not resolved at the time of the report. The outcomes of the other events were unknown at the time of the report. The history of concomitant administration of the AstraZeneca COVID-19 vaccines remains a confounder. The patient's gender remains a confounder for the event myocarditis. The benefit-risk relationship of the Moderna mRNA-1273 vaccine is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes: On 30-Dec-2021: Significant FU appended, event ,test results updated |
| 4.1(b) | 4.1(b) | This case was received via 4.1(b) (Reference number: 4.1(b) on 09-Nov-2021 and was forwarded to Moderna on 29-Dec-2021. |

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| | | This regulatory authority case was reported by an other health care professional and describes the occurrence of CHEST X-RAY (Chest X-ray), CHEST PAIN (Chest pain), ELECTROCARDIOGRAM (Electrocardiogram), LABORATORY TEST (Laboratory test) and PERICARDITIS (Pericarditis) in a 34-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 048C21A) for an unknown indication.<br><br>Concurrent medical conditions included Asthma.<br><br>On 09-Aug-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 06-Sep-2021, the patient experienced CHEST X-RAY (Chest X-ray), CHEST PAIN (Chest pain), ELECTROCARDIOGRAM (Electrocardiogram), LABORATORY TEST (Laboratory test) and PERICARDITIS (Pericarditis). At the time of the report, CHEST X-RAY (Chest X-ray), CHEST PAIN (Chest pain), ELECTROCARDIOGRAM (Electrocardiogram), LABORATORY TEST (Laboratory test) and PERICARDITIS (Pericarditis) had not resolved.<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments.<br><br>Other Medication included: Fluticasone Propionate 50 MCG/ACT Suspension 2 sprays DAILY START DATE 19-Aug-2021, Fluticasone-Salmeterol 250-50 MCG/DOSE Aerosol Powder Breath Activated 1 puff TWICE DAILY START DATE 19-Aug-2021, Ventolin HFA 108 (90 Base) MCG/ACT Aerosol Solution.<br><br>Symptom Text : The only symptom he had was left sided anterior chest pain with inspiration and he states it started 3-4 weeks after the second dose of Moderna vaccine which he received on 09-Aug-2021. His EKG was consistent with pericarditis. His labs/CXR and repeat EKG as well as Cardiology evaluation were pending. He was on Ibuprofen which helps him.<br><br>Company comment: This is a regulatory case concerning a 34 year-old, male patient with no relevant medical history, who experienced the expected, according CCDS, AESI of pericarditis. The event occurred approximately 29 days after the second dose of mRNA-1273 vaccine. The outcome of the event was reported as not recovered. He has received treatment with ibuprofen, only symptom reported was chest pain that started 3 to 4 weeks after vaccination, electrocardiogram was consistent with the diagnosis of pericartidis. The rechallenge was not applicable, as the event was reported exclusively after the second dose and no information on additional dosing is available. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. The case was reported as non serious by Regulatory authority. |
| 4.1(b) [redacted] | 4.1(b) [redacted] | This case was received via 4.1(b) [redacted] (Reference number: 4.1(b) [redacted]) on 23-Dec-2021 and was forwarded to Moderna on 23-Dec-2021.<br>This regulatory authority case was reported by a physician and describes the occurrence of CHILLS (rigors), MYALGIA (generalised muscle ache), |

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| | | MYOCARDITIS (Myocarditis), FATIGUE (Fatigue), CHEST PAIN (Chest Pain), PYREXIA (Fever), DYSPNOEA (Dyspnoea), PALPITATIONS (Palpitations) and SYNCOPE (Syncope) in a 29-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for COVID-19 vaccination.<br><br>No past medical history<br>Patient has not had symptoms associated with COVID-19.<br><br>On 19-Dec-2021, the patient received third dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 19-Dec-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criterion medically significant). On an unknown date, the patient experienced CHILLS (rigors) (seriousness criterion medically significant), MYALGIA (generalised muscle ache) (seriousness criterion medically significant), FATIGUE (Fatigue) (seriousness criterion medically significant), CHEST PAIN (Chest Pain) (seriousness criterion medically significant), PYREXIA (Fever) (seriousness criterion medically significant), DYSPNOEA (Dyspnoea) (seriousness criterion medically significant), PALPITATIONS (Palpitations) (seriousness criterion medically significant) and SYNCOPE (Syncope) (seriousness criterion medically significant). At the time of the report, CHILLS (rigors), MYALGIA (generalised muscle ache) and MYOCARDITIS (Myocarditis) had not resolved and FATIGUE (Fatigue), CHEST PAIN (Chest Pain), PYREXIA (Fever), DYSPNOEA (Dyspnoea), PALPITATIONS (Palpitations) and SYNCOPE (Syncope) outcome was unknown.