Case ID	WW Identifier	Narrative
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. This regulatory authority case was reported by a consumer and describes the occurrence of FATIGUE (Fatigue), PERIPHERAL SWELLING (Swollen arm), PALPITATIONS (Heart palpitations), TACHYCARDIA (Racing heart (tachycardia)) and MYOCARDITIS (Myocarditis) in a 36-year-old female patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) (batch no. 3005686) for COVID-19 vaccination. No Medical History information was reported. On 16-Dec-2021, the patient received third dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 17-Dec-2021, the patient experienced FATIGUE (Fatigue) (seriousness criterion medically significant) and PERIPHERAL SWELLING (Swollen arm) (seriousness criterion medically significant). On 21-Dec-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criterion medically significant). On an unknown date, the patient experienced PALPITATIONS (Heart palpitations) (seriousness criterion medically significant) and TACHYCARDIA (Racing heart (tachycardia)) (seriousness criterion medically significant). On 20-Dec-2021, PERIPHERAL SWELLING (Swollen arm) had resolved. At the time of the report, FATIGUE (Fatigue) and MYOCARDITIS (Myocarditis) was resolving and PALPITATIONS (Heart palpitations) and TACHYCARDIA (Racing heart (tachycardia)) outcome was unknown. No concomitant medications were reported. No treatment drug information was provided. Patient had not tested positive for COVID-19 since having the vaccine. Patient was not currently breastfeeding Patient was not enrolled in clinical trial. Patient's report relates to possible inflammation of the heart (myocarditis or pericarditis). Company Comment: This regulatory case concerns a 36-year-old, female patient with no medical history reported, who experienced the expected, serious AESI of myocarditis and the unexpected, serious events of fatigue, peripheral swelling, palpitations and tachycardia. The events fatigue and peripheral swelling occurred 1 day after administration of the third dose of the Moderna mRNA-1273 vaccine. The event myocarditis occurred 5 days after administration of the third dose of the Moderna mRNA-1273 vaccine. The start dates of the other events were not provided. Treatment information was also not provided. However, the event peripheral swelling had resolved at the time of the report. The events myocarditis and fatigue were resolving at the time of the report. The outcomes of the events palpitations and tachycardia were unknown at the time of the report. The benefit-risk relationship of the Moderna mRNA-1273 vaccine is not affected by this report.

Case ID	WW Identifier	Narrative
		Most recent FOLLOW-UP information incorporated above includes: On 30-Dec-2021: Follow-up received and included suspect coding, indication and Action taken with the suspect drug product were updated, Fatigue/tiredness event were removed.
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. This regulatory authority case was reported by a consumer and describes the occurrence of FATIGUE (Fatigue/unusual tiredness), CHEST PAIN (Chest pain), PYREXIA (Fever), DYSPNOEA (Shortness of breath), PALPITATIONS (Heart palpitations) and PERICARDITIS (Pericarditis) in a 28-year-old female patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for an unknown indication. No Medical History information was reported. On 20-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 PERICARDITIS (Pericarditis) (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), PYREXIA (Fever) (seriousness criteria hospitalization and medically significant), DYSPNOEA (Shortness of breath) (seriousness criteria hospitalization and medically significant) and PALPITATIONS (Heart palpitations) (seriousness criteria hospitalization and medically significant). At the time of the report, FATIGUE (Fatigue/unusual tiredness), CHEST PAIN (Chest pain), PYREXIA (Fever), DYSPNOEA (Shortness of breath) and PALPITATIONS (Heart palpitations) outcome was unknown and PERICARDITIS (Pericarditis) had not resolved. The action taken with mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown) was unknown. Patient has not had symptoms associated with COVID-19 and not had a COVID-19 test. Patient is not pregnant, Patient is not currently breastfeeding. No concomitant medication details was reported. Pericarditis was diagnosed in hospital urgent care. Patient has not tested positive for COVID-19 since having the vaccine. Patient is not enrolled in clinical trial. Patient said the report is related to possible inflammation of the heart (myocarditis or pericarditis). It was a diagnosis made by a medical professional who is a Urgent care doctor at hospital. Treatment medications include Naproxen and cocodamol.

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		Laboratory tests such as imaging carried out, but not limited to, chest X-ray, echocardiogram, cardiac MRI, chest computerised tomography. This is a regulatory case concerning a 28-year-old female patient with no reported medical history, who experienced the serious expected AESI event of pericarditis and serious per reported severity unexpected events of fatigue, chest pain, pyrexia, dyspnoea and palpitations. The event of pericarditis occurred on the next day after the third dose of mRNA-1273 vaccine administration and the events of fatigue, chest pain, pyrexia, dyspnoea and palpitations occurred on unknown date. The events were assessed as related to the product administration. The rechallenge was reported as unknown; however, could be considered as not applicable since the events occurred after the third dose and no further dosing is expected. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 24-Dec-2021: Follow up received contains non significant information.
4.1(b)	4.1(b)	This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b)) on 27-Dec-2021 and was forwarded to Moderna on 29-Dec-2021. 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 22-Oct-2021, the patient received the 2nd dose of this vaccine. On 23-Oct-2021, the patient was observed with pyrexia of 39 degrees Celsius, but it was decided to wait and see. On 24-Oct-2021, at 18:30, acute myocarditis developed. The patient was aware of chest pressure sensation at night. On 25-Oct-2021, chest pressure sensation was aggravated and the patient visited a previous physician. On 26-Oct-2021, although the patient was scheduled to be referred to the initial visit outpatient of the reporting hospital in the morning, the patient visited the emergency department due to a flare-up of chest pain. The patient was diagnosed with findings that are no different myocarditis based on electrocardiogram changes and elevated cardiac enzymes and was hospitalized. On 27-Oct-2021, coronary angiography, right heart catheterization, and myocardial biopsy were performed to confirm the absence of coronary artery disease. Then resolving was done by symptomatic therapy with antipyretic analgesics. On 01-Nov-2021. the patient was discharged from the hospital because of resolving symptoms. The results of the myocardial biopsy showed obvious diagnostic criteria for inflammatory cells, but edematous changes were observed. Considering his age, it was diagnosed as possible inflammation. Virus tests were also performed, but there was no obvious suspicion. The outcome of acute myocarditis was reported as resolving. Follow-up investigation will be made.

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		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 4.1(b) (Reference number: 4.1(b) on 09-Nov-2021 and was forwarded to Moderna on 29-Dec-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of BLOOD TEST ABNORMAL (Blood test abnormal), CHEST PAIN (Chest pain), COMPUTERISED TOMOGRAM NORMAL (Computerised tomogram normal), PERICARDITIS (Pericarditis) and ULTRASOUND SCAN ABNORMAL (Ultrasound scan abnormal) in a 34-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 032F21A) for an unknown indication. No Medical History information was reported. On 23-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 BLOOD TEST ABNORMAL (Blood test abnormal), CHEST PAIN (Chest pain), COMPUTERISED TOMOGRAM NORMAL (Computerised tomogram normal), PERICARDITIS (Pericarditis) and ULTRASOUND SCAN ABNORMAL (Ultrasound scan abnormal). At the time of the report, BLOOD TEST ABNORMAL (Blood test abnormal), CHEST PAIN (Chest pain), COMPUTERISED TOMOGRAM NORMAL (Computerised tomogram normal), PERICARDITIS (Pericarditis) and ULTRASOUND SCAN ABNORMAL (Ultrasound scan abnormal) had resolved. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Concomitant product use was not provided by the reporter. No treatment information was provided. Patient experienced extreme chest pain on the left chest around the heart starting on the evening of 2nd dose vaccine and continued into the following day. The doctor at the emergency room conducted an ultra sound to see around the heart. Excess fluid around the heart indicating inflammation of the lining of the heart. Blood test results were elevated so CT scans were conducted to verify if any blood clots around the heart were present. CT scans show no signs of blood clot. Anti-inflammation medication was administer via IV and prescribed for treatment. Company Comment: This case concerns a 34-year old, male subject with unknown medical history, who experienced the unexpected event of Chest pain and the expected event of Pericarditis(AESI). The events occurred on the same day after the second dose of mRNA1273 vaccine. According to the patient, there was extreme chest pain on the left chest around the heart starting on the evening of 2nd dose vaccine and continued into the following day. This prompted an emergency room visit where an ultrasound around the heart was done. The result showed excess fluid around the heart indicating inflammation of the lining of the heart. Unspecified blood test results were elevated so CT scans were

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		done, with normal findings (no blood clots around the heart). Anti-inflammatory medication was administer via IV and prescribed as treatment. At the time of the report, all the events were resolved. The patient's age and gender, which are associated with a higher incidence of Pericarditis, remain as confounders. The benefit-risk relationship of mRNA1273 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 28-Dec-2021 and was forwarded to Moderna on 28-Dec-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCARDITIS (Myocarditis) and TROPONIN INCREASED (Troponin increased) in a 26-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for an unknown indication. The patient's past medical history included Kidney stones. On 07-Dec-2021, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 10-Dec-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant) and TROPONIN INCREASED (Troponin increased) (seriousness criterion hospitalization). At the time of the report, MYOCARDITIS (Myocarditis) and TROPONIN INCREASED (Troponin increased) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 11-Dec-2021, Troponin: results not reported (Inconclusive) Results not reported. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medication reported. No treatment information was provided. COMPANY COMMENT: This is a regulatory case concerning a 26-year-old male patient with clinical history of Nephrolithiasis who experienced the expected event of Myocarditis (AESI) and the unexpected event of Troponin increased The events occurred 4 days after 3rd dose of mRNA-1273. The rechallenge was not applicable since only information about 3rd dose was disclosed The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Event terms, seriousness and onset dates were captured as provided by the Regulatory Authority
4.1(b)	4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b) on 28-Dec-2021 and was forwarded to Moderna on 28-Dec-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of ELECTROCARDIOGRAM T WAVE INVERSION (Electrocardiogram T wave inversion), PERICARDIAL EFFUSION (Pericardial effusion), MYOCARDITIS

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		(Myocarditis), CHEST PAIN (Chest pain) and ECHOCARDIOGRAM (Echocardiogram) in a 35-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. The patient's past medical history included Renal cell carcinoma (Resected Renal Cell Carcinoma in remission without active treatment.). Concurrent medical conditions included Drug allergy (Vancomycin - Itching) and Drug allergy (Morphine - Itching). On 11-Dec-2021, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 13-Dec-2021, the patient experienced ELECTROCARDIOGRAM T WAVE INVERSION (Electrocardiogram T wave inversion), PERICARDIAL EFFUSION (Pericardial effusion), MYOCARDITIS (Myocarditis), CHEST PAIN (Chest pain), ECHOCARDIOGRAM (Echocardiogram), ELECTROCARDIOGRAM (Electrocardiogram), FLANK PAIN (Flank pain), HYPERHIDROSIS (Hyperhidrosis), PAIN (Pain), TROPONIN (Troponin) and VOMITING (Vomiting). At the time of the report, ELECTROCARDIOGRAM T WAVE INVERSION (Electrocardiogram T wave inversion), PERICARDIAL EFFUSION (Pericardial effusion), MYOCARDITIS (Myocarditis), CHEST PAIN (Chest pain), ECHOCARDIOGRAM (Echocardiogram), ELECTROCARDIOGRAM (Electrocardiogram), FLANK PAIN (Flank pain), HYPERHIDROSIS (Hyperhidrosis), PAIN (Pain), TROPONIN (Troponin) and VOMITING (Vomiting) outcome was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Other medications included Testosterone and Adderall. At 48 hours on 13-Dec-2021, the patient developed left sided flank pain. Progressed to severe sub-sternal chest pain on 15-Dec-2021 prompting emergency department visit. Chest pain radiated to neck, worse with deep inspiration, relieved with sitting forward. Chest pain associated with diaphoresis and vomiting secondary to pain. Electrocardiogram changes new T wave inversions V4-V6, and I and II Bedside echo without clinically significant effusion. Troponin negative twice 2 and discharged home with presumptive diagnosis of pericarditis or myocarditis. No treatment medication was provided.
4.1(b)	4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b) on 28-Dec-2021 and was forwarded to Moderna on 28-Dec-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCARDITIS (Myocarditis) in a 32-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for an unknown indication. No Medical History information was reported.

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		On 12-Sep-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 12-Sep-2021, received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 14-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) had not resolved. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medications were reported. It was reported that patient had 1 ER visit, multiple doctor visits, and cardiologist finally told him it was myocarditis. Patient was treated for Myocarditis due to Moderna COVID-19 vaccine. No treatment medications were reported.
4.1(b)	4.1(b)	This case was initially received via 4.1(b) (Reference number: 4.1(b) on 28-Dec-2021. The most recent information was received on 28-Dec-2021 and was forwarded to Moderna on an unknown date. This regulatory authority case was reported by an other health care professional and describes the occurrence of CHEST PAIN (Chest pain), DISORIENTATION (Disorientation), DYSPNOEA (Dyspnoea), HEPATIC ENZYME ABNORMAL (Hepatic enzyme abnormal) and HYPERHIDROSIS (Hyperhidrosis) in a 32-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 939904) for an unknown indication. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 24-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), DISORIENTATION (Disorientation), DYSPNOEA (Dyspnoea), HEPATIC ENZYME ABNORMAL (Hepatic enzyme abnormal), HYPERHIDROSIS (Hyperhidrosis), IMPAIRED WORK ABILITY (Impaired work ability), SYNCOPE (Syncope), PERICARDITIS (Pericarditis) and NAUSEA (Nausea). At the time of the report, CHEST PAIN (Chest pain), DISORIENTATION (Disorientation), DYSPNOEA (Dyspnoea), HEPATIC ENZYME ABNORMAL (Hepatic enzyme abnormal), HYPERHIDROSIS (Hyperhidrosis), IMPAIRED WORK ABILITY (Impaired work ability), SYNCOPE (Syncope), PERICARDITIS (Pericarditis) and NAUSEA (Nausea) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Hepatic enzyme: high (High) Had high liver enzymes on 10/08 1; 10/10..

Case ID	WW Identifier	Narrative
		For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. No Concomitant and Treatment medication were reported. On 01-Dec-2021 She woke up with intense chest pain and short breath. she started sweating, felt nauseous, became disoriented and fainted. her partner called 911 and an ambulance took her to the ER. she saw a cardiologist on 12/10 1; it was seen through ultrasound that she has pericarditis. she was currently at home taking medication as prescribed; she unable to work or do much physical activity. Company comment: This case concerns a 32-year-old female patient with no medical history, who experienced the expected event of special interest, Pericarditis, as well as non-serious unexpected events of Chest pain, Disorientation, Dyspnoea, Hepatic enzyme abnormal, Hyperhidrosis, Impaired work ability, Syncope, as well as expected non-serious event of Nausea. The events occurred 7 days after receiving the third dose of mRNA-1273 Vaccine. The patient woke up with intense chest pain and shortness of breath. She started sweating, felt nauseous, became disoriented and fainted. The patient visited emergency department and a cardiologist. An ultrasound showed pericarditis. At the time of this report, the events were still ongoing, and the patient was taking prescribed medication (at home) and was unable to work or do much physical activity. The re-challenge is not applicable since the events occurred after the third dose of the mRNA-1273 vaccine. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report. The events were assessed as non-serious as per Regulatory Authority reporting and were kept as such. Most recent FOLLOW-UP information incorporated above includes: On 28-Dec-2021: Upon internal Review on 10-JAN-2022, Significant correction was made to update expectedness of the event Pericarditis in company comment.
4.1(b)	4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b)) on 24-Dec-2021 and was forwarded to Moderna on 24-Dec-2021. This regulatory authority case was reported by a physician and describes the occurrence of INFLUENZA LIKE ILLNESS (flu like symptoms), PERICARDITIS (Pericarditis), CHEST PAIN (Chest Pain), PYREXIA (Fever), DYSPNOEA (Dyspnoea), SYNCOPE (Syncope) and HYPOAESTHESIA (Numbness of limbs) in a 29-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for COVID-19 vaccination. TMJ dysfunction TB when younger Patient has not had symptoms associated with COVID-19. The patient's past medical history included TMJ syndrome (TMJ dysfunction) and TB (TB when younger). Concomitant products included TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) and TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) for COVID-19 vaccination.

Case ID	WW Identifier	Narrative
		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, after starting mRNA-1273 (Moderna CoviD-19 Vaccine), the patient experienced PERICARDITIS (Pericarditis) (seriousness criteria hospitalization, disability and medically significant). On an unknown date, the patient experienced INFLUENZA LIKE ILLNESS (flu like symptoms) (seriousness criteria hospitalization and disability), CHEST PAIN (Chest Pain) (seriousness criteria hospitalization and disability), PYREXIA (Fever) (seriousness criteria hospitalization and disability), DYSPNOEA (Dyspnoea) (seriousness criteria hospitalization and disability), SYNCOPE (Syncope) (seriousness criteria hospitalization, disability and medically significant) and HYPOAESTHESIA (Numbness of limbs) (seriousness criteria hospitalization and disability). At the time of the report, INFLUENZA LIKE ILLNESS (flu like symptoms) had not resolved, PERICARDITIS (Pericarditis) was resolving and CHEST PAIN (Chest Pain), PYREXIA (Fever), DYSPNOEA (Dyspnoea), SYNCOPE (Syncope) and HYPOAESTHESIA (Numbness of limbs) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 22-Dec-2021, Electrocardiogram: normal (normal) Normal. On 22-Dec-2021, SARS-CoV-2 test: negative (Negative) No - Negative COVID-19 test. On 22-Dec-2021, Troponin: 3000 (abnormal) 3000. For mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. The patient experienced Chest pain/left arm numbness, Flu like symptoms. Some subjective shortness of breath (SOB). Rise in troponin to 3000. Settling with NSAIDs. The patient's report was related to possible myocarditis or pericarditis. The patient was hospitalized for 2 days. The patient seen by a cardiologist and diagnosed with Myopericarditis. The patient received treatment Aspirin/Colchicine/PPI. Company comment:This RA case concerns a male patient of 29 years with medical history of Interchange of vaccine products (was with 2 doses of TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) before current vaccination) and past medical history of TMJ syndrome and TB, who experienced the unexpected serious events of Pericarditis, Influenza like illness, Chest pain, Pyrexia, Dyspnea Syncope and Hypoesthesia (Hospitalization and Disability). The event Pericarditis occurred same day after the third dose of mRNA1273 vaccine. The events Influenza like illness, Chest pain, Dyspnea, Hypoesthesia, Pyrexia and Syncope occurred on unknown date after the third dose of mRNA1273 vaccine. Reportedly, SARS-CoV-test Negative Troponin: 3000 (abnormal)and Electrocardiogram was normal (22 Dec 2021). The outcome was reported not recovered for Influenza like illness, resolving for Pericarditis and unknown for other events. The Interchange of vaccine products remains a confounder. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report.

Case ID	WW Identifier	Narrative
		Most recent FOLLOW-UP information incorporated above includes: On 24-Dec-2021: Fu received on 26-DEC-2021. Lab data updated, AT/DC updated. Indication for con-meds updated.
4.1(b)	4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b) on 28-Dec-2021 and was forwarded to Moderna on 28-Dec-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of PERICARDITIS (Pericarditis), PNEUMONIA (Pneumonia), CHEST PAIN (Chest pain), CHEST DISCOMFORT (Chest discomfort) and PAIN (Pain) in a 32-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 006C21A) for an unknown indication. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 03-Dec-2021, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 06-Dec-2021, the patient experienced PERICARDITIS (Pericarditis), PNEUMONIA (Pneumonia), CHEST PAIN (Chest pain), CHEST DISCOMFORT (Chest discomfort), PAIN (Pain), CHEST X-RAY ABNORMAL (Chest X-ray abnormal) and ELECTROCARDIOGRAM (Electrocardiogram). At the time of the report, PERICARDITIS (Pericarditis), PNEUMONIA (Pneumonia), CHEST PAIN (Chest pain), CHEST DISCOMFORT (Chest discomfort), PAIN (Pain), CHEST X-RAY ABNORMAL (Chest X-ray abnormal) and ELECTROCARDIOGRAM (Electrocardiogram) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 07-Dec-2021, Chest X-ray: abnormal (abnormal) found minimal traces of Pneumonia. On 07-Dec-2021, Electrocardiogram: result not provided Result not provided. On 09-Dec-2021, Electrocardiogram: abnormal (abnormal) without much concern- Dr states he saw something that may be related to Pericarditis. On 10-Dec-2021, Chest X-ray: result not provided Result not provided. On 10-Dec-2021, Electrocardiogram: result not provided Result not provided. On an unknown date, Laboratory test: ruled out blood clots and am currently on naproxen Ruled out Blood clots and am currently on Naproxen 375 MG for the pain. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Other Medications: d-amphetamine er 15mg salt combo cp. Pressure/pain in the Left side of chest around heart, Increases in pressure/pain with physical activity. Increased pressure in the morning but subsides during the day/night. Dull pain that was inconsistent and varies throughout the day but was always constant at a 1-2 / 10 for pressure/pain.

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		No treatment information and concomitant were provided by the reporter. This case concerns a 32-year-old male patient with no medical history, who experienced the unexpected non-serious events of Pneumonia, Chest Discomfort, Chest Pain, and expected non-serious adverse event of special interest, Pericarditis. The events occurred 3 days after receiving the third dose of mRNA-1273 Vaccine. The rechallenge was reported as not applicable by the regulatory authority. No clinical or treatment details were given. It was reported that the events had not resolved. 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 27-Dec-2021. The most recent information was received on 09-Jan-2022 and was forwarded to Moderna on 09-Jan-2022. This regulatory authority case was reported by a consumer and describes the occurrence of CHEST PAIN (Chest pain), DYSPNOEA (Shortness of breath), FATIGUE (Fatigue/unusual tiredness), SYNCOPE (Fainting) and PERICARDITIS (Pericarditis) in a 40-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) (batch no. 3004737) for COVID-19 vaccination. Patient has not had symptoms associated with COVID-19. The patient's past medical history included Heart murmur (I have a heart murmurs.). Concurrent medical conditions included Asthma. On 16-Dec-2021, the patient received third dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 18-Dec-2021, the patient experienced PERICARDITIS (Pericarditis) (seriousness criteria hospitalization and medically significant). On an unknown date, the patient experienced CHEST PAIN (Chest pain) (seriousness criteria hospitalization and medically significant), DYSPNOEA (Shortness of breath) (seriousness criteria hospitalization and medically significant), FATIGUE (Fatigue/unusual tiredness) (seriousness criteria hospitalization and medically significant) and SYNCOPE (Fainting) (seriousness criteria hospitalization and medically significant). At the time of the report, CHEST PAIN (Chest pain), DYSPNOEA (Shortness of breath), FATIGUE (Fatigue/unusual tiredness), SYNCOPE (Fainting) and PERICARDITIS (Pericarditis) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 06-Nov-2021, SARS-CoV-2 test: negative (Negative) No - Negative COVID-19 test. On an unknown date, Blood test: result not reported Result not reported. On an unknown date, Electrocardiogram: result not reported Result not reported. The patient went to the accident and emergency during the night of 18/19 December.

Case ID	WW Identifier	Narrative
		The patient was diagnosticated a pericaditis. Doctor prescribed him treatment 7 days of 500mg of naproxen. The symptoms did not lead to a hospital stay. Diagnosis was made by a medical professional Doctor in Accident and emergency. Patient has not tested positive for COVID-19 since having the vaccine.Patient was not enrolled in clinical trial. The report was related to possible inflammation of the heart (myocarditis or pericarditis). Imaging carried out such as, chest X-ray, echocardiogram, cardiac MRI, chest computerised tomography (CT) but results were not specified. It was unknown if Blood tests, such as for certain proteins (called troponin) that signal heart muscle damage taken. Patient has not had symptoms associated with COVID-19. No concomitant medication details was provided. Company comment:This regulatory authority case concerns a 40-year-old male patient with a medical history of Asthma and Cardiac murmur, who experienced the unexpected serious events of Syncope, Fatigue, Chest pain, Dyspnoea and the expected serious event of Pericarditis after mRNA- 1273 Moderna vaccine. The events Syncope, Fatigue, Chest pain, Dyspnoea occurred on an unknown date after the third dose of mRNA- 1273 vaccine (dosage unknown). Pericarditis was diagnosed 2 days after the third dose of the vaccine. The patient went to the emergency department and stayed during the night, treatment included naproxen for 7 days. Diagnostic work-up was said to be done, but no further information provided. The patient's history of asthma and cardiac murmur remain as confounders to the events.. The benefit-risk relationship of mRNA- 1273 vaccine is not affected by this report. Patient was recovered from the events after 2 weeks and half with the treatment of 500mg of naproxen. Most recent FOLLOW-UP information incorporated above includes: On 09-Jan-2022: Significant Follow Up appended and lab test, event outcomes were 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. This regulatory authority case was reported by a physician and describes the occurrence of CHEST PAIN (Chest Pain), PALPITATIONS (Palpitations), TACHYCARDIA (Tachycardia), LEFT VENTRICULAR DYSFUNCTION (Left ventricular dysfunction) and MYOCARDITIS (Myocarditis) in a 21-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for COVID-19 immunisation. Concomitant products included TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) from 25-Jun-2021 to an unknown date and TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) from 25-Jun-2021 to 03-Sep-2021 for COVID-19 immunisation. On 20-Dec-2021, the patient received third dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 22-Dec-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criterion medically significant). On an unknown date, the

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		patient experienced CHEST PAIN (Chest Pain) (seriousness criterion medically significant), PALPITATIONS (Palpitations) (seriousness criterion medically significant), TACHYCARDIA (Tachycardia) (seriousness criterion medically significant) and LEFT VENTRICULAR DYSFUNCTION (Left ventricular dysfunction) (seriousness criterion medically significant). At the time of the report, CHEST PAIN (Chest Pain), PALPITATIONS (Palpitations), TACHYCARDIA (Tachycardia) and LEFT VENTRICULAR DYSFUNCTION (Left ventricular dysfunction) outcome was unknown and MYOCARDITIS (Myocarditis) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 22-Dec-2021, SARS-CoV-2 test: negative (Negative) No - Negative COVID-19 test. On 22-Dec-2021, Troponin: 490 (normal) Troponin 490. On 23-Dec-2021, Troponin: 833 level raised (High) 833 level raised. On 24-Dec-2021, Magnetic resonance imaging heart: myocarditis with oedema and subepicardial enhancem (abnormal) Myocarditis with oedema and subepicardial enhancem. On an unknown date, Chest X-ray: result not reported Result not reported. On an unknown date, Echocardiogram: nomal (normal) Echocardiogram normal. On an unknown date, Electrocardiogram: sinus tachycardia on telemetry " (abnormal) Sinus tachycardia on telemetry ". For mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Patient reported that he experienced Chest pain, Myocarditis, Palpitations and Tachycardia. Patient had vaccine on Sunday. On Wednesday had chest pains waking him up at nigh. Presented with raised troponins 400 more than 800. This report was related to possible myocarditis or pericarditis. MRI confirmed myocarditis with mild LV impairment. Patient was admitted to hospital for 2 days and still ongoing. Ibuprofen was used as treatment for the patient. Troponin was measured on 22-Dec-2021 was 490 and on 23-Dec-2021 was 833. Cardiac troponin was raised. 851 was the peak troponin value. ECG was carried out and result was sinus tachycardia on telemetry. Patient had not tested positive for COVID-19 since having the vaccine. Patient had not had symptoms associated with COVID-19. Patient was not enrolled in clinical trial. No treatment medication were reported. Company Comment - This case concerns a 21 year old male patient with no relevant medical history, who experienced the serious (medically significant) unexpected events of chest pain, palpitations, tachycardia, left ventricular dysfunction .and the expected event of myocarditis. The event myocarditis occurred 2 days after the third dose of mRNA-1273 vaccine, the other events occurred on an unknown date after the third dose of mRNA-1273 vaccine. The rechallenge was not applicable as there are no

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		plans for future dosing. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 30-Dec-2021: Follow up received Suspect product, Indication, Event updated.
4.1(b)	4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b) on 28-Dec-2021 and was forwarded to Moderna on 28-Dec-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of BLOOD POTASSIUM DECREASED (Blood potassium decreased), CARDIAC TELEMETRY (Cardiac telemetry), CHEST DISCOMFORT (Chest discomfort), CHEST PAIN (Chest pain), DIFFERENTIAL WHITE BLOOD CELL COUNT (Differential white blood cell count), ECHOCARDIOGRAM (Echocardiogram), ELECTROCARDIOGRAM NORMAL (Electrocardiogram normal), FIBRIN D DIMER NORMAL (Fibrin D dimer normal), FULL BLOOD COUNT (Full blood count), HYPOKALAEMIA (Hypokalaemia), LABORATORY TEST ABNORMAL (Laboratory test abnormal), NAUSEA (Nausea), SLEEP DISORDER (Sleep disorder), TROPONIN INCREASED (Troponin increased) and MYOCARDITIS (Myocarditis) in a 21-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for an unknown indication. Concurrent medical conditions included Penicillin allergy. On 10-Dec-2021, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 12-Dec-2021, the patient experienced BLOOD POTASSIUM DECREASED (Blood potassium decreased) (seriousness criterion hospitalization), CARDIAC TELEMETRY (Cardiac telemetry) (seriousness criterion hospitalization), CHEST DISCOMFORT (Chest discomfort) (seriousness criterion hospitalization), CHEST PAIN (Chest pain) (seriousness criterion hospitalization), DIFFERENTIAL WHITE BLOOD CELL COUNT (Differential white blood cell count) (seriousness criterion hospitalization), ECHOCARDIOGRAM (Echocardiogram) (seriousness criterion hospitalization), ELECTROCARDIOGRAM NORMAL (Electrocardiogram normal) (seriousness criterion hospitalization), FIBRIN D DIMER NORMAL (Fibrin D dimer normal) (seriousness criterion hospitalization), FULL BLOOD COUNT (Full blood count) (seriousness criterion hospitalization), HYPOKALAEMIA (Hypokalaemia) (seriousness criterion hospitalization), LABORATORY TEST ABNORMAL (Laboratory test abnormal) (seriousness criterion hospitalization), NAUSEA (Nausea) (seriousness criterion hospitalization), SLEEP DISORDER (Sleep disorder) (seriousness criterion hospitalization), TROPONIN INCREASED (Troponin increased) (seriousness criterion hospitalization) and MYOCARDITIS (Myocarditis) (seriousness criterion hospitalization). At the time of the report, BLOOD POTASSIUM DECREASED (Blood potassium decreased), CARDIAC TELEMETRY (Cardiac telemetry), CHEST DISCOMFORT (Chest discomfort), CHEST PAIN (Chest pain), DIFFERENTIAL WHITE BLOOD CELL COUNT (Differential white blood cell count), ECHOCARDIOGRAM (Echocardiogram), ELECTROCARDIOGRAM NORMAL (Electrocardiogram normal), FIBRIN

Case ID	WW Identifier	Narrative
		D DIMER NORMAL (Fibrin D dimer normal), FULL BLOOD COUNT (Full blood count), HYPOKALAEMIA (Hypokalaemia), LABORATORY TEST ABNORMAL (Laboratory test abnormal), NAUSEA (Nausea), SLEEP DISORDER (Sleep disorder), TROPONIN INCREASED (Troponin increased) and MYOCARDITIS (Myocarditis) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 13-Dec-2021, Blood potassium: 3.4 (Low) Chem panel - K = 3.4 (low). On 13-Dec-2021, Cardiac telemetry: 60-65% (Low) 60-65%. On 13-Dec-2021, Ejection fraction: 60-65 ECHO -LVEF 60-65%. On 13-Dec-2021, Electrocardiogram: normal (normal) normal. On 13-Dec-2021, Fibrin D dimer: 0.33 0.33. On 13-Dec-2021, Full blood count: results not reported CBC w/ diff. On 13-Dec-2021, Troponin: 4396 (High) 4396 pg/mL and 3377.4 1 3377.4 1. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Patient had hives. Other medications included creatine powder, occasional ibuprofen use. No treatment drug reported. College student received Moderna booster on 12/10/21. He had got his 2 dose series with Pfizer initially. He flew on the 12/11 or 12/12. He began experiencing mild diffuse anterior chest discomfort on 12/12 3PM. At 3:30AM on 12/13, he was awakened from sleep with severe diffuse anterior chest pain, non-radiating. He had associated nausea without vomiting. He sought care in the ER where he was given morphine and ondansetron that improved his symptoms. He was admitted for myocarditis and mild hypokalemia. This is a regulatory case concerning a 21-year-old male patient with relevant medical history of drug hypersensitivity, who experienced the serious expected AESI event of myocarditis and serious unexpected events of blood potassium decreased, cardiac telemetry, chest discomfort, chest pain, differential white blood cell count, echocardiogram, electrocardiogram normal, fibrin D dimer normal, full blood count, hypokalaemia, laboratory test abnormal, nausea, sleep disorder, troponin increased. The events occurred 3 days after the third dose of mRNA-1273 vaccine administration. The events were assessed as related to the product administration. The rechallenge was not applicable since the events occurred after the third dose and no further dosing is expected. The medical history of drug hypersensitivity considered 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 28-Dec-2021 and was forwarded to Moderna on 28-Dec-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of CARDIOMYOPATHY (Cardiomyopathy), CATHETERISATION CARDIAC ABNORMAL (Catheterisation cardiac abnormal), CHEST PAIN (Chest pain), ECHOCARDIOGRAM (Echocardiogram), EJECTION FRACTION

Case ID	WW Identifier	Narrative
		(Ejection fraction), ELECTROCARDIOGRAM ST SEGMENT ELEVATION (Electrocardiogram ST segment elevation), TROPONIN INCREASED (Troponin increased), VACCINATION COMPLICATION (Vaccination complication) and MYOCARDITIS (Myocarditis) in a 23-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for an unknown indication. No Medical History information was reported. On 10-Dec-2021, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 10-Dec-2021, the patient experienced CARDIOMYOPATHY (Cardiomyopathy) (seriousness criteria hospitalization, medically significant and life threatening), CATHETERISATION CARDIAC ABNORMAL (Catheterisation cardiac abnormal) (seriousness criteria hospitalization and life threatening), CHEST PAIN (Chest pain) (seriousness criteria hospitalization and life threatening), ECHOCARDIOGRAM (Echocardiogram) (seriousness criteria hospitalization and life threatening), EJECTION FRACTION (Ejection fraction) (seriousness criteria hospitalization and life threatening), ELECTROCARDIOGRAM ST SEGMENT ELEVATION (Electrocardiogram ST segment elevation) (seriousness criteria hospitalization, medically significant and life threatening), TROPONIN INCREASED (Troponin increased) (seriousness criteria hospitalization and life threatening), VACCINATION COMPLICATION (Vaccination complication) (seriousness criteria hospitalization and life threatening) and MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization, medically significant and life threatening). At the time of the report, CARDIOMYOPATHY (Cardiomyopathy), CATHETERISATION CARDIAC ABNORMAL (Catheterisation cardiac abnormal), CHEST PAIN (Chest pain), ECHOCARDIOGRAM (Echocardiogram), EJECTION FRACTION (Ejection fraction), ELECTROCARDIOGRAM ST SEGMENT ELEVATION (Electrocardiogram ST segment elevation), TROPONIN INCREASED (Troponin increased), VACCINATION COMPLICATION (Vaccination complication) and MYOCARDITIS (Myocarditis) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Catheterisation cardiac: negative for obstruction (Negative) negative for obstruction. On an unknown date, Echocardiogram: 45% Echocardiogram with EF of 45%. On an unknown date, Troponin: 18 Peaked. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medications were reported. No treatment medications were reported. Soon after receiving vaccine, patient developed severe chest pain. Sought care at the hospital, noted ST elevation. Urgent cardiac catheterization and echocardiogram showed Myopericarditis with

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		cardiomyopathy due to Moderna booster vaccine and was hospitalized for 3 days. Company Comment: This case concerns a 23 year-old male patient with no reported medical history who experienced the unexpected serious adverse events of special interest of cardiomyopathy and myocarditis, and the unexpected serious events of chest pain and vaccination complication which occurred 1 day after vaccination with mRNA-1273 administered as a third dose. 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 28-Dec-2021 and was forwarded to Moderna on 28-Dec-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of CHEST PAIN (Chest pain), ANTICOAGULANT THERAPY (Anticoagulant therapy), BLOOD CREATINE PHOSPHOKINASE MB (Blood creatine phosphokinase MB), BLOOD CREATINE PHOSPHOKINASE ABNORMAL (Blood creatine phosphokinase abnormal), C-REACTIVE PROTEIN ABNORMAL (C-reactive protein abnormal), CHEST X-RAY (Chest X-ray), DIFFERENTIAL WHITE BLOOD CELL COUNT ABNORMAL (Differential white blood cell count abnormal), ECHOCARDIOGRAM (Echocardiogram), ELECTROCARDIOGRAM (Electrocardiogram), FIBRIN D DIMER INCREASED (Fibrin D dimer increased), FULL BLOOD COUNT ABNORMAL (Full blood count abnormal), INFLUENZA A VIRUS TEST (Influenza A virus test), INFLUENZA B VIRUS TEST (Influenza B virus test), LABORATORY TEST ABNORMAL (Laboratory test abnormal), N-TERMINAL PROHORMONE BRAIN NATRIURETIC PEPTIDE ABNORMAL (N-terminal prohormone brain natriuretic peptide abnormal), SARS-COV-2 TEST (SARS-CoV-2 test), TROPONIN I ABNORMAL (Troponin I abnormal) and MYOCARDITIS (Myocarditis) in a 31-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 069H21A) for an unknown indication. No Medical History information was reported. On 04-Dec-2021, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 09-Dec-2021, the patient experienced CHEST PAIN (Chest pain) (seriousness criterion hospitalization), ANTICOAGULANT THERAPY (Anticoagulant therapy) (seriousness criterion hospitalization), BLOOD CREATINE PHOSPHOKINASE MB (Blood creatine phosphokinase MB) (seriousness criterion hospitalization), BLOOD CREATINE PHOSPHOKINASE ABNORMAL (Blood creatine phosphokinase abnormal) (seriousness criterion hospitalization), C-REACTIVE PROTEIN ABNORMAL (C-reactive protein abnormal) (seriousness criterion hospitalization), CHEST X-RAY (Chest X-ray) (seriousness criterion hospitalization), DIFFERENTIAL WHITE BLOOD CELL COUNT ABNORMAL (Differential white blood cell count abnormal) (seriousness criterion hospitalization), ECHOCARDIOGRAM (Echocardiogram) (seriousness criterion hospitalization), ELECTROCARDIOGRAM (Electrocardiogram) (seriousness criterion hospitalization), FIBRIN D DIMER INCREASED (Fibrin D dimer increased) (seriousness criterion

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		hospitalization), FULL BLOOD COUNT ABNORMAL (Full blood count abnormal) (seriousness criterion hospitalization), INFLUENZA A VIRUS TEST (Influenza A virus test) (seriousness criterion hospitalization), INFLUENZA B VIRUS TEST (Influenza B virus test) (seriousness criterion hospitalization), LABORATORY TEST ABNORMAL (Laboratory test abnormal) (seriousness criterion hospitalization), N-TERMINAL PROHORMONE BRAIN NATRIURETIC PEPTIDE ABNORMAL (N-terminal prohormone brain natriuretic peptide abnormal) (seriousness criterion hospitalization), SARS-COV-2 TEST (SARS-CoV-2 test) (seriousness criterion hospitalization), TROPONIN I ABNORMAL (Troponin I abnormal) (seriousness criterion hospitalization) and MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, CHEST PAIN (Chest pain), ANTICOAGULANT THERAPY (Anticoagulant therapy), BLOOD CREATINE PHOSPHOKINASE MB (Blood creatine phosphokinase MB), BLOOD CREATINE PHOSPHOKINASE ABNORMAL (Blood creatine phosphokinase abnormal), C-REACTIVE PROTEIN ABNORMAL (C-reactive protein abnormal), CHEST X-RAY (Chest X-ray), DIFFERENTIAL WHITE BLOOD CELL COUNT ABNORMAL (Differential white blood cell count abnormal), ECHOCARDIOGRAM (Echocardiogram), ELECTROCARDIOGRAM (Electrocardiogram), FIBRIN D DIMER INCREASED (Fibrin D dimer increased), FULL BLOOD COUNT ABNORMAL (Full blood count abnormal), INFLUENZA A VIRUS TEST (Influenza A virus test), INFLUENZA B VIRUS TEST (Influenza B virus test), LABORATORY TEST ABNORMAL (Laboratory test abnormal), N-TERMINAL PROHORMONE BRAIN NATRIURETIC PEPTIDE ABNORMAL (N-terminal prohormone brain natriuretic peptide abnormal), SARS-COV-2 TEST (SARS-CoV-2 test), TROPONIN I ABNORMAL (Troponin I abnormal) and MYOCARDITIS (Myocarditis) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 09-Dec-2021, C-reactive protein: abnormal (abnormal) The result is abnormal Lab C-REACTIVE PROTEIN Physician Assistant. On 09-Dec-2021, Electrocardiogram: 12 (abnormal) Other type of result ECG 12 LEAD Physician Assistant. On 09-Dec-2021, Full blood count: abnormal (abnormal) The result is abnormal Lab CBC W/DIFFERENTIAL Physician Assistant. On 09-Dec-2021, Metabolic function test: abnormal (abnormal) The result is abnormal Lab COMPREHENSIVE METABOLIC PANEL Physician Assistant. On 09-Dec-2021, N-terminal prohormone brain natriuretic peptide: abnormal (abnormal) The result is abnormal Lab NT-PRO BNP Physician Assistant. On 09-Dec-2021, Troponin I: abnormal (abnormal) The result is abnormal Lab POC TROPONIN I (RESULTS ONLY) Physician Assistant. On 10-Dec-2021, Blood creatine phosphokinase MB: abnormal (abnormal) The result is abnormal Lab CK TOTAL AND CKMB Doctor. On 10-Dec-2021, C-reactive protein: abnormal (abnormal) The result is abnormal Lab C-REACTIVE PROTEIN Doctor. On 10-Dec-2021, Electrocardiogram: 12 (abnormal) Other type of result ECG 12 LEAD Advance Registered Nurse Practitioner. On 10-Dec-2021, Full blood count: abnormal (abnormal) The result is abnormal Lab CBC NO DIFFERENTIAL Doctor.