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 20-Dec-2021, SARS-CoV-2 test: negative (Negative) No - Negative COVID-19 test.<br>On 22-Dec-2021, Troponin I (0-50): 3379 (Inconclusive) 3379.<br>On an unknown date, C-reactive protein: 31 (Inconclusive) 31.<br>On an unknown date, Chest X-ray: normal (normal) normal.<br>On an unknown date, Electrocardiogram: results not reported Results not reported.<br><br>The action taken with mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown) was unknown.<br><br>For mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown), the reporter did not provide any causality assessments.<br><br>No concomitant medication was provided by reporter.<br>In the source document patient stated Generalised muscle ache, left sided sharp chest pain, fever/rigors, SOB, palpitations. Patient has not tested positive for COVID-19 since having the vaccine. Does your report relate to possible myocarditis or pericarditis? If yes, we will ask you additional questions at the end of this report: "Yes" Suspect Reactions Please provide details of any relevant investigations or tests conducted: "Trop I 3379, CRP 31" Myocarditis and pericarditis What treatment was provided to the patient? For example, NSAIDs, steroids or other anti inflammatory agents "Ibuprofen " If the troponin was measured, please |

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| | | provide the date this was taken: "22/12/21" Was the cardiac troponin normal or raised? : "raised: 3379" What was the peak troponin: "3379" What was the troponin reference range?: "0-50 ng/L" If a Chest Xray was performed, please provide the date and results: "Normal" Was an Echocardiogram carried out?: "Unknown"<br><br>Company Comment: This is a regulatory case concerning a 29-year-old, male patient with no medical history, who experienced the expected serious AESI event of Myocarditis, expected serious event of Syncope and unexpected serious events of Chills, Malaise, Fatigue, Chest pain, Pyrexia, Dyspnoea and palpitations. The event Myocarditis occurred on the same day and all the other events occurred on an unknown date after the third dose of mRNA-1273 vaccine. Investigations like Troponin I, C-reactive protein are reported as Inconclusive, Chest X-ray is normal, and Electrocardiogram results not reported. The outcome of the events Myocarditis, chills and Malaise was reported as not resolved and other events outcome was reported as unknown. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.<br><br>Most recent FOLLOW-UP information incorporated above includes: On 24-Dec-2021: follow up received on 24Dec 2021 , added lab test :Troponin I , C-reactive protein. |
| 4.1(b) | 4.1(b) | This case was received via 4.1(b) (Reference number: 4.1(b) on 09-Nov-2021 and was forwarded to Moderna on 28-Dec-2021.<br>This regulatory authority case was reported by an other health care professional and describes the occurrence of CHEST DISCOMFORT (Chest discomfort), CHEST PAIN (Chest pain), ECHOCARDIOGRAM NORMAL (Echocardiogram normal), ELECTROCARDIOGRAM ST SEGMENT ELEVATION (Electrocardiogram ST segment elevation), EPISTAXIS (Epistaxis), HYPERTENSION (Hypertension), INFLAMMATION (Inflammation), NAUSEA (Nausea), RETCHING (Retching), SLEEP DISORDER (Sleep disorder), TACHYCARDIA (Tachycardia), TROPONIN INCREASED (Troponin increased), MYOCARDITIS (Myocarditis) and EXTRA DOSE ADMINISTERED (Extra dose administered) in a 29-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 035c21a) for an unknown indication.<br><br>The patient's past medical history included Psoriasis.<br><br>On 15-Oct-2021, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 19-Oct-2021, the patient experienced CHEST DISCOMFORT (Chest discomfort) (seriousness criterion hospitalization), CHEST PAIN (Chest pain) (seriousness criterion hospitalization), ECHOCARDIOGRAM NORMAL (Echocardiogram normal) (seriousness criterion hospitalization), ELECTROCARDIOGRAM ST SEGMENT ELEVATION (Electrocardiogram ST segment elevation) (seriousness criterion hospitalization), EPISTAXIS (Epistaxis) (seriousness criterion hospitalization), HYPERTENSION (Hypertension) (seriousness criterion hospitalization), INFLAMMATION (Inflammation) (seriousness criterion |