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		On 10-Dec-2021, Metabolic function test: abnormal (abnormal) The result is abnormal Lab BASIC METABOLIC PANEL Doctor. On 10-Dec-2021, Troponin I: abnormal (abnormal) The result is abnormal Lab TROPONIN I Doctor and abnormal (abnormal) The result is abnormal Lab TROPONIN I Doctor. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Concomitant product was not provided by the reporter Patient had Myocarditis and went to hospital on 09-DEC after experiencing chest pains 08-DEC and 09-DEC, discharged on 12-DEC. Pending follow-up with cardiologist and cardiac MRI. Treating with 975mg of Aspirin 3x daily. Company Comment: This case concerns a 31 year-old male patient with no reported medical history who experienced the unexpected serious adverse event of special interest of myocarditis, and the unexpected serious event of chest pain which occurred 6 days after vaccination with mRNA-1273 administered as a third dose. 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 28-Dec-2021 and was forwarded to Moderna on 28-Dec-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of PERICARDITIS (Pericarditis), CHEST PAIN (Chest pain), ELECTROCARDIOGRAM NORMAL (Electrocardiogram normal), LYMPHADENOPATHY (Lymphadenopathy) and HEADACHE (Headache) in a 27-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. No Medical History information was reported. On 10-Dec-2021, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 11-Dec-2021, the patient experienced PERICARDITIS (Pericarditis), CHEST PAIN (Chest pain), ELECTROCARDIOGRAM NORMAL (Electrocardiogram normal), LYMPHADENOPATHY (Lymphadenopathy), HEADACHE (Headache) and CHILLS (Chills). At the time of the report, PERICARDITIS (Pericarditis), CHEST PAIN (Chest pain), ELECTROCARDIOGRAM NORMAL (Electrocardiogram normal), LYMPHADENOPATHY (Lymphadenopathy), HEADACHE (Headache) and CHILLS (Chills) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 13-Dec-2021, Electrocardiogram: normal (normal) normal.

Case ID	WW Identifier	Narrative
		For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No other medications were provided. 12 Hours post vaccination the patient experienced headache, chills 24 hours post - headache, lymph node swelling in booster arm, chest ache 48-72 hours post - chest ache. Doctor prescribed 800mg ibuprofen regimen for suspected pericarditis. Company comment- This case concerns a 27-year-old female patient with no medical history, who experienced the expected non-serious adverse event of special interest, Pericarditis. The event occurred 1 day after receiving the third dose of mRNA-1273 Vaccine. The rechallenge was reported as not applicable by the regulatory authority. No clinical or treatment details were given. It was reported that the event outcome was unknown. 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 PYREXIA (Fever (39°C)), CHEST PAIN (I'm still experiencing strong chest pain), BACK PAIN (I'm still experiencing back pain), ABDOMINAL PAIN UPPER (I'm still experiencing stomach pain), PALPITATIONS (I'm still experiencing fast beating/I'm still experiencing pounding heart), DYSPNOEA (I'm still experiencing shortness of breath) and MYOCARDITIS (I'm one of the few unfortunate persons that experienced after the second dose of the Moderna vaccine) in a 30-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 13-Aug-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. In August 2021, the patient experienced PYREXIA (Fever (39°C)) (seriousness criterion hospitalization), CHEST PAIN (I'm still experiencing strong chest pain) (seriousness criterion hospitalization), BACK PAIN (I'm still experiencing back pain) (seriousness criterion hospitalization), ABDOMINAL PAIN UPPER (I'm still experiencing stomach pain) (seriousness criterion hospitalization), PALPITATIONS (I'm still experiencing fast beating/I'm still experiencing pounding heart) (seriousness criterion hospitalization) and DYSPNOEA (I'm still experiencing shortness of breath) (seriousness criterion hospitalization). On 16-Aug-2021, after starting mRNA-1273 (Spikevax), the patient experienced MYOCARDITIS (I'm one of the few unfortunate persons that experienced after the second dose of the Moderna vaccine) (seriousness criteria hospitalization and medically significant). On an unknown date, the patient experienced TACHYCARDIA (Tachycardia). The patient was hospitalized from 07-Sep-2021 to 09-Sep-2021 due to ABDOMINAL PAIN UPPER, BACK PAIN, CHEST PAIN, DYSPNOEA, MYOCARDITIS, PALPITATIONS and PYREXIA. The patient was treated with IBUPROFEN in October 2021 for Adverse event, at an unspecified dose and frequency and PREDNISOLONE in September 2021 for Adverse event, at an unspecified dose and frequency. At the time of the report, PYREXIA

Case ID	WW Identifier	Narrative
		(Fever (39ºC)), CHEST PAIN (I'm still experiencing strong chest pain), BACK PAIN (I'm still experiencing back pain), ABDOMINAL PAIN UPPER (I'm still experiencing stomach pain), PALPITATIONS (I'm still experiencing fast beating/I'm still experiencing pounding heart), DYSPNOEA (I'm still experiencing shortness of breath) and MYOCARDITIS (I'm one of the few unfortunate persons that experienced after the second dose of the Moderna vaccine) had not resolved and TACHYCARDIA (Tachycardia) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In August 2021, Body temperature: high (High) 39 degree celsius. In August 2021, Troponin I: abnormal (abnormal) Abnormal. In October 2021, Troponin I: normal (normal) Normal. For mRNA-1273 (Spikevax) (Unknown), the reporter considered MYOCARDITIS (I'm one of the few unfortunate persons that experienced after the second dose of the Moderna vaccine) to be related. No further causality assessments were provided for PYREXIA (Fever (39ºC)), CHEST PAIN (I'm still experiencing strong chest pain), BACK PAIN (I'm still experiencing back pain), ABDOMINAL PAIN UPPER (I'm still experiencing stomach pain), PALPITATIONS (I'm still experiencing fast beating/I'm still experiencing pounding heart), DYSPNOEA (I'm still experiencing shortness of breath) and TACHYCARDIA (Tachycardia). Patient never had heart issues before. The myocarditis was confirmed 3 days later by altered levels of "troponin I" and an MRT. The NFD test showed that the patient have myocarditis. The troponin levels and the heart functionality got back to normal around the end of October. No concomitant medications were reported. Company Comment: This spontaneous case concerns a 30-year-old, male patient with no medical history reported, who experienced the expected, serious AESI of myocarditis and the unexpected, serious events of pyrexia, chest pain, back pain, abdominal pain upper, palpitations and dyspnoea. The event myocarditis, which resulted in hospitalization, occurred 3 days after administration of the second dose of the Moderna mRNA-1273 vaccine. The other symptoms occurred at the end of the second day after administration of the second dose of the Moderna mRNA-1273 vaccine. The patient experienced fever (39ºC), strong chest pain, back pain, stomach pain, fast beating and pounding heart, and shortness of breath. The diagnosis of Myocarditis was confirmed 3 days later by altered levels of Troponin I. The patient was hospitalized from 07Sep2021 to 09Sep2021. The 'NFD test' showed Myocarditis. The patient's doctor stated that the vaccination was the likely the cause for Myocarditis. The patient was prescribed with Prednisone at the beginning of Sep2021, and Ibuprofen in the middle of Oct2021 which he took for 6 weeks. However, the events had not resolved at the time of the report. The rechallenge was not applicable as no additional dosing will

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		be given. The patient's gender remains a confounder for the event of myocarditis. The benefit-risk relationship of the Moderna mRNA-1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 04-Jan-2022: Additional event of Tachycardia was updated.
4.1(b)	4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b) on 28-Dec-2021 and was forwarded to Moderna on 28-Dec-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of PERICARDITIS (Pericarditis), CHEST PAIN (Chest pain), TACHYCARDIA (Tachycardia), FIBRIN D DIMER NORMAL (Fibrin D dimer normal) and TROPONIN NORMAL (Troponin normal) in a 24-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for an unknown indication. Concurrent medical conditions included Lactose intolerance, Shellfish allergy, Allergy to animal (Animal fur) and Asthma. On 09-Dec-2021, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 09-Dec-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form and first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 11-Dec-2021, the patient experienced PERICARDITIS (Pericarditis), CHEST PAIN (Chest pain), TACHYCARDIA (Tachycardia), FIBRIN D DIMER NORMAL (Fibrin D dimer normal) and TROPONIN NORMAL (Troponin normal). At the time of the report, PERICARDITIS (Pericarditis), CHEST PAIN (Chest pain), TACHYCARDIA (Tachycardia), FIBRIN D DIMER NORMAL (Fibrin D dimer normal) and TROPONIN NORMAL (Troponin normal) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Fibrin D dimer: negative (Negative) Negative. On an unknown date, Troponin: result not reported (Inconclusive) result not reported. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Other medications included Albuterol-sulfate HFA, Budesonide-Formoterol, Flonase, Zyrtec, OTC-Sronyx. Treatment information was unknown. On 09-Dec-2021, the patient received Moderna booster vaccine to left arm . On 11-Dec-2021, the patient was diagnosed with Pericarditis in Hospital emergency room . The Patient had chest pain, tachycardia with S1Q3T3 pathology and negative D dimer and troponin.

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		This case concerns a 24-year-old female patient with no medical history, who experienced the expected non-serious adverse event of special interest, Pericarditis. The event occurred 2 days after receiving both the third and second dose of mRNA-1273 Vaccine (both vaccines were given on the same date as reporter by the RA). The rechallenge was reported as not applicable by the regulatory authority. No clinical or treatment details were given. It was reported that the event has not resolved. 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 29-Dec-2021 and was forwarded to Moderna on 29-Dec-2021. This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Acute myocarditis) in a 16-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 3006273) for COVID-19 vaccination. No Medical History information was reported. On 06-Oct-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) .5 milliliter. On 09-Oct-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. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Concomitant medication information was not provided by the reporter. Treatment medication information was not provided by the reporter. Company comment: This case concerns a 16-year-old female patient with no medical history reported, who experienced the expected serious event of Myocarditis. The event occurred approximately 3 days after the administration of the second dose of mRNA-1273. Details regarding concomitant medications, diagnosis procedures and treatment were not 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 4.1(b) (Reference number: 4.1(b) on 28-Dec-2021 and was forwarded to Moderna on 28-Dec-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of CARDIAC FAILURE (Cardiac failure), CHEST X-RAY (Chest X-ray), CHEST PAIN (Chest pain), COMPUTERISED TOMOGRAM THORAX ABNORMAL (Computerised tomogram thorax abnormal), ELECTROCARDIOGRAM (Electrocardiogram), HAEMATOLOGY TEST (Haematology test), HILAR LYMPHADENOPATHY (Hilar lymphadenopathy), LEFT ATRIAL ENLARGEMENT (Left atrial enlargement), LUNG DISORDER (Lung disorder), MEDIASTINITIS (Mediastinitis), PAIN (Pain), PAIN IN EXTREMITY (Pain in extremity), PLEURAL EFFUSION (Pleural effusion), PULMONARY OEDEMA (Pulmonary oedema), TISSUE INFILTRATION (Tissue infiltration), TROPONIN INCREASED (Troponin increased) and

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		MYOCARDITIS (Myocarditis) in a 26-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for an unknown indication. The patient's past medical history included Asthma, Supraventricular tachycardia (SVT), Myopia, Obesity, Vitamin D deficiency and Congenital diaphragmatic hernia. Concurrent medical conditions included House dust mite allergy. On 06-Dec-2021, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 13-Dec-2021, the patient experienced CARDIAC FAILURE (Cardiac failure) (seriousness criterion hospitalization), CHEST X-RAY (Chest X-ray) (seriousness criterion hospitalization), CHEST PAIN (Chest pain) (seriousness criterion hospitalization), COMPUTERISED TOMOGRAM THORAX ABNORMAL (Computerised tomogram thorax abnormal) (seriousness criterion hospitalization), ELECTROCARDIOGRAM (Electrocardiogram) (seriousness criterion hospitalization), HAEMATOLOGY TEST (Haematology test) (seriousness criterion hospitalization), HILAR LYMPHADENOPATHY (Hilar lymphadenopathy) (seriousness criterion hospitalization), LEFT ATRIAL ENLARGEMENT (Left atrial enlargement) (seriousness criterion hospitalization), LUNG DISORDER (Lung disorder) (seriousness criterion hospitalization), MEDIASTINITIS (Mediastinitis) (seriousness criterion hospitalization), PAIN (Pain) (seriousness criterion hospitalization), PAIN IN EXTREMITY (Pain in extremity) (seriousness criterion hospitalization), PLEURAL EFFUSION (Pleural effusion) (seriousness criterion hospitalization), PULMONARY OEDEMA (Pulmonary oedema) (seriousness criterion hospitalization), TISSUE INFILTRATION (Tissue infiltration) (seriousness criterion hospitalization), TROPONIN INCREASED (Troponin increased) (seriousness criterion hospitalization) and MYOCARDITIS (Myocarditis) (seriousness criterion hospitalization). At the time of the report, CARDIAC FAILURE (Cardiac failure), CHEST X-RAY (Chest X-ray), CHEST PAIN (Chest pain), COMPUTERISED TOMOGRAM THORAX ABNORMAL (Computerised tomogram thorax abnormal), ELECTROCARDIOGRAM (Electrocardiogram), HAEMATOLOGY TEST (Haematology test), HILAR LYMPHADENOPATHY (Hilar lymphadenopathy), LEFT ATRIAL ENLARGEMENT (Left atrial enlargement), LUNG DISORDER (Lung disorder), MEDIASTINITIS (Mediastinitis), PAIN (Pain), PAIN IN EXTREMITY (Pain in extremity), PLEURAL EFFUSION (Pleural effusion), PULMONARY OEDEMA (Pulmonary oedema), TISSUE INFILTRATION (Tissue infiltration), TROPONIN INCREASED (Troponin increased) and MYOCARDITIS (Myocarditis) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 14-Dec-2021, Chest X-ray: result not reported Result not reported. On 14-Dec-2021, Haematology test: result not reported Result not reported. On 15-Dec-2021, Computerised tomogram thorax: abnormal The result showed combination of airspace disease, interlobular septal thickening, and bilateral simple attenuating pleural effusions that were most consistent with pulmonary edema due to heart failure. The left atrium was borderline enlarged. The findings were most consistent with the clinical diagnosis of myo-pericarditis. There was a mildly enlarged bilateral hilar

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		lymph nodes, likely related to pulmonary edema. Mediastinal soft tissue infiltration was likely related to patient's pulmonary edema or associated viral mediastinitis.. On 15-Dec-2021, Electrocardiogram: result not reported Result not reported. On 15-Dec-2021, Troponin: 22 22. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Concomitant medications were not reported. Treatment medications were not reported. The patient had burning chest pain radiating to arms This is a regulatory case concerning a 26-year-old male patient with relevant medical history of supraventricular tachycardia, obesity, congenital diaphragmatic hernia and allergy, who experienced the serious expected AESI event of myocarditis, serious unexpected AESI events of cardiac failure, mediastinitis, pulmonary oedema, and serious unexpected events of chest X-ray, chest pain, computerised tomogram thorax abnormal, electrocardiogram, haematology test, hilar lymphadenopathy, left atrial enlargement, lung disorder, pain, pain in extremity, pleural effusion, tissue infiltration and troponin increased. The events occurred 8 days after the third dose of mRNA-1273 vaccine administration. The events were assessed as related to the product administration. The rechallenge was not applicable since the events occurred after the third dose and no further dosing is expected. The medical history of supraventricular tachycardia, obesity, congenital diaphragmatic hernia and allergy considered as 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 28-Dec-2021 and was forwarded to Moderna on 28-Dec-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of BLOOD CREATINE PHOSPHOKINASE MB INCREASED (Blood creatine phosphokinase MB increased), BLOOD CREATINE PHOSPHOKINASE NORMAL (Blood creatine phosphokinase normal), CHEST X-RAY NORMAL (Chest X-ray normal), CHEST PAIN (Chest pain), COMPUTERISED TOMOGRAM THORAX NORMAL (Computerised tomogram thorax normal), ECHOCARDIOGRAM NORMAL (Echocardiogram normal), ELECTROCARDIOGRAM ST SEGMENT ELEVATION (Electrocardiogram ST segment elevation), FULL BLOOD COUNT NORMAL (Full blood count normal), MYOCARDITIS (Myocarditis), PERICARDITIS (Pericarditis), SARS-COV-2 TEST NEGATIVE (SARS-CoV-2 test negative) and TROPONIN INCREASED (Troponin increased) in a 19-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for an unknown indication. Concurrent medical conditions included Allergy to nuts and Oil allergy.

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		On 27-Apr-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 27-Apr-2021, the patient experienced BLOOD CREATINE PHOSPHOKINASE MB INCREASED (Blood creatine phosphokinase MB increased) (seriousness criterion hospitalization), BLOOD CREATINE PHOSPHOKINASE NORMAL (Blood creatine phosphokinase normal) (seriousness criterion hospitalization), CHEST X-RAY NORMAL (Chest X-ray normal) (seriousness criterion hospitalization), CHEST PAIN (Chest pain) (seriousness criterion hospitalization), COMPUTERISED TOMOGRAM THORAX NORMAL (Computerised tomogram thorax normal) (seriousness criterion hospitalization), ECHOCARDIOGRAM NORMAL (Echocardiogram normal) (seriousness criterion hospitalization), ELECTROCARDIOGRAM ST SEGMENT ELEVATION (Electrocardiogram ST segment elevation) (seriousness criterion hospitalization), FULL BLOOD COUNT NORMAL (Full blood count normal) (seriousness criterion hospitalization), MYOCARDITIS (Myocarditis) (seriousness criterion hospitalization), PERICARDITIS (Pericarditis) (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, BLOOD CREATINE PHOSPHOKINASE MB INCREASED (Blood creatine phosphokinase MB increased), BLOOD CREATINE PHOSPHOKINASE NORMAL (Blood creatine phosphokinase normal), CHEST X-RAY NORMAL (Chest X-ray normal), CHEST PAIN (Chest pain), COMPUTERISED TOMOGRAM THORAX NORMAL (Computerised tomogram thorax normal), ECHOCARDIOGRAM NORMAL (Echocardiogram normal), ELECTROCARDIOGRAM ST SEGMENT ELEVATION (Electrocardiogram ST segment elevation), FULL BLOOD COUNT NORMAL (Full blood count normal), MYOCARDITIS (Myocarditis), PERICARDITIS (Pericarditis), SARS-COV-2 TEST NEGATIVE (SARS-CoV-2 test negative) and TROPONIN INCREASED (Troponin increased) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Blood creatine phosphokinase: 149 (normal) 149. On an unknown date, Blood creatine phosphokinase MB: 153.3 (High) 153.3. On an unknown date, Chest X-ray: no acute disease (normal) No acute disease. On an unknown date, Computerised tomogram: negative (Negative) negative. On an unknown date, Echocardiogram: normal (normal) normal LV function, no right side cavity strain, no pleural effusion. Working diagnosis is acute pericarditis with myocarditis. On an unknown date, Electrocardiogram: diffuse st elevation diffuse ST elevation. On an unknown date, Full blood count: wnl (normal) WNL. On an unknown date, SARS-CoV-2 test: negative (Negative) negative. On an unknown date, Troponin: 30.760 (High) 30.760 and 31.893 (High) 31.893.