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| | | hospitalization), RETCHING (Retching) (seriousness criterion hospitalization), SLEEP DISORDER (Sleep disorder) (seriousness criterion hospitalization), TACHYCARDIA (Tachycardia) (seriousness criterion hospitalization), TROPONIN INCREASED (Troponin increased) (seriousness criterion hospitalization), MYOCARDITIS (Myocarditis) (seriousness criterion hospitalization) and EXTRA DOSE ADMINISTERED (Extra dose administered) (seriousness criterion hospitalization). 19-Oct-2021, the patient experienced NAUSEA (Nausea) (seriousness criterion hospitalization). At the time of the report, CHEST DISCOMFORT (Chest discomfort), CHEST PAIN (Chest pain), ECHOCARDIOGRAM NORMAL (Echocardiogram normal), ELECTROCARDIOGRAM ST SEGMENT ELEVATION (Electrocardiogram ST segment elevation), EPISTAXIS (Epistaxis), HYPERTENSION (Hypertension), INFLAMMATION (Inflammation), NAUSEA (Nausea), RETCHING (Retching), SLEEP DISORDER (Sleep disorder), TACHYCARDIA (Tachycardia), TROPONIN INCREASED (Troponin increased), MYOCARDITIS (Myocarditis) and EXTRA DOSE ADMINISTERED (Extra dose administered) outcome was unknown.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 19-Oct-2021, Electrocardiogram: normal (normal) WNL(Within normal limits).<br>On 19-Oct-2021, Troponin: 13,000 (High) Increased.<br>On 20-Oct-2021, Electrocardiogram: elevation (High) some degree of ST elevation in a fairly widespread distribution consistent with myopericarditis and normal (normal) WNL(Within normal limits).<br>On 20-Oct-2021, Troponin: 14,000 (High) Troponin rose further to 14,000 and 7000 (Low) dropped on morning of (10/20) to approximately 7,000.<br>On an unknown date, Echocardiogram: normal (normal) normal.<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments.<br><br>Other medications include Humira 40 mg/0.8 mL subcutaneous syringe kit inject 0.8 mL by subcutaneous route every 2 weeks in the abdomen or thigh (rotate sites) for an unknown indication.<br><br>Not able to copy Company Comment due to limited characters. DJG<br>This regulatory case concerns a 29-year-old, male patient with no relevant medical history reported, who experienced the expected, serious AESI of myocarditis and the unexpected, serious events of chest discomfort, chest pain, epistaxis, hypertension, inflammation, nausea, retching, sleep disorder, tachycardia; echocardiogram normal, electrocardiogram ST segment elevation, troponin increased and extra dose administered. The events, which resulted in hospitalization, occurred 4 days after administration of the booster dose of the Moderna mRNA-1273 vaccine. The patient was awoken at 4:00 am with chest pain (middle of the chest). He also experienced chest tightness, nausea and felt like vomiting, dry heaving along with bloody nose from dry heaving. He denied shortness of breath, pain traveling into arm, shoulder, ear, jaw, dizziness, cool moist skin and blue lips. He was advised to seek consult at the Emergency Room (ER). The patient presented at the ER on 19Oct2021. ECG done showed 'some degree of ST elevation in a fairly widespread |

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| | | distribution consistent with myopericarditis'. Troponin was elevated (13,000) which further increased (14,000) before it decreased (7,000) the following day. Impression were: 1) Acute myopericarditis. Likely referable to the recent booster dose of Moderna vaccine: The expected clinical course would be resolution. He was prescribed with anti-inflammatory agents for symptomatic treatment. The declining troponin levels and resolution of chest pain were encouraging for recovery. 2) Hypertensive disorder: The hypertension and tachycardia were suspected to be secondary to the underlying inflammatory condition which will resolve. The patient was prescribed with Metoprolol succinate 25 mg daily (which is likely to be discontinued at follow-up) and Ibuprofen 800 mg every 8 hours, as needed for recurrent chest pain. The patient was discharged on 20Oct2021 and was advised to return for follow-up in approximately 2 weeks for an Echocardiogram on the same day. The outcomes of the events were unknown at the time of the report. The rechallenge was not applicable as no additional dosing will be given. The patient's gender remains a confounder. The benefit-risk relationship of the Moderna mRNA-1273 vaccine is not affected by this report. |