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		For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Concomitant product use was not provided by the reporter. The patient received the second Moderna vaccine in the series in outside location. He began having chest pain that day after receiving the vaccine and came to the hospital on day 3 of chest pain. No prior similar events, no cardiovascular risk factors. Patient was better with sitting up and leaning forward was admitted to the hospital and started on Ibuprofen and Colchicine. Patient was discharged after 3 days with significant improvement in his status. On discharge pain was 0 out of 10. To continue Ibuprofen for 1 week and colchicine for 6 weeks. Cardiology cleared patient for discharge. Treatment medications included Ibuprofen and Colchicine. Company comment: This is a regulatory case concerning a 19-year-old, male patient with no relevant medical history reported, who experienced the serious expected , according CCDS, events of Miocarditis, Pericarditis, and the serious unexpected, according CCDS, events of Chest pain, Electrocardiogram ST segment elevation, Blood creatine phosphokinase MB increased and Troponin increased. The events occurred approximately the same day after the second dose of mRNA-1273 vaccine. The rechallenge was not applicable since the events happened after the second dose and no information on additional dosing is available. At the time of the report, the outcome of the events was recovered/resolved. The case was assessed as serious as per Regulatory Authority´s report due to hospitalization. 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 28-Dec-2021 and was forwarded to Moderna on 28-Dec-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of MAGNETIC RESONANCE IMAGING HEART (Magnetic resonance imaging heart) and MYOCARDITIS (Myocarditis) in a 37-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for an unknown indication. No Medical History information was reported. On 03-Nov-2021, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 06-Dec-2021, the patient experienced MAGNETIC RESONANCE IMAGING HEART (Magnetic resonance imaging heart) and MYOCARDITIS (Myocarditis). At the time of the report, MAGNETIC RESONANCE IMAGING HEART (Magnetic resonance imaging heart) and MYOCARDITIS (Myocarditis) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Magnetic resonance imaging heart: results not reported (Inconclusive) Results not reported.

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		For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Other medication reported included Wellbutrin. No treatment medications were reported. Company comment: This case concerns a 37-year-old female patient with no medical history reported, who experienced the adverse event of special interest myocarditis. The event occurred approximately 33 days after the booster dose of mRNA-1273. Information regarding clinical presentation, diagnostic tests and treatment provided has not been disclosed. 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 28-Dec-2021 and was forwarded to Moderna on 28-Dec-2021. This regulatory authority case was reported by a physician and describes the occurrence of CHEST PAIN (Precordial pain extended to left and right scapula) and PERICARDITIS (Pericarditis) in a 39-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 immunisation. Concurrent medical conditions included Hypothyroidism (Medication-T4 50 mcg once daily). Concomitant products included LEVOTHYROXINE SODIUM (T4) for an unknown indication. On 14-Jul-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 19-Jul-2021, the patient experienced CHEST PAIN (Precordial pain extended to left and right scapula) (seriousness criterion medically significant) and PERICARDITIS (Pericarditis) (seriousness criterion medically significant). At the time of the report, CHEST PAIN (Precordial pain extended to left and right scapula) and PERICARDITIS (Pericarditis) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 19-Jul-2021, Echocardiogram: normal (normal) Ejection fraction 60% without pericardial effusion. On 19-Jul-2021, Electrocardiogram: normal (normal) Within normal limits. On 24-Aug-2021, Magnetic resonance imaging heart: abnormal (abnormal) Acute pericarditis in remission, no indication of structural cardiomyopathy and myocarditis, ejection fraction 56%, mild pericardial effusion. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Treatment medications were not provided. Company Comment: This case concerns a 39 year-old female patient with a history of hypothyroidism on levothyroxine sodium who experienced the unexpected serious adverse event of special interest of

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		pericarditis, and the unexpected serious event of chest pain which occurred 6 days after the second dose of mRNA-1273 vaccine. The medical history of hypothyroidism remains a confounder for the events. 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 28-Dec-2021 and was forwarded to Moderna on 28-Dec-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of PERICARDITIS (Pericarditis), CHEST PAIN (Chest pain), BLOOD TEST (Blood test), ECHOCARDIOGRAM (Echocardiogram) and ELECTROCARDIOGRAM (Electrocardiogram) in an 18-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 008B21A) for an unknown indication. No Medical History information was reported. On 06-Apr-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 10-Apr-2021, the patient experienced PERICARDITIS (Pericarditis), CHEST PAIN (Chest pain), BLOOD TEST (Blood test), ECHOCARDIOGRAM (Echocardiogram) and ELECTROCARDIOGRAM (Electrocardiogram). At the time of the report, PERICARDITIS (Pericarditis), CHEST PAIN (Chest pain), BLOOD TEST (Blood test), ECHOCARDIOGRAM (Echocardiogram) and ELECTROCARDIOGRAM (Electrocardiogram) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Blood test: not reported (Inconclusive) Not reported. On an unknown date, Electrocardiogram: not reported (Inconclusive) Not reported. On an unknown date, Ultrasound scan: not reported (Inconclusive) Not reported. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Concomitant medication was not provided. Treatment information was not provided. Patient developed chest pain on his left upper chest that felt better. The patient was diagnosed with Pericarditis on 04/13 or the 15th either of those days. The patient underwent an ultrasound with his heart, EKG, and blood work. He took colchicine and ibuprofen (800mg) 3x a day and his symptoms subsided within a week. This case concerns an 18-year-old male patient with no medical history, who experienced the expected non-serious adverse event of special interest, Pericarditis. The event occurred 4 days after receiving the second dose of mRNA-1273 Vaccine. The rechallenge was reported as not applicable by the regulatory authority. No clinical or treatment details

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		were given. It was reported that the event has not resolved. 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 28-Dec-2021 and was forwarded to Moderna on 28-Dec-2021. This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (Myocarditis) in a 20-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. No Medical History information was reported. On 29-Apr-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 01-Jun-2021, the patient experienced MYOCARDITIS (Myocarditis). At the time of the report, MYOCARDITIS (Myocarditis) had not resolved. The action taken with mRNA-1273 (Spikevax) (Intramuscular) was unknown. No concomitant product use was provided by the reporter. No treatment medications were reported. Company comment: case concerns a 20-year-old female patient with no medical history reported, who experienced the adverse event of special interest myocarditis. The event occurred approximately 33 days after the booster dose of mRNA-1273. Information regarding clinical presentation, diagnostic tests and treatment provided has not been disclosed. 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 28-Dec-2021 and was forwarded to Moderna on 28-Dec-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of PERICARDITIS (Pericarditis), CHEST PAIN (Chest pain), PAIN IN EXTREMITY (Pain in extremity), BLOOD TEST NORMAL (Blood test normal) and CHEST X-RAY NORMAL (Chest X-ray normal) in a 25-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 012H21B) for an unknown indication. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 05-Dec-2021, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 10-Dec-2021, the patient experienced PERICARDITIS (Pericarditis), CHEST PAIN (Chest pain), PAIN IN EXTREMITY (Pain in extremity), BLOOD TEST NORMAL (Blood test normal), CHEST X-RAY NORMAL (Chest X-ray normal), ELECTROCARDIOGRAM NORMAL (Electrocardiogram

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		normal), ULTRASOUND SCAN NORMAL (Ultrasound scan normal) and ARTHRALGIA (Arthralgia). At the time of the report, PERICARDITIS (Pericarditis), CHEST PAIN (Chest pain), PAIN IN EXTREMITY (Pain in extremity), BLOOD TEST NORMAL (Blood test normal), CHEST X-RAY NORMAL (Chest X-ray normal), ELECTROCARDIOGRAM NORMAL (Electrocardiogram normal), ULTRASOUND SCAN NORMAL (Ultrasound scan normal) and ARTHRALGIA (Arthralgia) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 10-Dec-2021, Blood test: normal (normal) normal. On 10-Dec-2021, Chest X-ray: normal (normal) normal. On 10-Dec-2021, Electrocardiogram: normal (normal) normal. On 10-Dec-2021, Ultrasound scan: normal (normal) normal. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Patient reported treatment medication as 600mg of ibuprofen 3 times a day. Concomitant medications included Dietary supplements: Adult multivitamin (One-a-day brand) Whey protein powder Creatine monohydrate. Patient reported that he experienced Pericarditis Severe chest, shoulder, and arm pain in the early morning, he visited urgent care later in the morning and was sent to cardio specialist. This case concerns a 25-year-old male patient with no medical history, who experienced the expected non-serious adverse event of special interest, Pericarditis. The event occurred 5 days after receiving the third dose of mRNA-1273 Vaccine. The rechallenge was reported as not applicable by the regulatory authority. No clinical or treatment details were given. It was reported that the event has resolved. 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. This regulatory authority case was reported by a consumer and describes the occurrence of PERICARDITIS (Pericarditis), CHEST PAIN (Chest pain), DYSPNOEA (Shortness of breath) and PALPITATIONS (Heart palpitations) in a 26-year-old female patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. On 17-Dec-2021, the patient received third dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 18-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 CHEST PAIN (Chest pain) (seriousness criterion medically significant), DYSPNOEA (Shortness of breath) (seriousness criterion medically significant) and PALPITATIONS (Heart palpitations) (seriousness criterion

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		medically significant). At the time of the report, PERICARDITIS (Pericarditis) had not resolved and CHEST PAIN (Chest pain), DYSPNOEA (Shortness of breath) and PALPITATIONS (Heart palpitations) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Blood pressure measurement: not reported (Inconclusive) No results provided. On an unknown date, Blood test: not reported (Inconclusive) No results provided. On an unknown date, Electrocardiogram: not reported (Inconclusive) No results provided. On an unknown date, SARS-CoV-2 test: negative (Negative) No - Negative COVID-19 test. On an unknown date, Troponin: normal (normal) Normal. Concomitant medications were not reported. Patient had No issues. Patient has not had symptoms associated with COVID-19 and Patient is not currently breastfeeding. Patient developed Pericarditis, Chest pain, palpitations and shortness breath. Patient has not tested positive for COVID-19 since having the vaccine and Patient is not enrolled in clinical trial The patient report relate to possible inflammation of the heart (myocarditis or pericarditis) was reported as yes Patient relevant investigations or tests conducted were reported as Electrocardiogram (ECG), blood tests and blood pressure" Patient diagnosis was made by a medical professional as Yes. It was reported that any imaging carried out such as, but not limited to, chest X-ray, echocardiogram, cardiac MRI, chest computerized tomography (CT) as ECG. Patient Troponin level was normal (Patient peak troponin value (Troponin reference range and troponin serial values as Normal)) The patient blood tests, such as for certain proteins (called troponin) that signal heart muscle damage taken was reported as Yes. No treatment information was reported. Company comment:This RA case concerns a female patient of 26 years with no medical history, who experienced the expected serious AESI event of Pericarditis and unexpected serious event Chest pain, Dyspnea and Palpitation. The Pericarditis occurred one day after the third dose of mRNA-1273 vaccine. The events Chest pain, Dyspnea and Palpitation occurred on unknown date after the third dose of mRNA-1273 vaccine. The outcome of events was reported as not recovered for Pericarditis and unknown for Chest pain, Dyspnea and Palpitation. Additionally it was reported that Troponin values were normal. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report. The case was assessed as serious as per Regulatory Authority 's report due to important medical condition.
4.1(b)	4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b)) on 28-Dec-2021 and was forwarded to Moderna on 28-Dec-2021.

Case ID	WW Identifier	Narrative
	4.1(b) [redacted]	This regulatory authority case was reported by a consumer and describes the occurrence of CHEST PAIN (Chest pain), DYSPNOEA (Shortness of breath), PALPITATIONS (Heart palpitations), TACHYCARDIA (Racing heart (tachycardia)), FATIGUE (Fatigue/unusual tiredness), PYREXIA (Fever) and MYOCARDITIS (Myocarditis) in a 23-year-old female patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. On 12-Dec-2021, the patient received third dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 13-Dec-2021, the patient experienced PYREXIA (Fever) (seriousness criteria hospitalization and medically significant). On 15-Dec-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). On an unknown date, the patient experienced CHEST PAIN (Chest 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), TACHYCARDIA (Racing heart (tachycardia)) (seriousness criteria hospitalization and medically significant) and FATIGUE (Fatigue/unusual tiredness) (seriousness criteria hospitalization and medically significant). On 14-Dec-2021, PYREXIA (Fever) had resolved. At the time of the report, CHEST PAIN (Chest pain), DYSPNOEA (Shortness of breath), PALPITATIONS (Heart palpitations), TACHYCARDIA (Racing heart (tachycardia)) and FATIGUE (Fatigue/unusual tiredness) outcome was unknown and MYOCARDITIS (Myocarditis) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Blood test: results not reported Results not reported. On an unknown date, Electrocardiogram: results not reported Results not reported. On an unknown date, SARS-CoV-2 test: negative (Negative) No - Negative COVID-19 test. Concomitant medication use information was not provided by reporter. Patient had prior vaccination history that includes SARS-COV-2 VIRUS with COVID-19 Vaccination as indication took twice. Diagnosis was made by a medical professional. The symptoms were lead to a hospital stay. Patient was admitted to the hospital for 1 night. The laboratory exam was done that includes ECG and the result were unknown, also blood tests such as for certain proteins called troponin that signal heart muscle damage. Patient was not tested positive for COVID-19 since the vaccine. Patient was not enrolled in clinical trial.

Case ID	WW Identifier	Narrative
		Company Comment: This case concerns a 23 year-old female patient with no reported medical history who experienced the unexpected serious adverse event of special interest of myocarditis, and the unexpected serious event of pyrexia which occurred 2 to 4 days after vaccination with mRNA-1273 administered as a booster third dose, and the unexpected serious events of fatigue, tachycardia, palpitations, dyspnea, and chest pain which occurred on an unknown date relative to vaccination. The benefit-risk relationship of mRNA-1273 is not affected by this report. Events' seriousness assessed as per Regulatory Authority reporting. Most recent FOLLOW-UP information incorporated above includes: On 30-Dec-2021: Laboratory tests added. Suspect indication added. Heart racing removed as event. Action taken updated.
4.1(b)	4.1(b)	This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Post-vaccine myopericarditis) in a 15-year-old female patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination. No Medical History information was reported. On 10-Oct-2021, the patient received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form once a day. On 15-Oct-2021, after starting mRNA-1273 (COVID-19 Vaccine Moderna), the patient experienced MYOCARDITIS (Post-vaccine myopericarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Post-vaccine myopericarditis) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 17-Oct-2021, Electrocardiogram: normal (normal) Regular sinus rhythm at 82 bpm, normal axis at 64. On 18-Oct-2021, Echocardiogram: normal (normal) Left ventricle not dilated, not hypertrophied. On 20-Oct-2021, Echocardiogram: normal (normal) Sinus rhythm 85/min, normal axis, no hypertension. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered MYOCARDITIS (Post-vaccine myopericarditis) to be related. Concomitant product use was not provided by the reporter. The patient was in usual good health. On 17-Oct-2021 patient was hospitalized for finding of perimyocarditis and admitted to intensive care on due to post-vaccination myopericarditis. Patient was subsequently developed a slight flu-like syndrome at 3.10 pm as well as transfixing chest pains with regard to the xyphoid appendix, of varying intensity, associated with nausea. The electrocardiogram and the cardiac enzyme assessment are compatible with myopericarditis. Simple pain relief was introduced. The transthoracic echocardiography showed a contractile segmentation and

Case ID	WW Identifier	Narrative
		global normal function of the left ventricle and an absence of pericardial panicum. A beta-blocker treatment was introduced in small doses. A ban from moderate to intensive sport for 3 to 6 months was recommended. The patient was transferred from intensive care to pediatrics at 19-Oct-2021 and then following a cardiological consultation in the hospital at 20-Oct-2021. Pediatric cardiologist on 20-Oct-2021 stated that the patient showed a practically normal echocardiography, just with the most sensitive measurements (strain) there was the suspicion of a slight decrease in systolic function in the posterolateral regions of the left ventricle. With the elevation of troponin (672 ng/L), CK (632 U/L) and CK-MB (67 U/L) cardiac MRI was recommended. On 03-Dec-2021 the referring physician also reported again, confirmation from the doctor who on MRI stated that this examination showed small sequelae of the myocardium typical for myocarditis. The diagnosis of vaccine myocarditis therefore be confirmed. Patient took beta-blocker as a treatment medication. Most recent FOLLOW-UP information incorporated above includes: On 30-Dec-2021: Translation received on 04-Jan-2022 that contains patient laboratory data and inarrative 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 19-year-old female patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination. No Medical History information was reported. On 08-Oct-2021, the patient received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form once a day. On 09-Oct-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. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In October 2021, Electrocardiogram: perikarditis (abnormal) Perikarditis. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered PERICARDITIS (Pericarditis) to be possibly related. Patient woman 19 years old, no known pathologies or allergies. Patient healthy and young took second dose of spikevax. Patient had burning and stinging in the thoracic region, ECG confirmed pericarditis. Urgent V.D No concomitant medications were provided by reporter. No treatment medications were provided by reporter. Burning and stinging in the left thoracic region, ECG confirmed pericarditis Urgent VD.a. pericarditis after Covid vaccination

Case ID	WW Identifier	Narrative
		Company comment: This case concerns a 19-year-old, female patient with no medical history, who experienced the expected event of pericarditis. The events occurred approximately 1 day after the second dose of mRNA-1273. As reported, patient had burning and stinging in the thoracic region and ECG confirmed pericarditis. The reporter assessed the event as related to the product. 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 regulatory authority case was reported by a physician and describes the occurrence of PERICARDITIS (pericarditis) in a 31-year-old patient of an unknown gender who received mRNA-1273 (Moderna CoviD-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. In August 2021, the patient received first dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (Intramuscular) 1 dosage form once a day. On 01-Sep-2021, received second dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 24-Oct-2021, the patient experienced PERICARDITIS (pericarditis) (seriousness criterion medically significant). At the time of the report, PERICARDITIS (pericarditis) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Blood test: gb = 7320 including 54% pnn, crp <5 rets bs normal GB = 7320 including 54% PNN, CRP <5 rets BS normal. On an unknown date, Electrocardiogram: sinus, regular. discrete sus st (<2mm) sinus, regular. discrete sus ST (<2mm). For mRNA-1273 (Moderna CoviD-19 Vaccine) (Intramuscular), the reporter considered PERICARDITIS (pericarditis) to be related. Concomitant product use was not provided by the reporter. Patient is 31 years old, unknown sex, weight 75 kg, height 185 cm. Performed the second dose of Spikevax on 01-Sep-2021. First dose presumably performed in August 2021 (date not indicated). On 24-Oct-2021 the patient experienced pericarditis. The doctor's examination reports: patient was conscious, oriented. No sensitivomotor deficit. Glasgow Score 4Y + 5V + 6M = 15. Symmetrical and reactive pupils. Headache. Examine cardios: Regular heart sounds, no murmur, pericardial friction with mitral focus +++ Distal pulses present and symmetrical . Tests performed ECG: sinus, regular. discrete sus ST (<2mm) in V2 / V3 -blood tests: GB = 7320 including 54% PNN, CRP <5 rets BS normal, too <10 and DDimeres = 211 <500. Reaction reported as severe. The symptoms are not resolved at the time of reporting. Further course not known. No treatment information was provided. Company comment: This case concerns a 31-year-old patient with no medical history, who experienced the expected event of pericarditis. The event occurred approximately 53 days after the second dose of mRNA-1273. As reported, cardiac examination showed regular heart sounds, no

Case ID	WW Identifier	Narrative
		murmur, pericardial friction with mitral focus +++ Distal pulses present and symmetrical . Tests performed showed ECG: sinus, regular. discrete sus ST (<2mm) in V2 / V3. The reporter assessed the event as related to the product. 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 4.1(b) (Reference number: 4.1(b)) on 31-Dec-2021 and was forwarded to Moderna on 31-Dec-2021. This regulatory authority case was reported by a physician and describes the occurrence of PERICARDITIS (Pericarditis), FATIGUE (Fatigue), CHEST PAIN (Chest Pain) and PALPITATIONS (Palpitations) in a 26-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for an unknown indication. The patient's past medical history included Asthma. On 28-Dec-2021, the patient received third dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 29-Dec-2021, the patient experienced PERICARDITIS (Pericarditis). On an unknown date, the patient experienced FATIGUE (Fatigue), CHEST PAIN (Chest Pain) and PALPITATIONS (Palpitations). At the time of the report, PERICARDITIS (Pericarditis) was resolving and FATIGUE (Fatigue), CHEST PAIN (Chest Pain) and PALPITATIONS (Palpitations) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Chest X-ray: results not reported (Inconclusive) Results not reported. On an unknown date, Electrocardiogram: results not reported (Inconclusive) Results not reported. On an unknown date, SARS-CoV-2 test: no - negative covid-19 test (Negative) Negative. The action taken with mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown) was unknown. For mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. It was reported that chest pain started 6 hours following the vaccine.Patient woke up with sudden onset left sided chest pain and chest wall tenderness. Had sharp, shooting pain - radiating down L arm and legs- relieved on leaning forward. Patient had not tested positive for COVID-19 since having the vaccine and was not enrolled in clinical trial The patient had no report related to possible blood clots or low platelet counts. The patient had report related to possible myocarditis or pericarditis.

Case ID	WW Identifier	Narrative
		Lab investigations included: ECG showed mild saddling on ST, normal cardiac troponin, the peak troponin value was 2, Chest X-ray was normal. Patient had not taken echocardiogram, chest computed tomography, cardiac MRI, Cardiac biopsy, coronary angiography, there was no presence of pericardial rub, or changes in heart sounds and the patient was not asymptomatic. No concomitant medications reported No treatment medications provided Company comment: This is a regulatory case concerning a 26-year-old male patient with medical history of asthma who experienced the AESI pericarditis along with the non- serious events of palpitations, chest pain and fatigue. The event pericarditis occurred the following day a third dose of mRNA-1273 vaccine was administered. Chest pain started 6 hours following vaccine, woke up with sudden left sided chest pain and chest wall tenderness radiating down left arm and legs relieved on leaning forward. ECG showed mild saddling on ST, cardiac troponin was normal and chest X-ray was normal. There was no presence of pericardial rub, or changes in heart sounds. Medical history of asthma remains as a confounder. The benefit-risk relationship of the 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 31-Dec-2021. The most recent information was received on 02-Jan-2022 and was forwarded to Moderna on 02-Jan-2022. This regulatory authority case was reported by a consumer and describes the occurrence of PERICARDITIS (Pericarditis), HEART RATE INCREASED (Pulse rapid), DIZZINESS (Dizziness), PAIN (Pain) and FATIGUE (Fatigue/unusual tiredness) in a 35-year-old female patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) (batch no. 3005686) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Autism and Post-traumatic stress disorder. Concurrent medical conditions included Asthma and Endometriosis. Concomitant products included FLUTICASONE PROPIONATE, SALMETEROL XINAFOATE (SERETIDE) for Asthma, DULOXETINE, IBUPROFEN and PARACETAMOL for Pain, TOZINAMERAN (COVID-19 MRNA VACCINE BNT162B2) from 14-Apr-2021 to an unknown date and INFLUENZA VACCINE (INFLUENZA VIRUS) from 12-Oct-2021 to an unknown date for Vaccination. On 14-Dec-2021, the patient received third dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 14-Dec-2021, the patient experienced HEART RATE INCREASED (Pulse rapid) and PAIN (Pain). 14-Dec-2021, the patient experienced DIZZINESS (Dizziness). On 18-Dec-2021, the patient experienced PERICARDITIS (Pericarditis). On an unknown date, the patient experienced FATIGUE (Fatigue/unusual tiredness), CHEST PAIN (Chest pain), DYSPNOEA (Shortness of breath) and CHEST DISCOMFORT (Chest pressure). On 15-Dec-2021, DIZZINESS (Dizziness) had resolved. On 16-Dec-2021, HEART RATE INCREASED (Pulse rapid) was

Case ID	WW Identifier	Narrative
		resolving. On 18-Dec-2021, PAIN (Pain) was resolving. At the time of the report, PERICARDITIS (Pericarditis), FATIGUE (Fatigue/unusual tiredness), CHEST PAIN (Chest pain), DYSPNOEA (Shortness of breath) and CHEST DISCOMFORT (Chest pressure) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Blood test: normal (normal) normal. On an unknown date, Electrocardiogram: normal (normal) normal. On an unknown date, Heart rate: normal (normal) normal. On an unknown date, Physical examination: normal (normal) normal. Patient has not had symptoms associated with COVID-19, Not had a COVID-19 test, Patient is not pregnant, Patient is not currently breastfeeding.Patient LMP was 20-DEC-2021. The dizziness onset after one hour post administration and was bad enough i had to lie down for the rest of the day. It was about 4 days later patient noticed the pressure in her chest and that had been ongoing.BPM returned to normal within a couple of days. The Patient was diagnosed with possible mild pericarditis.Patient visited her GP 2 weeks post administration who did a physical exam, blood test for inflammatory markers, and ECG. All came back normal, but she was still experiencing discomfort. Advised to take aspirin and return if it hadn't settled. No prescription, told to rest and take aspirin and return in two weeks if discomfort in chest still present Were any blood tests, such as for certain proteins (called troponin) that signal heart muscle damage was observed. Her troponin level was normal. Company comment:This is a regulatory case concerning a 35 year-old, female patient with no relevant medical history, Interchange of vaccine products (vaccination with two doses of COVID-19 vaccine BioNTech approximately 6 months prior) and administration of influenza vaccine 2 months prior, who experienced the non-serious expected, according CCDS, AESI of pericarditis. The event occurred approximately 4 days after the booster dose of mRNA-1273 vaccine. The outcome of the event was reported as recovering. Blood tests and an electrocardiogram were performed and results were normal. The patient was prescribed aspirin and rest. The rechallenge was not applicable, as the event was reported exclusively after the booster dose. Interchange of vaccine products (vaccination with two doses of COVID-19 vaccine BioNTech approximately 6 months prior) and administration of influenza vaccine 2 months prior remain as confounders. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report Most recent FOLLOW-UP information incorporated above includes: On 02-Jan-2022: Significant F/U Case AE Updates. On 11-Jan-2022: The recent follow up contains significant information due to concomitant vaccine batch numbers, chest pressure event outcome has been updated.
4.1(b)	4.1(b)	This regulatory authority case was reported by a physician and describes the occurrence of CHEST PAIN (Chest Pain), PERICARDIAL RUB (pericardial), TACHYCARDIA (tachycardia), COUGH (tachycardia), PYREXIA (fever), FATIGUE (tiredness) and MYOCARDITIS (myocarditis)

Case ID	WW Identifier	Narrative
		in an 18-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) (batch nos. 1. + 2. 4.1(b) 300 29 18 and 1. + 2. 4.1(b) 300 29 18) for COVID-19 vaccination. No Medical History information was reported. On 18-Jun-2021, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form once a day. On 16-Jul-2021, received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) dosage was changed to 1 dosage form. On 16-Jul-2021, the patient experienced CHEST PAIN (Chest Pain) (seriousness criterion medically significant), PERICARDIAL RUB (pericardial) (seriousness criterion medically significant), TACHYCARDIA (tachycardia) (seriousness criterion medically significant), COUGH (tachycardia) (seriousness criterion medically significant), PYREXIA (fever) (seriousness criterion medically significant), FATIGUE (tiredness) (seriousness criterion medically significant) and MYOCARDITIS (myocarditis) (seriousness criterion medically significant). On 05-Aug-2021, CHEST PAIN (Chest Pain), PERICARDIAL RUB (pericardial), TACHYCARDIA (tachycardia), COUGH (tachycardia), PYREXIA (fever), FATIGUE (tiredness) and MYOCARDITIS (myocarditis) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In 2021, Fibrin D dimer: negative (Negative) test_result = negativa;. In 2021, Laboratory test: test 10061576 (24.1) troponin (2021): troponin; te (Inconclusive) TEST 10061576 (24.1) troponin (2021): troponin; TEST 10016577 (24.1) D-dimers (2021): D-dimers neg.. In 2021, Troponin: negative (Negative) test_result = negativa;. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered CHEST PAIN (Chest Pain), PERICARDIAL RUB (pericardial), TACHYCARDIA (tachycardia), COUGH (tachycardia), PYREXIA (fever), FATIGUE (tiredness) and MYOCARDITIS (myocarditis) to be related. Concomitant product was not provided by the reporter Patient was of 18 years, no pathology, pharmacotherapy, allergy, non-smoker and non-alcohol user, received Spikevax on 18-JUN-2021 and 16-JUL-2021 Two days after the last injection, on 16-JUL-2021, had developed myocarditis with fever, fatigue, chest pain, tachycardia, cough and 4.1(b) The patient, after 21 days, was said to had recovered. Lab data was provided as unknown with result as TEST 10061576 (24.1) troponin (2021): troponin; TEST 10016577 (24.1) D-dimers (2021): D-dimers neg on unknown date Treatment product was not provided by the reporter Company comment: This regulatory authority case concerns a 18-year-old male patient with no relevant medical history who experienced serious unexpected events of chest pain, pericardial rub, tachycardia, cough, pyrexia, fatigue and expected myocarditis, that occurred on the same day after the 2nd dose of the mRNA-1273 . No further details regarding the events were provided. The patient recovered 3 weeks later. The rechallenge was not applicable due to occurrence after the 2nd dose. The benefit-risk relationship of mRNA-1273 is not affected by this report.

Case ID	WW Identifier	Narrative
4.1(b)	4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b)) on 31-Dec-2021 and was forwarded to Moderna on 31-Dec-2021. This regulatory authority case was reported by a consumer and describes the occurrence of DYSPNOEA (trouble breathing), PYREXIA (fever), TREMOR (shaking), FATIGUE (Fatigue/unusual tiredness), CHEST PAIN (Chest pain), DYSPNOEA (Shortness of breath), PALPITATIONS (Heart palpitations), TACHYCARDIA (Racing heart (tachycardia)) and PERICARDITIS (Pericarditis) in a 19-year-old female patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for an unknown indication. The patient's past medical history included Suspected COVID-19 from 09-Mar-2020 to 31-Mar-2020 and Steroid therapy (Taking regular steroid treatment (e.g. orally or rectally)) since an unknown date. Concurrent medical conditions included Psoriatic arthritis (Awaiting diagnosis), Bronchiolitis (Bronchiolitis Obliterains), Asthma and Rheumatoid arthritis (Taking regular medicines for rheumatoid arthritis (or other types of arthritis except osteoarthr...). On 24-Nov-2021, the patient received third dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 08-Dec-2021, the patient experienced PERICARDITIS (Pericarditis) (seriousness criterion medically significant). On an unknown date, the patient experienced DYSPNOEA (trouble breathing) (seriousness criterion medically significant), PYREXIA (fever) (seriousness criterion medically significant), TREMOR (shaking) (seriousness criterion medically significant), 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) and TACHYCARDIA (Racing heart (tachycardia)) (seriousness criterion medically significant). At the time of the report, DYSPNOEA (trouble breathing), PYREXIA (fever), TREMOR (shaking), FATIGUE (Fatigue/unusual tiredness), CHEST PAIN (Chest pain), DYSPNOEA (Shortness of breath), PALPITATIONS (Heart palpitations) and TACHYCARDIA (Racing heart (tachycardia)) outcome was unknown and PERICARDITIS (Pericarditis) was resolving. The action taken with mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown) was unknown. Patient was advised to continue taking paracetamol, Ventolin inhaler and the preventer inhaler which she had already. Treatment given because of symptoms was Ibuprofen and Naproxen Patient has not tested positive for COVID-19 since having the vaccine. Company Comment- This case refers to a 19-year-old female patient with a medical history of Psoriatic arthritis, Bronchiolitis, Asthma and Rheumatoid arthritis who

Case ID	WW Identifier	Narrative
		experienced the unexpected events of Dyspnoea, Pyrexia, Tremor, Fatigue, Chest pain, Dyspnoea, Palpitations, Tachycardia and the expected event of Pericarditis. Pericarditis occurred approximately 15 days after the third dose of mRNA-1273 vaccine while the events of Dyspnoea, Pyrexia, Tremor, Fatigue, Chest pain, Dyspnoea, Palpitations and Tachycardia occurred after an unspecified number of days post exposure to the vaccine. No causality assessment was provided by the reporter. The medical history of Psoriatic arthritis, Bronchiolitis, Asthma and Rheumatoid arthritis remains a confounder. The benefit-risk relationship of mRNA-1273 is not affected by this report. Events seriousness assessed as per Regulatory Authority reporting.

20.11.8. Myocarditis/Pericarditis: Patients ≤ 40 years of age Brighton CDC and WHO Assessments after Dose 2 and Dose 3: Case Listings

Case ID	Country	PT	Event Seriousness	ALL PTs	Age	Gender	Event Outcome	Medical History	Concomitant Medications	Dose	TTO	BC	WW Identifier
4.1(b)		Myocarditis	Serious	Asthenia, Chest discomfort, Chest pain, Malaise, Myocarditis, Myocarditis infectious, Vomiting	15	Male	Recovering/Resolving			2	1	Level 1	4.1(b)
		Myocarditis	Serious	Myocarditis	17	Male	Recovering/Resolving			2	3	Level 1	
		Myocarditis	Serious	Chest discomfort, Chest pain, Myocarditis	15	Male	Recovering/Resolving	Troponin I increased(C); Protein C increased(C)		2	4	Level 2	
		Myocarditis	Serious	Myocarditis	17	Male	Recovering/Resolving			2	3	Level 2	
		Myocarditis	Serious	Myocarditis	17	Male	Recovering/Resolving	Accommodation disorder(C); Papilloma(H)		2	3	Level 2	
		Myocarditis	Serious	Myocarditis	14	Male	Recovering/Resolving			2	2	Level 2	
		Myocarditis	Serious	Myocarditis, Pyrexia	17	Male	Recovered/Resolved			2	2	Level 2	
		Myocarditis	Serious	Myocarditis, Pyrexia	17	Male	Not Recovered/Not Resolved			2	3	Level 2	
		Myocarditis	Serious	Hypoaesthesia, Myocarditis	16	Male	Recovered/Resolved			1	3	Level 2	
		Myocarditis	Serious	Myocarditis	15	Male	Recovering/Resolving			2	2	Level 1	
		Myocarditis	Serious	Chest pain, Myocarditis	15	Male	Not Recovered/Not Resolved			Unknown	2	Level 2	
		Myocarditis	Serious	Electrocardiogram QT prolonged, Malaise, Myocarditis, Palpitations	37	Male	Not Recovered/Not Resolved	HypertensionFH; Anxiety(H)		2	1	Level 2	
		Pericarditis	Serious	Chest pain, COVID-19 immunisation, Heart rate increased, Pericarditis	37	Female	Recovering/Resolving	Comirnaty		2	3	Level 2	
		Myocarditis	Serious	COVID-19 immunisation, Myocarditis	31	Male	Recovering/Resolving	COMIRNATY		2	23	Level 1	
		Myocarditis	Serious	Acute pulmonary oedema, COVID-19 immunisation, Myocarditis	37	Male	Recovered/Resolved	COMIRNATY		2	3	Level 1	
		Myocarditis	Serious	Chest pain, Heart rate increased, Myocarditis, Pain in jaw	19	Male	Recovering/Resolving	Myocarditis(C)		2	3	Level 1	
		Myocarditis	Serious	Myocarditis, Pain	24	Male	Recovered/Resolved	Anxiety(H); Depression(H)	LEXAPRO	2	3	Level 2	
		Myocarditis	Serious	Chest pain, Dyspnoea, Myocarditis	33	Male	Unknown			2	0	Level 2	
		Myocarditis	Serious	Myocarditis, Pyrexia	20	Male	Unknown			2	3	Level 2	
		Myocarditis	Serious	Myocarditis, Pyrexia	28	Male	Recovered/Resolved			2	2	Level 1	
		Myocarditis	Serious	Acute myocardial infarction, Chest pain, Dyspnoea, Myocardial infarction, Myocarditis, Troponin increased	25	Male	Not Recovered/Not Resolved	Allergy to vaccine		2	0	Level 1	
		Myocarditis	Serious	Electrocardiogram normal, Myocardial infarction, Myocarditis	19	Male	Recovering/Resolving			2	3	Level 1	
		Myocarditis	Serious	Myocarditis	21	Male	Recovered/Resolved			2	2	Level 1	
		Pericarditis	Serious	Myocarditis, Pericarditis, Pyrexia	22	Male	Recovered/Resolved			2	2	Level 1	
		Myocarditis	Serious	Myocarditis	27	Male	Recovering/Resolving	Cholecystectomy(H); Drug hypersensitivity		2	21	Level 1	
		Myocarditis	Serious	Myocarditis	20	Male	Not Recovered/Not Resolved			2	3	Level 2	
		Myocarditis	Serious	Chest discomfort, Myocarditis, Tachycardia	19	Male	Recovered/Resolved			2	2	Level 2	
		Myocarditis	Serious	Malaise, Myocarditis, Pericarditis, Pyrexia, Vomiting	24	Male	Recovered/Resolved			2	2	Level 2	
		Myocarditis	Serious	Myocarditis	22	Male	Recovered/Resolved			2	1	Level 2	
		Myocarditis	Serious	Myocarditis, Ventricular dysfunction	21	Male	Recovering/Resolving	Tobacco user(H)		2	2	Level 2	
		Myocarditis	Serious	Dyspnoea, Myocarditis	25	Male	Recovering/Resolving			2	5	Level 2	
		Myocarditis	Serious	COVID-19 immunisation, Myocarditis, Pericarditis	24	Male	Recovering/Resolving	COMIRNATY(H)		2	28	Level 2	
		Myocarditis	Serious	Asthenia, Chest discomfort, Chest pain, Chills, Influenza like illness, Myocarditis, Presyncope, Vomiting	33	Male	Recovered/Resolved			2	1	Level 2	
		Pericarditis	Serious	Chest pain, Pericarditis, Pyrexia	18	Female	Recovering/Resolving			2	1	Level 2	
		Myocarditis	Serious	Myocarditis	18	Male	Recovered/Resolved			2	2	Level 1	
		Myocarditis	Serious	Chest pain, Malaise, Myocarditis	29	Male	Not Recovered/Not Resolved			2	0	Level 2	