| 4.1(b) | 4.1(b) | This case was received via United States FDA VAERS (Reference number: 4.1(b) on 09-Nov-2021 and was forwarded to Moderna on 28-Dec-2021.<br>This regulatory authority case was reported by an other health care professional and describes the occurrence of DEATH (Death), HYPERSENSITIVITY (Hypersensitivity), MYOCARDITIS (Myocarditis), PRURITUS (Pruritus) and SWELLING (Swelling) in a 33-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for an unknown indication.<br><br>The patient's past medical history included Cystic fibrosis.<br><br>On 04-Mar-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 20-Jul-2021, the patient experienced DEATH (Death) (seriousness criterion death), HYPERSENSITIVITY (Hypersensitivity) (seriousness criterion death), MYOCARDITIS (Myocarditis) (seriousness criteria death and medically significant), PRURITUS (Pruritus) (seriousness criterion death) and SWELLING (Swelling) (seriousness criterion death). The patient died on 26-Jul-2021. The reported cause of death was Hypersensitivity, Myocarditis, Pruritus and Swelling. It is unknown if an autopsy was performed.<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments.<br><br>It was reported that patient is having other medication for cystic fibrosis.<br><br>The patient went to the emergency room on 20-Jul-2021 with an allergic reaction. Later reported that patient had itching all over and there was swelling.<br><br>On 26-Jul-2021 patient died due to myocarditis. The cdc website reported a direct side effect of the moderna shot. |

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| | | Company comment:<br>This regulatory authority case concerns a 33-year-old female patient with relevant medical history of cystic fibrosis, who experienced the unexpected events of death, hypersensitivity, pruritus, swelling and expected AESI myocarditis. that occurred approximately 4.5 months after the 2nd dose of the mRNA-1273 . Reportedly, the patient went to the emergency room with an allergic reaction with symptoms of generalized itching and swelling. Six days later, the patient died due to myocarditis. No further details were provided. The rechallenge was not applicable due to occurrence after the 2nd dose and fatal outcome so , no rechallenge was done and recurrence was not applicable. The benefit-risk relationship of mRNA-1273 is not affected by this report. |
| 4.1(b) | 4.1(b) | This case was received via 4.1(b) (Reference number: 4.1(b) on 09-Nov-2021 and was forwarded to Moderna on 29-Dec-2021.<br>This regulatory authority case was reported by an other health care professional and describes the occurrence of ATRIAL FIBRILLATION (Atrial fibrillation), CARDIAC FAILURE CONGESTIVE (Cardiac failure congestive), DYSPNOEA (Dyspnoea) and MYOCARDITIS (Myocarditis) in a 34-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for an unknown indication.<br><br>The patient's past medical history included Testosterone deficiency (due to orchidectomy).<br><br>On 22-Oct-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 23-Oct-2021, the patient experienced ATRIAL FIBRILLATION (Atrial fibrillation) (seriousness criteria hospitalization and medically significant), CARDIAC FAILURE CONGESTIVE (Cardiac failure congestive) (seriousness criteria hospitalization and medically significant), DYSPNOEA (Dyspnoea) (seriousness criterion hospitalization) and MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, ATRIAL FIBRILLATION (Atrial fibrillation), CARDIAC FAILURE CONGESTIVE (Cardiac failure congestive), DYSPNOEA (Dyspnoea) and MYOCARDITIS (Myocarditis) outcome was unknown.<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments.<br><br>Other Meds included NOS energy drinks, testosterone injections<br>Symptom Text : A. fib c RVR, CHF, myocarditis. Diltiazem. Shipped to higher level of care. Sxs: SOB, CP.<br><br>Company comment: This case concerns a 34-year-old, male patient with medical history of testosterone deficiency, who experienced the unexpected events of atrial fibrillation, cardiac failure congestive and dyspnoea and expected event of myocarditis, which required hospitalization. The events occurred approximately 1 day after the second dose of mRNA-1273. Above mentioned medical history is a confounding factor. The benefit-risk relationship of mRNA-1273 is not affected by this report. Event seriousness assessed as per Regulatory Authority reporting. |