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	Myocarditis	Serious	Myocarditis, Pyrexia	18	Male	Recovering/Resolving			2	3	Level 2		
	Myocarditis	Serious	Myocarditis, Pyrexia	18	Male	Recovering/Resolving			2	2	Level 1		
	Pericarditis	Serious	Chest discomfort, Concomitant disease aggravated, COVID-19 immunisation, Dizziness, Pericarditis	39	Male	Not Recovered/Not Resolved	Emergency care examination(H); Chest discomfort(H); Chest discomfort(H); COMIRNATY		2	41	Level 2		
	Myocarditis	Serious	Myocarditis, Pyrexia	28	Male	Unknown			2	2	Level 2		
	Myocarditis	Serious	Chest pain, Dyspnoea, Myocarditis, Palpitations, Pyrexia	23	Male	Recovering/Resolving			2	3	Level 2		
	Myocarditis	Serious	Myocarditis, Ventricular extrasystoles	19	Female	Recovering/Resolving			2	0	Level 2		
	Myocarditis	Serious	Myocarditis	19	Male	Recovering/Resolving			2	3	Level 2		
	Myocarditis	Serious	Myocarditis	20	Male	Recovering/Resolving			2	2	Level 2		
	Pericarditis	Serious	Myocarditis, Pericarditis	20	Male	Unknown			2	2	Level 1		
	Pericarditis	Serious	Chest discomfort, Chest pain, Cough, Dyspnoea, Pericardial effusion, Pericarditis, Pyrexia	24	Male	Recovering/Resolving			2	1	Level 1		
	Myocarditis	Serious	Acute myocardial infarction, Chest pain, Limb discomfort, Myocardial infarction, Myocarditis, Pain, Pain in extremity	37	Male	Unknown	Asthma(C); Arthritis(C); Drug hypersensitivity	SYMBICORT; ALBUTEROL [SALBUTAMOL]; TYLENOL; IBUPROFEN	2	238	Level 1		
	Myocarditis	Serious	Chest discomfort, Chest pain, Dyspnoea, Ejection fraction decreased, Myocardial oedema, Myocarditis, Pain, Pain in jaw, Pericardial effusion, Pericarditis, Pyrexia, Sleep disorder, Ventricular hypokinesia	21	Male	Recovered/Resolved		ASPIRIN (E.C.); COLCHICINE; IBUPROFEN; FENTANYL; METOPROLOL SUCCINATE	2	1	Level 1		
	Myocarditis	Serious	Chest pain, Dyspnoea, Myocarditis	23	Male	Unknown			2	2	Level 2		
	Myocarditis	Serious	Myocarditis, Pyrexia, Ventricular hypokinesia	18	Male	Recovering/Resolving			2	3	Level 1		
	Myocarditis	Serious	Chest pain, Myocarditis	18	Male	Recovered/Resolved			2	1	Level 2		
	Myocarditis	Serious	Myocarditis	22	Male	Unknown		IBUPROFEN	2	2	Level 2		
	Myocarditis	Serious	Abdominal pain upper, Influenza like illness, Myocarditis	38	Male	Not Recovered/Not Resolved	Hypersensitivity; Nephrolithiasis(H); Hidradenitis(H); Ex-tobacco user(H)		2	0	Level 1		
	Myocarditis	Serious	Myocarditis	25	Male	Recovered/Resolved			2	2	Level 1		
	Myocarditis	Serious	Myocarditis	39	Male	Recovering/Resolving	Autoimmune thyroiditis(C)	EUTHYROX	2	2	Level 2		
	Myocarditis	Serious	Myocarditis	29	Male	Recovering/Resolving	Adenoidectomy; Obesity(C); Drug hypersensitivity		2	1	Level 2		
	Myocarditis	Serious	Enterocolitis, Myocarditis	26	Male	Recovering/Resolving	Hepatic function abnormal(C)		2	2	Level 2		
	Myocarditis	Serious	Myocarditis, Pyrexia	22	Male	Recovering/Resolving			2	3	Level 2		
	Myocarditis	Serious	Chest pain, Hyperhidrosis, Myocarditis	20	Male	Not Recovered/Not Resolved			2	3	Level 2		
	Pericarditis	Serious	Medication error, Pericarditis	40	Male	Recovered/Resolved with Sequelae			2	8	Level 1		
	Myocarditis	Serious	Chest pain, Myocarditis, Pericarditis	32	Male	Recovered/Resolved			2	4	Level 1		
	Myocarditis	Serious	Chest pain, Myocarditis	25	Male	Unknown			2	3	Level 2		
	Myocarditis	Serious	Chest pain, Myocarditis, Sensory disturbance	23	Male	Recovered/Resolved			2	2	Level 1		
	Myocarditis	Serious	Chest pain, Myocarditis	34	Female	Recovered/Resolved			2	0	Level 1		
	Pericarditis	Serious	Dyspnoea, Induced labour, Maternal exposure during pregnancy, Pericarditis, Premature delivery	28	Female	Not Recovered/Not Resolved	Drug hypersensitivity		2	1	Level 2		
	Myocarditis	Serious	Chills, Feeling abnormal, Myocarditis, Pyrexia	31	Male	Recovered/Resolved			2	3	Level 2		
	Myocarditis	Serious	Myocarditis	22	Male	Recovered/Resolved	Drug hypersensitivity(H); Faropenem sodium(H)		2	1	Level 2		
	Myocarditis	Serious	Myocarditis	27	Male	Recovered/Resolved			2	3	Level 2		
	Myocarditis	Serious	Myocarditis	27	Male	Not Recovered/Not Resolved			2	4	Level 1		
	Myocarditis	Serious	Myocarditis, Pyrexia	27	Male	Unknown			2	1	Level 2		
	Myocarditis	Serious	Chest pain, Myocarditis, Pyrexia	25	Male	Recovered/Resolved			2	3	Level 1		
	Myocarditis	Serious	Myocarditis	37	Male	Recovering/Resolving	Familial risk factorFH		2	3	Level 1		

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Myocarditis	Serious	Chest discomfort, Cough, Dyspnoea, Fatigue, Headache, Hyperhidrosis, Impaired work ability, Myocarditis, Pyrexia	19	Male	Recovering/Resolving	(H)		2	0	Level 1
Pericarditis	Serious	Pericarditis	35	Male	Recovering/Resolving	Drug hypersensitivity; Drug hypersensitivity; Alcoholism(C)		2	1	Level 3
Myocarditis	Serious	Abdominal pain upper, Chest discomfort, Discomfort, Malaise, Musculoskeletal pain, Myocarditis, Pyrexia	21	Male	Recovering/Resolving	Asthma(C)		2	3	Level 2
Myocarditis	Serious	Chest pain, Myocarditis	22	Male	Recovering/Resolving			2	4	Level 2
Myocarditis	Serious	Myocarditis, Pericarditis	23	Male	Not Recovered/Not Resolved			2	2	Level 2
Myocarditis	Serious	Myocarditis	30	Male	Recovering/Resolving			2	2	Level 2
Myocarditis	Serious	Myocarditis, Pyrexia	37	Female	Not Recovered/Not Resolved	Palpitations(C)		2	7	Level 2
Myocarditis	Serious	Myocarditis	35	Male	Recovering/Resolving	Tobacco user(C); Alcohol use(C); Seasonal allergy; Allergy to animal	DOXYCLIN [DOXYCYCLINE HYCLATE]	2	2	Level 2
Myocarditis	Serious	Influenza like illness, Myocarditis	18	Male	Recovering/Resolving			2	2	Level 2
Myocarditis	Serious	Abdominal pain upper, Chest pain, Malaise, Myocarditis, Palpitations, Pyrexia	21	Male	Recovering/Resolving	(H)		3	3	Level 1
Myocarditis	Serious	Myocarditis	20	Male	Recovering/Resolving			2	3	Level 2
Myocarditis	Serious	COVID-19 immunisation, Myocarditis	25	Male	Recovering/Resolving	Comirnaty		2	3	Level 2
Pericarditis	Serious	Chest pain, COVID-19 immunisation, Pericarditis	33	Male	Unknown	COMIRNATY		2	0	Level 3
Myocarditis	Serious	Chest pain, COVID-19 immunisation, Fatigue, General physical health deterioration, Myocarditis, Respiratory symptom	19	Male	Recovering/Resolving	Comirnaty; Comirnaty(H)		2	2	Level 2
Myocarditis	Serious	Myocarditis	20	Male	Recovering/Resolving			2	1	Level 2
Myocarditis	Serious	Myocarditis	22	Male	Recovering/Resolving			2	3	Level 1
Pericarditis	Serious	Chest discomfort, COVID-19 immunisation, Pericarditis	22	Male	Unknown			2	4	Level 2
Myocarditis	Serious	Chest pain, Myocarditis, Tachycardia	22	Male	Unknown	Asthma(H)	ALVESCO; ZODAC	2	4	Level 1
Myocarditis	Serious	Myocarditis	22	Male	Not Recovered/Not Resolved			2	2	Level 2
Myocarditis	Serious	Chest discomfort, Myocarditis, Pain in jaw	26	Female	Unknown		MULTIVITAMIN [VITAMINS NOS]	2	3	Level 1
Myocarditis	Serious	Abdominal pain upper, Cold sweat, COVID-19 immunisation, Influenza like illness, Myocarditis, Nausea, Vomiting	22	Male	Recovering/Resolving	Comirnaty(H)		2	2	Level 2
Pericarditis	Serious	COVID-19 immunisation, Pericarditis	35	Male	Unknown	Comirnaty(H)		2	3	Level 1
Myocarditis	Serious	Chest pain, Myocarditis	18	Male	Recovering/Resolving	COMIRNATY(H)		2	3	Level 2
Myocarditis	Serious	Chest pain, COVID-19 immunisation, Myocarditis	33	Male	Not Recovered/Not Resolved			2	4	Level 1
Myocarditis	Serious	Chest pain, COVID-19 immunisation, Incorrect dose administered, Myocarditis	24	Male	Recovering/Resolving	Childhood asthma(C); Comirnaty(H)		2	2	Level 1
Myocarditis	Serious	Chest pain, Myocarditis	29	Male	Recovering/Resolving			2	1	Level 2
Myocarditis	Serious	Impaired work ability, Loss of personal independence in daily activities, Myocarditis	22	Male	Recovering/Resolving			2	1	Level 2
Myocarditis	Serious	Myocarditis	33	Male	Not Recovered/Not Resolved	Alcohol use(C); Tobacco user(C)		2	42	Level 2
Myocarditis	Serious	Abdominal pain, Chest pain, Headache, Limb discomfort, Myocarditis, Pyrexia	37	Male	Recovering/Resolving			2	4	Level 2
Pericarditis	Serious	Pericarditis	28	Male	Unknown			2	1	Level 2
Myocarditis	Serious	Myocarditis	24	Male	Recovering/Resolving			2	3	Level 2
Pericarditis	Serious	Pericarditis	28	Male	Recovered/Resolved			2	1	Level 2
Myocarditis	Serious	Myocarditis, Pericarditis	26	Male	Recovering/Resolving			2	3	Level 1
Pericarditis	Serious	Myocarditis, Pericarditis	26	Male	Recovering/Resolving			2	1	Level 1
Myocarditis	Serious	Myocarditis	20	Male	Recovering/Resolving			2	2	Level 2
Myocarditis	Serious	Myocarditis	25	Male	Recovering/Resolving			2	3	Level 2
Myocarditis	Serious	Chest pain, Dyspnoea, Electrocardiogram change, Myocarditis, Troponin I increased	19	Male	Recovering/Resolving			2	1	Level 2
Myocarditis	Serious	Myocarditis	18	Male	Recovered/Resolved			2	1	Level 2

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Myocarditis	Serious	Myocarditis, Pyrexia	23	Male	Unknown			2	2	Level 2
Pericarditis	Serious	Abdominal distension, C-reactive protein increased, Chest discomfort, Chest pain, Cough, Deep vein thrombosis, Discomfort, Dizziness, Dyspnoea, Ejection fraction decreased, Hyperhidrosis, Myalgia, Myocarditis, Pain, Pain in extremity, Pericardial effusion, Pericardial fibrosis, Pericarditis, Peripheral swelling, Pyrexia, Red blood cell sedimentation rate increased, Troponin increased	30	Male	Not Recovered/Not Resolved	Dyslipidaemia(H)		2	1	Level 2
Myocarditis	Serious	Abdominal distension, C-reactive protein increased, Chest discomfort, Chest pain, Cough, Deep vein thrombosis, Discomfort, Dizziness, Dyspnoea, Ejection fraction decreased, Hyperhidrosis, Myalgia, Myocarditis, Pain, Pain in extremity, Pericardial effusion, Pericardial fibrosis, Pericarditis, Peripheral swelling, Pyrexia, Red blood cell sedimentation rate increased, Troponin increased	30	Male	Not Recovered/Not Resolved	Dyslipidaemia(H)		2	1	Level 2
Pericarditis	Serious	Chest pain, Myocarditis, Palpitations, Pericarditis	35	Female	Not Recovered/Not Resolved	Food allergy		2	111	Level 2
Myocarditis	Serious	Chest pain, Myocarditis, Palpitations, Pericarditis	35	Female	Not Recovered/Not Resolved	Food allergy		2	111	Level 2
Myocarditis	Serious	Chest pain, Malaise, Myocarditis, Pyrexia	25	Male	Recovering/Resolving	Migraine(H); COMIRNATY; COVID-19 immunisation	ISOPTIN [VERAPAMIL]	2	3	Level 1
Myocarditis	Serious	Myocarditis	20	Male	Recovered/Resolved			2	4	Level 2
Myocarditis	Serious	Myocarditis	20	Male	Recovered/Resolved			2	2	Level 2
Myocarditis	Serious	Myocarditis	24	Male	Recovering/Resolving	Tobacco user(C)		2	2	Level 2
Myocarditis	Serious	Dyspnoea, Myocarditis, Palpitations	27	Male	Not Recovered/Not Resolved			2	2	Level 1
Myocarditis	Serious	Chest pain, Myocarditis, Pain, Pyrexia	25	Male	Not Recovered/Not Resolved			2	2	Level 2
Myocarditis	Serious	Chest crushing, Chest discomfort, Chest pain, Hyperdynamic left ventricle, Myalgia, Myocarditis, Painful respiration, Pleuritic pain, Pyrexia	21	Male	Unknown	Asthma(C); Depression(C)		2	2	Level 2
Myocarditis	Serious	Myocarditis	19	Male	Unknown			2	3	Level 1
Myocarditis	Serious	Arthralgia, Chest discomfort, Headache, Malaise, Myocarditis	20	Male	Recovering/Resolving	Seasonal allergy		2	4	Level 1
Myocarditis	Serious	Chest pain, Chills, Headache, Myocarditis	26	Male	Recovered/Resolved			2	2	Level 1
Myocarditis	Serious	Chest pain, Myocarditis	28	Male	Recovered/Resolved		SERTRALINE	2	3	Level 1
Myocarditis	Serious	Chest pain, Inappropriate schedule of product administration, Myocarditis	28	Male	Recovering/Resolving	Tobacco user(C)		2	3	Level 1
Myocarditis	Serious	Myocarditis	20	Male	Unknown			2	1	Level 1
Myocarditis	Serious	Cardiovascular disorder, Chills, Myocarditis, Nausea, Sinus bradycardia	18	Male	Recovering/Resolving			2	3	Level 2
Myocarditis	Serious	Chest pain, Chills, Myocarditis, Pain, Pain in jaw, Painful respiration, Ventricular tachycardia	21	Male	Recovered/Resolved			2	3	Level 2
Myocarditis	Serious	Myocarditis	21	Male	Unknown	Non-tobacco user(H)		2	1	Level 1
Myocarditis	Serious	Myocarditis, Pericarditis, Viral myocarditis	27	Male	Not Recovered/Not Resolved			2	3	Level 2
Myocarditis	Serious	Chest pain, Inappropriate schedule of product administration, Myocarditis	25	Male	Recovering/Resolving			2	3	Level 2
Myocarditis	Serious	Myocarditis	19	Male	Unknown			2	2	Level 2
Myocarditis	Serious	Myocarditis	22	Male	Recovering/Resolving			2	1	Level 2
Myocarditis	Serious	Chest pain, Myocarditis	18	Male	Not Recovered/Not Resolved			2	3	Level 2
Myocarditis	Serious	Myocarditis, SARS-CoV-2 test positive	20	Male	Recovering/Resolving			2	2	Level 2
Myocarditis	Serious	Inappropriate schedule of product administration, Myocarditis	26	Male	Recovering/Resolving			2	1	Level 2
Myocarditis	Serious	Chills, Myocarditis, Night sweats, Pyrexia	27	Male	Unknown	Gastrooesophageal reflux disease(C)		2	2	Level 2
Myocarditis	Serious	Chills, Headache, Myocarditis, Nausea, Pericarditis	18	Male	Not Recovered/Not Resolved	Asthma(C)		2	2	Level 2
Myocarditis	Serious	Myalgia, Myocarditis, Pyrexia	21	Male	Not Recovered/Not Resolved	Tobacco user(C)		2	4	Level 2
Myocarditis	Serious	Myocarditis	20	Male	Recovered/Resolved			2	4	Level 2

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Myocarditis	Serious	Chest discomfort, Chest pain, Left ventricular dysfunction, Myocarditis, Nasopharyngitis, Pericarditis, Sleep disorder, Stress	23	Male	Recovered/Resolved	Dyspnoea(C); Asthma(C); Depression(H)	ALBUTEROL [SALBUTAMOL]	2	2	Level 1	
Myocarditis	Serious	Chest pain, Chills, Fatigue, Myalgia, Myocarditis, Nausea	27	Male	Recovered/Resolved	Food allergy	BUPROPION	2	4	Level 2	
Myocarditis	Serious	Cardio-respiratory arrest, Headache, Myocardial necrosis marker increased, Myocarditis, Pyrexia, Ventricular fibrillation	20	Male	Not Recovered/Not Resolved	Lung assist device therapy		2	2	Level 2	
Myocarditis	Serious	Myocarditis	29	Male	Not Recovered/Not Resolved			2	4	Level 1	
Myocarditis	Serious	Chest pain, Myocarditis	28	Male	Recovering/Resolving	Myocarditis(H); Familial risk factor(H); Seasonal allergy; Non-tobacco user(C)		2	3	Level 2	
Myocarditis	Serious	Chest pain, Hypersensitivity, Myocarditis, Pyrexia, Vaccination site lymphadenopathy	29	Male	Unknown			2	0	Level 2	
Myocarditis	Serious	Myocarditis	21	Male	Recovered/Resolved			2	4	Level 2	
Myocarditis	Serious	Myocarditis	18	Male	Not Recovered/Not Resolved			2	3	Level 2	
Myocarditis	Serious	Chest pain, Dyspnoea exertional, Fatigue, Myocarditis, Pyrexia	21	Male	Recovering/Resolving	Seasonal allergy; Food allergy; Tobacco user(C)	AERIUS [DESLORATADINE]	2	1	Level 2	
Myocarditis	Serious	Fatigue, Hypertension, Myocardial infarction, Myocarditis, Pain, Tremor, Vomiting	21	Male	Recovering/Resolving	Mood altered(H); Hypertension(C); Pregnancy(H)		2	3	Level 2	
Myocarditis	Serious	Chest pain, Myocarditis, Product administered to patient of inappropriate age	17	Male	Recovered/Resolved	Type 1 diabetes mellitus(C)	INSULIN	1	1	Level 2	
Myocarditis	Serious	Chest pain, Chills, Fatigue, Myocarditis, SARS-CoV-2 test positive, Tachycardia	15	Male	Not Recovered/Not Resolved	Wolff-Parkinson-White syndrome(H)	GARDASIL 9	2	1	Level 1	
Myocarditis	Serious	Chest pain, Myocarditis, Palpitations, Product administered to patient of inappropriate age, Vaccination complication	15	Female	Recovered/Resolved	Tic(C)	GUANFACINE	Unknown	1	Level 2	
Myocarditis	Serious	Chest pain, Myocarditis	17	Male	Not Recovered/Not Resolved			2	3	Level 2	
Myocarditis	Serious	Myocarditis, Pyrexia	16	Male	Recovering/Resolving			2	2	Level 1	
Pericarditis	Serious	Chest pain, Pericarditis, Pyrexia	14	Male	Recovering/Resolving			2	1	Level 1	
Myocarditis	Serious	Chest pain, COVID-19 immunisation, Myocarditis	17	Female	Recovering/Resolving	Comirnaty(H)		2	0	Level 2	
Myocarditis	Serious	Cardiac arrest, Inappropriate schedule of product administration, Myocarditis, Pyrexia, Vaccination complication	55	Male	Recovering/Resolving	Hypertension(C)		2	5	Level 1	
Pericarditis	Serious	Chest pain, Dyspnoea, Myocarditis, Nausea, Pericarditis	37	Male	Recovering/Resolving	Drug hypersensitivity	IBUPROFEN; PARACETAMOL; CARVEDILOL	2	31	Level 1	
Myocarditis	Serious	Chest pain, Dyspnoea, Myocarditis, Nausea, Pericarditis	37	Male	Recovering/Resolving	Drug hypersensitivity	IBUPROFEN; PARACETAMOL; CARVEDILOL	2	31	Level 1	
Myocarditis	Serious	Chest pain, Myocarditis, Pyrexia	32	Male	Recovering/Resolving	Not reported		2	5	Level 2	
Myocarditis	Serious	Myocarditis	20	Male	Recovering/Resolving	Not reported		2	3	Level 1	
Myocarditis	Serious	Myocarditis	27	Male	Not Recovered/Not Resolved	Not reported		2	2	Level 1	
Myocarditis	Serious	Chest pain, Myocarditis, Pyrexia	19	Male	Unknown	Type 1 diabetes mellitus(C); Dyslipidaemia(C)	INSULIN GLARGINE; INSULIN REGULAR [INSULIN BOVINE]; ZOCOR	2	1	Level 1	
Myocarditis	Serious	Chest discomfort, Myocarditis, Pain	20	Male	Unknown	Not reported	[redacted] [DEXMETHYLPHENIDATE HYDROCHLORIDE]; MINOCYCLINE	2	1	Level 1	
Myocarditis	Serious	Chest pain, Myocarditis, Nausea, Sinus bradycardia, Vomiting	18	Male	Recovered/Resolved	Not reported		2	0	Level 2	
Myocarditis	Serious	Chest pain, Myocarditis, Nausea	32	Male	Recovered/Resolved	Not reported	PROBIOTICS NOS	2	1	Level 2	
Myocarditis	Serious	Chest discomfort, Chest pain, Headache, Lymphadenopathy, Myocarditis, Tachycardia	24	Male	Not Recovered/Not Resolved	Not reported		2	0	Level 2	
Myocarditis	Serious	Acute myocardial infarction, Coronary artery disease, Myocarditis	52	Male	Unknown	Not reported		2	5	Level 1	
Myocarditis	Serious	Myocarditis, Pericardial effusion	23	Male	Recovering/Resolving	Not reported	NEXIUM; AJOVY [FREMANEZUMAB VFRM]	2	4 days	Level 1	
Myocarditis	Serious	Chest discomfort, Dyspnoea, Myocarditis	25	Male	Unknown	Not reported		2	3 days	Level 2	
Myocarditis	Serious	Chest pain, Myocarditis	23	Male	Recovered/Resolved	Gout(C)	COLCHICINE; FAMOTIDINE	2	2 days	Level 2	
Pericarditis	Serious	Chest pain, Pericardial effusion, Pericarditis, Pleuritic pain	75	Male	Recovered/Resolved	Rhinitis allergic(C); Hypertension(C); Hyperlipidaemia(C)	ATENOLOL; MONTELUKAST; ROSUVASTATIN; OLMESARTAN; TAMSULOSIN; ACETYLSALICYLIC ACID	2	0 day	Level 2	
Myocarditis	Serious	Chest pain, Fatigue, Headache, Myocarditis, Pain, Sinus tachycardia	20	Male	Unknown	Not reported		2	0 day	Level 2	
Myocarditis	Serious	Chest discomfort, Chest pain, Headache, Malaise, Myocarditis, Nausea, Painful respiration, Pyrexia	21	Male	Unknown	Not reported	FLONASE [FLUTICASONE PROPIONATE]	2	4 days	Level 2	
Myocarditis	Serious	Chest pain, Myocarditis	20	Male	Recovered/Resolved	Drug hypersensitivity(C); Autism spectrum disorder(C)		2	2 days	Level 2	

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Viral myocarditis	Serious	Chest pain, Chills, Hyperhidrosis, Pain, Sinus bradycardia, Syncope, Ventricular extrasystoles, Viral myocarditis	23	Male	Recovered/Resolved	Drug hypersensitivity; Asthma(C)	VITAMIN D [VITAMIN D NOS]	2	3 days	Level 2	
Myocarditis	Serious	Chest pain, Myocarditis	21	Male	Unknown	Not reported		2	2 days	Level 1	
Myocarditis	Serious	Chest pain, Myocarditis, Thrombosis	23	Male	Recovered/Resolved	Not reported		2	3 days	Level 1	
Pericarditis	Serious	Chest discomfort, General symptom, Pericarditis, Pleuritic pain	20	Male	Not Recovered/Not Resolved	Not reported		2	1 day	Level 2	
Myocarditis	Serious	Dyspnoea, Malaise, Myocarditis, Pyrexia	37	Male	Recovered/Resolved	Factor V Leiden carrier(C); Drug hypersensitivity	TYLENOL	2	1 day	Level 1	
Myocarditis	Serious	Chest pain, Myocarditis	24	Male	Recovered/Resolved	Zoonotic bacterial infection(C); Bronchial hyperreactivity(C); Back pain(C)		2	3 days	Level 1	
Myocarditis	Serious	Chest pain, Incorrect route of product administration, Myocarditis, Pain, Painful respiration, Sleep disorder	18	Male	Unknown	Asthma exercise induced(H)		2	2 days	Level 1	
Myocarditis	Serious	Chest pain, Dyspnoea, Fatigue, Myocarditis	46	Male	Not Recovered/Not Resolved	Post-traumatic stress disorder(C); Anxiety(C)	ESCITALOPRAM; VYVANSE; BUPROPION; OMEGA-3 FISH OIL; ALPRAZOLAM; ROSUVASTATIN; PRAZOSIN; CETIRIZINE; FAMOTIDINE	2	1 day	Level 1	
Myocarditis	Serious	Chest pain, Dyspnoea, Myocarditis, Pyrexia	28	Male	Recovered/Resolved	Hypertension(C)	RAMIPRIL	2	1 month 6 days	Level 2	
Myocarditis	Serious	Chest pain, Cough, Dyspnoea, Myocarditis	18	Male	Recovering/Resolving	No adverse event(H)		2	2 days	Level 2	
Myocarditis	Serious	Chest pain, Myocarditis	23	Male	Not Recovered/Not Resolved	Not reported		2	3 days	Level 2	
Myocarditis	Serious	Chest discomfort, Chest pain, Ejection fraction decreased, Inflammatory marker increased, Myocardial necrosis marker increased, Myocarditis	21	Male	Recovered/Resolved	Not reported		2	2 days	Level 2	
Myocarditis	Serious	Chest pain, Myocarditis, Troponin increased	19	Male	Unknown	Not reported		2	1 day	Level 2	
Myocarditis	Serious	Chest pain, Dyspnoea, Myocarditis	29	Male	Recovering/Resolving			Dose 2	4	Level 1	
Pericarditis	Serious	Chest pain, Pericarditis, Pleuritic pain	20	Female	Not Recovered/Not Resolved	Drug hypersensitivity; Hypertension(C); Lupus nephritis(C); Aspergillus infection(H)	CELLCEPT [MYCOPHENOLATE MOFETIL]; LISINOPRIL; PLAQUENIL [HYDROXYCHLOROQUINE PHOSPHATE]; AMLODIPINE; CARVEDILOL; HYDRALAZINE; CRESEMBA	Dose 2	1	Level 2	
Myocarditis	Serious	Myocarditis	18	Male	Not Recovered/Not Resolved			Dose 2	3	Level 1	
Myocarditis	Serious	Chest pain, Feeling of body temperature change, Myalgia, Myocarditis	29	Male	Not Recovered/Not Resolved	Alcohol abuse(C); Tobacco user(C); Drug abuse(H)		Dose 2	2	Level 2	
Myocarditis	Serious	Chest pain, Dyspnoea, Fatigue, Myocarditis, Pain, Palpitations, Tachycardia	30	Female	Not Recovered/Not Resolved	Migraine(C)	AMITRIPTYLINE; COVID-19 MRNA VACCINE BNT162B2	Dose 3	4	Level 2	
Myocarditis	Serious	Myocarditis	35	Male	Recovering/Resolving	Viral myocarditis(H); Tobacco user(C); Allergy to chemicals		Dose 2	3	Level 1	
Myocarditis	Serious	Myocarditis	19	Male	Recovered/Resolved			Dose 2	3	Level 1	
Myocarditis	Serious	Asthenia, Chest discomfort, Chest pain, Cold sweat, Decreased appetite, Discomfort, Dizziness, Dyspnoea, General physical health deterioration, Head discomfort, Malaise, Musculoskeletal stiffness, Myocarditis, Palpitations	27	Male	Recovering/Resolving	Overweight(H)		Dose 2	33	Level 2	
Myocarditis	Serious	Myocarditis, Pyrexia	29	Male	Recovered/Resolved	Seasonal allergy		Dose 2	3	Level 1	
Myocarditis	Serious	Myocarditis	22	Female	Recovering/Resolving	Juvenile myoclonic epilepsy(C); Asthma(C)		Dose 2	16	Level 2	
Myocarditis	Serious	Cardiomyopathy, Chest pain, Myocarditis, Oedema	22	Male	Unknown	Drug hypersensitivity; Depression(C); Anxiety(C); Vitamin D deficiency(C); Hepatic steatosis(H); COVID-19(H)	ESCITALOPRAM OXALATE; VITAMIN D [VITAMIN D NOS]; MULTIVITAMIN [VITAMINS NOS]; FLAX OIL	Dose 3	6	Level 1	
Myocarditis	Serious	Myocarditis	37	Male	Recovering/Resolving			Dose 2	3	Level 1	
Myocarditis	Serious	Myocarditis, Pyrexia	15	Male	Unknown			Dose 2	2	Level 2	
Myocarditis	Serious	Chest pain, Myocardial necrosis marker increased, Myocarditis	28	Male	Recovering/Resolving			Dose 2	3	Level 1	
Myocarditis	Serious	Blood creatine phosphokinase increased, Myocarditis, Troponin increased	18	Male	Not Recovered/Not Resolved	COVID-19 VACCINE MODERNA(H)		Dose 2	0	Level 3	
Myocarditis	Serious	Chest pain, Myocarditis	23	Male	Unknown			Dose 2	1	Level 2	
Myocarditis	Serious	Chest pain, Discomfort, Myocarditis, Pyrexia	38	Male	Recovering/Resolving			Dose 2	59	Level 2	
Myocarditis	Serious	Myocarditis	19	Male	Recovering/Resolving			Dose 2	2	Level 2	
Myocarditis	Serious	Chest pain, Cold sweat, Dyspnoea, Fatigue, Illness, Malaise, Myocarditis, Palpitations, Pericarditis, Tachycardia	24	Male	Recovering/Resolving			Dose 2	1	Level 2	

4.1(b)	Myocarditis	Serious	Myocarditis	39	Male	Unknown	Neuroborreliosis(H)		Dose 2	3	Level 2	
	Myocarditis	Serious	Blood test abnormal, Cardiac monitoring, Chest discomfort, Chest pain, Chest X-ray normal, Dyspnoea, Electrocardiogram, Hypopnoea, Monocyte count increased, Myocarditis, Neutrophil count increased, Painful respiration, Respiratory viral panel, Troponin increased, White blood cell count increased	25	Male	Not Recovered/Not Resolved			Dose 2	1	Level 2	
	Myocarditis	Serious	Arthralgia, Chest pain, Dyspnoea, Ejection fraction decreased, Erectile dysfunction, Fatigue, Heart rate, Hyperhidrosis, Incoherent, Myocarditis, Night sweats, Pain, Palpitations, Paraesthesia, Pyrexia, Tachycardia, Urinary retention	29	Male	Not Recovered/Not Resolved			Dose 2	2	Level 3	
	Myocarditis	Serious	Myocarditis	16	Male	Not Recovered/Not Resolved	Drug hypersensitivity; Food allergy		Dose 2	2	Level 1	
	Myocarditis	Serious	Myalgia, Myocarditis, Pyrexia	18	Male	Recovered/Resolved			Dose 2	1	Level 1	
	Myocarditis	Serious	Arthralgia, Chills, Eye pain, Headache, Myalgia, Myocarditis, Pyrexia, Troponin increased	20	Male	Unknown			Dose 2	24	Level 2	
	Myocarditis	Serious	Chest pain, Chills, Dizziness, Dyspnoea, Myocarditis, Nausea, Pyrexia, Vomiting	30	Male	Recovering/Resolving	COVID-19 VACCINE MODERNA(H)		Dose 2	5	Level 2	
	Myocarditis	Serious	Myocarditis	20	Male	Recovering/Resolving			Dose 2	1	Level 3	
	Myocarditis	Serious	Myocarditis	28	Male	Recovered/Resolved			Dose 2	3	Level 1	
	Pericarditis	Serious	Malaise, Pericarditis, Pyrexia	17	Male	Recovering/Resolving			Dose 2	1	Level 2	
	Myocarditis	Serious	Myocarditis	14	Male	Recovering/Resolving			Dose 2	1	Level 2	
	Myocarditis	Serious	Myocarditis	17	Male	Unknown			Dose 2	4	Level 2	
	Myocarditis	Serious	Cerebral infarction, Embolic stroke, Myocarditis	38	Female	Recovering/Resolving			Dose 2	29	Level 1	
	Myocarditis	Serious	Chest discomfort, Chest pain, Headache, Myocarditis, Pericarditis, Pyrexia	14	Male	Recovered/Resolved			Dose 2	1	Level 1	
	Myocarditis	Serious	Myocarditis, Pyrexia	17	Male	Recovered/Resolved			Dose 2	3	Level 2	
	Myocarditis	Serious	Myocarditis	22	Male	Recovering/Resolving			Dose 2	2	Level 3	
	Pericarditis	Serious	Myocarditis, Pericarditis	22	Male	Recovering/Resolving	Food allergy; Milk allergy	EFFEXOR SR; EFFEXOR SR; 4.1(b)	Dose 2	2	Level 1	
	Myocarditis	Serious	Anxiety, C-reactive protein increased, Cardiac imaging procedure abnormal, Chest discomfort, Chest pain, Chills, Cough, Ear pain, Echocardiogram normal, Ejection fraction normal, Electrocardiogram abnormal, Electrocardiogram T wave inversion, Fatigue, Headache, Hyperhidrosis, Left ventricular dilatation, Magnetic resonance imaging heart, Malaise, Myocardial oedema, Myocarditis, N-terminal prohormone brain natriuretic peptide increased, Nausea, Pain, Pericardial fibrosis, Pleuritic pain, Pyrexia, Red blood cell sedimentation rate increased, Retching, Sleep disorder, Troponin increased, Ventricular hypokinesia, Vomiting	39	Female	Recovered/Resolved	Drug hypersensitivity; Drug hypersensitivity		Dose 3	0	Level 1	
	Myocarditis	Serious	Chest pain, Dyspnoea, Fatigue, Myocarditis, Tachycardia	19	Female	Recovering/Resolving			Dose 2	3	Level 2	
	Myocarditis	Serious	Chest pain, Myocarditis	25	Male	Recovering/Resolving			Dose 2	4	Level 2	
	Pericarditis	Serious	Myocarditis, Pericarditis	21	Male	Recovering/Resolving	Bundle branch block right(H)		Dose 2	3	Level 1	
	Pericarditis	Serious	Atrioventricular block second degree, Chest discomfort, Headache, Hypoaesthesia, Malaise, Myocarditis, Pericarditis, Platelet count increased, Pyrexia	34	Male	Recovering/Resolving	Sinusitis(H); Gastric cancer(C); Lung neoplasm malignant(C); Aneurysm ruptured(H)		Dose 2	5	Level 1	
	Myocarditis	Serious	Arthralgia, Fatigue, Myocarditis, Pyrexia	21	Male	Unknown			Dose 2	3	Level 2	
	Myocarditis	Serious	C-reactive protein increased, Carditis, Chest discomfort, Chest pain, Chest X-ray normal, Dyspnoea, Echocardiogram, Electrocardiogram abnormal, Hypoaesthesia, Laboratory test, Lymphadenopathy, Myocarditis, Pain in extremity, Paraesthesia, Troponin increased	34	Female	Not Recovered/Not Resolved			Dose 3	1	Level 2	

[redacted]		Myocarditis	Serious	Blood creatine phosphokinase increased, C-reactive protein increased, Chest pain, Dyspnoea, Echocardiogram, Ejection fraction, Myalgia, Myocarditis, Pyrexia, Troponin increased	19	Male	Unknown			Dose 2	2	Level 2	
		Myocarditis	Serious	Blood creatine phosphokinase increased, Chest pain, Chills, Diarrhoea, Echocardiogram normal, Electrocardiogram abnormal, Electrocardiogram ST segment elevation, Fatigue, Hyperhidrosis, Myocarditis, Pericarditis, Pyrexia, SARS-CoV-2 test negative, Troponin I increased, Viral test negative, Vomiting	26	Female	Recovered/Resolved			Dose 3	3	Level 2	
		Myocarditis	Serious	Myocarditis	34	Female	Recovering/Resolving			Dose 2	2	Level 2	[redacted]
		Myocarditis	Serious	Myocarditis	30	Male	Recovering/Resolving			Dose 2	3	Level 2	
		Myocarditis	Serious	Myocarditis	26	Male	Recovering/Resolving			Dose 2	3	Level 2	
		Myocarditis	Serious	Myocarditis	24	Male	Recovering/Resolving			Dose 2	3	Level 2	
		Myocarditis	Serious	Myocarditis	35	Female	Recovering/Resolving	Mitral valve prolapse(C)		Dose 2	8	Level 2	
		Myocarditis	Serious	Myocarditis	15	Male	Recovered/Resolved with Sequelae	Overweight(C)		Dose 2		Level 2	
		Myocarditis	Serious	Chest discomfort, Chest pain, Hypoxia, Myocarditis, Palpitations	25	Male	Unknown	Asthma(C); COMIRNATY		Dose 2		Level 2	
		Myocarditis	Serious	Myocarditis	25	Male	Recovered/Resolved			Dose 2	1	Level 2	
		Pericarditis	Serious	Arthralgia, Chest pain, Dyspnoea, Echocardiogram abnormal, Pain, Pericardial effusion, Pericarditis	40	Male	Recovered/Resolved	End stage renal disease(C); Blood cholesterol increased(C); Hypertension(C); Gout(C); Mesangioproliferative glomerulonephritis(C)		Dose 2	31	Level 2	
		Myocarditis	Non Serious	C-reactive protein decreased, Chest pain, Dyspnoea, Echocardiogram abnormal, Electrocardiogram abnormal, Fatigue, Headache, Myocarditis, Nausea, Pericarditis, Pyrexia, Sinus tachycardia, Troponin normal, Vomiting	21	Female	Recovered/Resolved	Obesity(H)		Dose 2	1	Level 2	
		Myocarditis	Serious	Chest pain, Dyspnoea exertional, Electrocardiogram abnormal, Electrocardiogram ST segment elevation, Myocarditis, Pyrexia, Troponin increased	30	Male	Unknown			Dose 2	1	Level 2	
		Myocarditis	Serious	Chest pain, Dyspnoea, Fatigue, Hospitalisation, Myocarditis, Tachycardia	18	Male	Recovering/Resolving	Asthma(C); SARS-COV-2 VACCINE; COVID-19 VACCINE	SALBUTAMOL	Dose 3	4	Level 2	
		Myocarditis	Serious	Myocarditis	28	Male	Recovering/Resolving			Dose 2	3	Level 2	
		Pericarditis	Serious	Chest pain, Dyspnoea, Fatigue, Flank pain, Gastric ulcer, Palpitations, Pericarditis, Peripheral swelling	38	Male	Not Recovered/Not Resolved	COVID-19 VACCINE MODERNA(H); Herpes zoster oticus(H)	COVID-19 VACCINE MODERNA	Dose 2	71	Level 2	
		Myocarditis	Serious	Chest discomfort, Dyspnoea, Malaise, Myalgia, Myocarditis, Pyrexia	28	Male	Recovering/Resolving	Substance use(H); Tobacco user(C); SPIKEVAX(H)		Dose 2	1	Level 2	
		Myocarditis	Serious	Myocarditis	35	Female	Recovering/Resolving			Dose 2	3	Level 2	
		Myocarditis	Serious	Chest pain, Myocarditis	16	Male	Recovered/Resolved			Dose 2	2	Level 1	
		Myocarditis	Serious	Myocarditis	18	Male	Recovering/Resolving			Dose 2	2	Level 2	
		Myocarditis	Serious	Chest pain, Dyspnoea, Fatigue, Myocarditis, Pain, Pericardial effusion, Pericarditis, Tachycardia	39	Female	Not Recovered/Not Resolved		COVID-19 VACCINE ASTRAZENECA	Dose 3	1	Level 1	
		Myocarditis	Serious	Chills, Myocarditis, Nausea, Vomiting	20	Male	Unknown	Substance use(C)		Dose 2		Level 1	
		Myocarditis	Serious	Influenza like illness, Myocarditis	21	Male	Unknown			Dose 2		Level 1	
		Myocarditis	Serious	C-reactive protein increased, Chest pain, Myocarditis, Troponin	25	Male	Not Recovered/Not Resolved			Dose 3	1	Level 2	
		Myocarditis	Serious	C-reactive protein increased, Chest pain, Chest X-ray normal, Computerised tomogram thorax normal, Echocardiogram abnormal, Effusion, Electrocardiogram abnormal, Fatigue, Fibrin D dimer increased, Magnetic resonance imaging abnormal, Myocarditis, Nausea, Tachycardia, Troponin increased	23	Male	Not Recovered/Not Resolved	Schizophrenia(C)		Dose 3	4	Level 1	

4.1(b)													4.1(b)
		Myocarditis	Non Serious	C-reactive protein increased, Echocardiogram normal, Electrocardiogram ST segment elevation, Myocarditis, Troponin increased	24	Male	Not Recovered/Not Resolved	Arnold-Chiari malformation(C); Scoliosis(C); Anxiety(C); Depression(C)		Dose 3	3	Level 2	
		Myocarditis	Serious	Myocarditis	20	Male	Unknown	Myocarditis(H)		Dose 2	2	Level 1	
		Myocarditis	Serious	Chest pain, Feeling cold, Malaise, Myocarditis	33	Male	Recovering/Resolving	SPIKEVAX		Dose 2	1	Level 2	
		Myocarditis	Serious	Adenovirus test, Cardiac telemetry normal, Chest pain, Echocardiogram, Electrocardiogram normal, HIV test negative, Human metapneumovirus test, Human rhinovirus test, Influenza A virus test negative, Influenza B virus test, Influenza virus test negative, Myocarditis, Respiratory syncytial virus test negative, SARS-CoV-2 test negative, Troponin increased	25	Male	Not Recovered/Not Resolved			Dose 3	1	Level 2	
		Myocarditis	Serious	Myocarditis, Pyrexia	21	Male	Recovering/Resolving			Dose 2	3	Level 2	
		Myocarditis	Serious	Myocarditis	22	Male	Recovering/Resolving			Dose 2	3	Level 1	
		Myocarditis	Serious	Myocarditis	14	Male	Recovering/Resolving			Dose 2	3	Level 1	
		Myocarditis	Serious	Myocarditis	20	Male	Recovered/Resolved	SPIKEVAX		Dose 2		Level 2	
		Myocarditis	Serious	Chest pain, Myocarditis	33	Female	Unknown	COVID-19(H); Myocardial ischaemiaFH		Dose 2		Level 1	
		Myocarditis	Serious	Back pain, Chest discomfort, Cough, Dyspnoea, Maternal exposure during pregnancy, Myocarditis, Night sweats, Palpitations	30	Female	Unknown	Hypothyroidism(C)	LEVOTHYROXINE	Dose 2		Level 2	
		Pericarditis	Serious	Pericarditis	17	Male	Recovered/Resolved			Dose 2	4	Level 2	
		Pericarditis	Serious	Angina pectoris, Cardiovascular disorder, Chest pain, Dyspnoea, Exercise tolerance decreased, Pericarditis, Sinus arrhythmia	24	Female	Recovering/Resolving	SPIKEVAX(H)		Dose 2		Level 3	
		Myocarditis	Serious	Myocarditis	34	Male	Recovering/Resolving	Tobacco user(C)		Dose 2	45	Level 1	
		Myocarditis	Serious	Chest pain, Myocarditis, Pyrexia	19	Female	Not Recovered/Not Resolved		COLCHICINE; DOXYCYCLINE; MEBEVERINE; SUMATRIPTAN	Dose 2	3	Level 2	
		Pericarditis	Serious	Chest pain, Fatigue, Pericarditis	22	Male	Recovering/Resolving		COVID-19 VACCINE MODERNA; COVID-19 VACCINE MODERNA	Dose 3	1	Level 2	
		Myocarditis	Serious	Chest pain, Dyspnoea, Fatigue, Myocarditis, Palpitations	34	Male	Recovering/Resolving	Electrocardiogram(H)		Dose 3	2	Level 2	
		Myocarditis	Serious	Chest pain, Myocarditis	35	Male	Not Recovered/Not Resolved	Congenital cystic kidney disease(C)	COVID-19 VACCINE ASTRAZENECA	Dose 3	4	Level 2	
		Myocarditis	Serious	Chest pain, Chills, Dyspnoea, Fatigue, Myalgia, Myocarditis, Palpitations, Pyrexia, Syncope	29	Male	Not Recovered/Not Resolved			Dose 3	0	Level 2	
		Myocarditis	Serious	Myocarditis	16	Male	Recovering/Resolving			Dose 2	2	Level 1	
		Myocarditis	Serious	Chest pain, Echocardiogram, Electrocardiogram, Electrocardiogram T wave inversion, Flank pain, Hyperhidrosis, Myocarditis, Pain, Pericardial effusion, Troponin, Vomiting	35	Male	Unknown	Renal cell carcinoma(H); Drug hypersensitivity; Drug hypersensitivity		Dose 3	2	Level 2	
		Myocarditis	Serious	Myocarditis	39	Male	Recovering/Resolving			Dose 3		Level 2	
		Pericarditis	Serious	Chest pain, Dyspnoea, Hypoaesthesia, Influenza like illness, Pericarditis, Pyrexia, Syncope	29	Male	Recovering/Resolving	Temporomandibular joint syndrome(H); Tuberculosis(H)	PFIZER BIONTECH COVID-19 VACCINE; PFIZER BIONTECH COVID-19 VACCINE	Dose 3	0	Level 2	
		Myocarditis	Serious	Chest pain, Left ventricular dysfunction, Myocarditis, Palpitations, Tachycardia	21	Male	Recovering/Resolving		PFIZER BIONTECH COVID-19 VACCINE; PFIZER BIONTECH COVID-19 VACCINE	Dose 3	2	Level 1	
		Myocarditis	Serious	Blood potassium decreased, Cardiac telemetry, Chest discomfort, Chest pain, Differential white blood cell count, Echocardiogram, Electrocardiogram normal, Fibrin D dimer normal, Full blood count, Hypokalaemia, Laboratory test abnormal, Myocarditis, Nausea, Sleep disorder, Troponin increased	21	Male	Unknown	Urticaria(H)		Dose 3	2	Level 1	
		Myocarditis	Serious	Cardiomyopathy, Catheterisation cardiac abnormal, Chest pain, Echocardiogram, Ejection fraction, Electrocardiogram ST segment elevation, Myocarditis, Troponin increased, Vaccination complication	23	Male	Not Recovered/Not Resolved			Dose 3	0	Level 2	

4.1(b)		Myocarditis	Serious	Anticoagulant therapy, Blood creatine phosphokinase abnormal, Blood creatine phosphokinase MB, C-reactive protein abnormal, Chest pain, Chest X-ray, Differential white blood cell count abnormal, Echocardiogram, Electrocardiogram, Fibrin D dimer increased, Full blood count abnormal, Influenza A virus test, Influenza B virus test, Laboratory test abnormal, Metabolic function test abnormal, Myocarditis, N-terminal prohormone brain natriuretic peptide abnormal, SARS-CoV-2 test, Troponin I abnormal	31	Male	Unknown			Dose 3	5	Level 2	4.1(b)
		Myocarditis	Serious	Abdominal pain upper, Back pain, Chest pain, Dyspnoea, Myocarditis, Palpitations, Pyrexia, Troponin I abnormal	30	Male	Unknown			Dose 2	3	Level 2	
		Myocarditis	Serious	Cardiac failure, Chest pain, Chest X-ray, Computerised tomogram thorax abnormal, Electrocardiogram, Haematology test, Hilar lymphadenopathy, Left atrial enlargement, Lung disorder, Mediastinitis, Myocarditis, Pain, Pain in extremity, Pleural effusion, Pulmonary oedema, Tissue infiltration, Troponin increased	26	Male	Not Recovered/Not Resolved	Mite allergy; Asthma(H); Supraventricular tachycardia(H); Myopia(H); Obesity(H); Vitamin D deficiency(H); Congenital diaphragmatic hernia(H)		Dose 3	7	Level 2	
		Myocarditis	Serious	Blood creatine phosphokinase MB increased, Blood creatine phosphokinase normal, Chest pain, Chest X-ray normal, Computerised tomogram thorax normal, Echocardiogram normal, Electrocardiogram ST segment elevation, Full blood count normal, Myocarditis, Pericarditis, SARS-CoV-2 test negative, Troponin increased	19	Male	Recovered/Resolved	Food allergy; Food allergy		Dose 2	0	Level 2	
		Pericarditis	Serious	Chest pain, Pericarditis	39	Female	Recovering/Resolving	Hypothyroidism(C)	T4	Dose 2	5	Level 2	
		Myocarditis	Serious	Myocarditis	15	Female	Recovering/Resolving			Dose 2	5	Level 1	
		Pericarditis	Serious	Chest discomfort, Dyspnoea, Fatigue, Pericarditis	38	Female	Recovering/Resolving	Thrombosis(H)		Dose 2		Level 2	
		Pericarditis	Serious	Pericarditis	31	Unknown	Not Recovered/Not Resolved			Dose 2	54	Level 1	
		Myocarditis	Serious	Myocarditis	30	Male	Not Recovered/Not Resolved	Tobacco user(H)		Dose 2		Level 2	
		Myocarditis	Serious	Chest pain, Cough, Fatigue, Myocarditis, Pericardial rub, Pyrexia, Tachycardia	18	Male	Recovered/Resolved			Dose 2	2	Level 2	
4.1(b)	JAPAN	Myocarditis	Serious	Cardiac tamponade, Cardio-respiratory arrest, Hypoxic-ischaemic encephalopathy, Multiple organ dysfunction syndrome, Myocarditis, Pericarditis	38	Male	Fatal	Diabetes mellitus(C); Diabetic nephropathy(C); Diabetic retinopathy(C); Hypertension(C); Dyslipidaemia(C)	NEXIUM EBB; ALFACALCIDOL; CANDESARTAN; NIFEDIPINE; CALTAN; NOVORAPID	Unknown		Level 2	

20.11.9. Myocarditis/Pericarditis: Patients ≤ 40 years of age Brighton CDC and WHO Assessments after Dose 2 and Dose 3: Case Narratives

Case ID	WW Identifier	Narrative	MAH Comment
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 15-Oct-2021 and was forwarded to Moderna on 15-Oct-2021. 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), MYOCARDITIS (Perimyocarditis) 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 immunisation. No Medical History information was reported. On 13-Aug-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. 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), MYOCARDITIS (Perimyocarditis) (seriousness criteria hospitalization and medically significant) 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),	15 years old male with unknown medical history who next days after the 2nd dose experienced chest pain, chest discomfort, malaise, vomiting, and asthenia, was hospitalized was diagnosed with myocarditis. Laboratory values showed elevated troponin, elevated CRP, abnormal ECG, and Echo. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for any other infectious process. There is a diagnosis of myocarditis infectious but no information provided for this diagnoisis. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and ECG and Echo results; a causal relationship cannot be excluded due to the lack of other information.

		MYOCARDITIS (Perimyocarditis) and MYOCARDITIS INFECTIOUS (Myocarditis infectious) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In September 2021, C-reactive protein: high (High) 68 (increased) mg/mL. In September 2021, Echocardiogram: abnormal (abnormal) OBS slightly decreased left ventricle function. In September 2021, Ejection fraction: 45 (abnormal) 45 (%percent) and 45 (Low) low. In September 2021, Electrocardiogram: abnormal (abnormal) Monstrous ST-elevations. In September 2021, Troponin T: 2289.3 (High) 2289.3 (increased) ng/L. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Concomitant medications was not reported. Treatment history was not reported. Company Comment: This case concerns a 15 year old male with no reported medical history , who experienced expected event of myocarditis and other unexpected events of chest pain, chest pressure, weakness , asthenia and malaise . These events occurred 2 days after vaccination with the 2nd dose of mRNA-1273 (Spikevax) and 1 month and 2 days post vaccination with the 1st dose. The rechallenge for this case is not applicable. The benefit risk relationship of mRNA-1273 (Spikevax) is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 15-Oct-2021: Follow-up received on 15-oct-2021. Significant follow up-seriousness criteria updated and new event added	
4.1(b) [redacted]	4.1(b) [redacted]	This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) [redacted] on 04-Oct-2021 and was forwarded to Moderna on 07-Oct-2021.	17 years old male with unknown medical history who 3 days after the 2nd dose experienced chest pain and was found to have elevated troponin,

		This case, initially reported to the 4.1(b) by a (physician), was received via the 4.1(b) (Ref, 4.1(b)). On 25-Aug-2021, the patient received the 1st dose of this vaccine. After the vaccination, there was no problem. On 22-Sep-2021, in the morning, the patient received the 2nd dose of this vaccine. 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. On 26-Sep-2021, electrocardiogram showed negative T wave. Cardiac function was normal by echocardiography. 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. On 02-Oct-2021, the symptoms were resolving. The outcome of myocarditis was reported as resolving. Follow-up investigation will be made. Company Comment: The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	CK and CRO, and abnormal ECG, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and ECG results; a causal relationship cannot be excluded due to the lack of other information.
4.1(b)	4.1(b)	This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Sep 21, 2nd dose of the Moderna Covid-19 vaccine; Sep 25, chest tightness and pain, troponin I elevation up to 4561 ng/L and CRP, waiting to perform cardiac MRI, suspected myocarditis) and CHEST PAIN (4.1(b)	15 years old male with unknown medical history who 4 days after the 2nd dose experienced chest pain, chest discomfort and was found to have elevated troponin, and was diagnosed with myocarditis. ECG and cMRI results pending. No other information was

		4.1(b) [redacted] in a 15-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 immunisation. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Troponin I increased on 25-Sep-2021 and Protein C increased on 25-Sep-2021. On 21-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 25-Sep-2021, the patient experienced MYOCARDITIS (Sep 21, 2nd dose of the Moderna Covid-19 vaccine; Sep 25, chest tightness and pain, troponin I elevation up to 4561 ng/L and CRP, waiting to perform cardiac MRI, suspected myocarditis) (seriousness criteria hospitalization and medically significant), CHEST PAIN (4.1(b) [redacted] (seriousness criterion hospitalization) and CHEST DISCOMFORT (chest tightness). At the time of the report, MYOCARDITIS (Sep 21, 2nd dose of the Moderna Covid-19 vaccine; Sep 25, chest tightness and pain, troponin I elevation up to 4561 ng/L and CRP, waiting to perform cardiac MRI, suspected myocarditis), CHEST PAIN (4.1(b) [redacted] and CHEST DISCOMFORT (chest tightness) was resolving. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. On 25-SEP-2021 the patient had an Echocardiogram and Troponin I done, Troponin was elevated to 4561 ng/L and	provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin; a causal relationship cannot be excluded due to the lack of other information.

		CRP was done. Patient was waiting to perform Cardiac MRI which resulted in myocarditis. Patient was suspected to myocarditis with a peak TNL 4500 ng/ml and chest pain in remission and TNL declining and after few days of second vaccination patient had preserved cardiac function and was awaiting for Cardiac MRI. Concomitant medications and treatment information was not provided. Patient had took the second dose on 21-SEP-2021 and on 25-SEP-2021 experienced chest tightness and pain. Lab data: On unknown date Echocardiogram was done with unknown results. On 25 Sep 2021: MRI, Troponin I, Blood test was done with unknown results. Most recent FOLLOW-UP information incorporated above includes: On 08-Oct-2021: Translation received on 12-OCT-2021 contains: Event Verbatim Updated and Reporter's comment updated in narrative. On 12-Oct-2021: Significant follow up received lab data and events were added.	
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. 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. No Medical History information was reported. On 13-Aug-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 24-Sep-2021, received second dose of mRNA-1273 (Spikevax)	17 years old male with unknown medical history who 3 days after the 2nd dose was found to have elevated troponin, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin; a causal relationship cannot be excluded due to the lack of other information.

		(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. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Concomitant product information was not provided. Treatment information was not provided. 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. 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. Most recent FOLLOW-UP information incorporated above includes: On 14-Oct-2021: Follow-up received contains added Route of administration and Indication for use. On 14-Oct-2021: Translation received on 20-Oct-2021 contains 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 14-Oct-2021 and was forwarded to Moderna on 14-Oct-2021. This regulatory authority case was reported by a physician and describes	17 years old male with medical history of disorders of refraction and accomodation and cutaneous papillomatosis who 3 days after the 2nd dose was diagnosed with

		the occurrence of MYOCARDITIS (Myocarditis) in a 17-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3005888) for COVID-19 vaccination. The patient's past medical history included Papillomatosis (Cutaneous Papillomatosis) in July 2020. Concurrent medical conditions included Disorders of refraction and accommodation, other since 2012. 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. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): 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 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.. 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-	myocarditis. ECG and Echo were abnromal. No other information was provided. Important information is missing in the report including patient’s medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the abnormal ECG and Echo results; a causal relationship cannot be excluded due to the lack of other information.

		dilated IVC with adequate inspiratory collapse. Normal diastolic function. Normal aortic arch and normal position of coronary arterial ostia. Normal PA.. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. No concomitant medications were provided. No treatment medications were reported. company comment: 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. Most recent FOLLOW-UP information incorporated above includes: 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 Takeda Pharmaceuticals (Reference number: 4.1(b)) on 11-Oct-2021 and was forwarded to Moderna on 18-Oct-2021. 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 02-Oct-2021, the patient received the 2nd dose of this vaccine. On 04-Oct-2021, chest pain and vomiting developed. 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. On 09-Oct-2021, the symptoms were resolving, and the patient was discharged from the hospital. 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 15-Oct-2021 and was forwarded to Moderna on 20-Oct-2021. 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 26-Sep-2021, the patient received the 2nd dose of this vaccine. On 27-Sep-2021, pyrexia in the 38 degrees Celsius developed. On 28-Sep-2021, in the morning, acute myocarditis 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. On 29-Sep-2021, the patient was referred to the reporting department. Echocardiography showed no abnormalities, but troponin I was elevated. The patient was hospitalized with a diagnosis of acute myocarditis. On 02-Oct-2021, the symptoms were confirmed as resolved. The outcome of pyrexia and acute myocarditis was reported as resolved. Follow-up investigation will be made. 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) on 19-Oct-2021 and was forwarded to Moderna on 22-Oct-2021. 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 the vaccine. On 09-Oct-2021, the patient received the 2nd dose of the vaccine.	17 years old male with unknown medical history who next day after the 2nd dose of Spikevax developed pyrexia and the next day expereinced chest discomfort and was found to have elevated cardiac enzymes (not especified), abnormal EGC, abnornal Echo with pericardial fluid. Myocardial biopsy showed normal findings. Patient was diagnosed with myopericarditis. No other

		From 10-Oct-2021 to 11-Oct-2021, the patient had pyrexia of 38s degrees Celsius. 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. 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. The outcome of pyrexia and myopericarditis was reported as ongoing and unchanged. Follow-up investigation will be made. Company Comment: The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated cardiac enzymes and ECG results; a causal relationship cannot be excluded due to the lack of other information.
4.1(b) [redacted]	4.1(b) [redacted]	This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) [redacted] on 15-Oct-2021 and was forwarded to Moderna on 25-Oct-2021. This case, initially reported to the 4.1(b) [redacted] by a pharmacist, was received via the 4.1(b) [redacted] (Ref, 4.1(b) [redacted]	16 years old male with unknown medical history who 3 days after the 1st dose experienced chest pain and numbness of limbs and was found to have elevated troponin, Ck, and abnormal EGC, and was diagnosed with myocarditis. No other

		On an unknown date, body temperature before the vaccination: 36.3 degrees Celsius. On 05-Oct-2021, the patient received the 1st dose of this vaccine. On 08-Oct-2021, myocarditis developed. Anterior chest pain and numbness of limbs were noted, and the patient was raced to a hospital. Troponin I increased to 0.707 and CK to 354. Acetaminophen 500 mg was intravenously infused for chest pain. Thereafter, the patient was hospitalized. On 09-Oct-2021, 12 lead electrocardiogram showed no changes in ST. Blood test showed troponin positive at 0.053 and CK was 225. Heart rate was 60 to 70 beats/min. Electrocardiogram showed negative T wave in V1 and aVL and early repolarization in V2 to V6. The patient did not have subjective symptoms. On 10-Oct-2021, normalization was confirmed with troponin of 0021 and CK of 125. No subjective symptoms were noted. On 11-Oct-2021, electrocardiogram showed no change in symptoms. On 12-Oct-2021, recovery of the symptoms was noted, and the patient was discharged from the hospital. The outcome of myocarditis and numbness of the limbs was reported as recovered. Follow-up investigation will be made. Company Comment: The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and ECG results; a causal relationship cannot be excluded due to the lack of other information.
4.1(b) [redacted]	4.1(b) [redacted]	This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) [redacted] on 22-Oct-2021 and was forwarded to Moderna on 29-Oct-2021.	15 years old male with unknown medical history who the next day after the the 2nd dose developed pyrexia and the next day

		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) Acute myocarditis was assessed as serious by the MAH. On 24-Sep-2021, at 17:00, the patient received the 1st dose of this vaccine. On 17-Oct-2021, at 13:00, the patient received the 2nd dose of this vaccine. On 18-Oct-2021, pyrexia of 39 degrees Celsius developed. 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. On 22-Oct-2021, resolving of the symptoms was confirmed. 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.	chest pain at rest and was found to have elevated troponin, CK, CK-MB, and abnormal EGC, and Echo and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and ECG and Echo results; a causal relationship cannot be excluded due to the lack of other 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. This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myocarditis) and CHEST PAIN	15 years old male with unknown medical history who 2 days after the 1st dose experienced chest pain and was found to have elevated troponin, Ck, and was diagnosed with myocarditis. No other information was provided.

		(Precordial pain) in a 15-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. No Medical History information was reported. On 08-Oct-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 10-Oct-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). On an unknown date, the patient experienced CHEST PAIN (Precordial pain) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Myocarditis) had not resolved and CHEST PAIN (Precordial pain) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Blood creatine phosphokinase: abnormal (High) ABNORMAL. On an unknown date, Troponin: 24.815,6 (High) 24.815,6 pg/ml. The action taken with mRNA-1273 (Spikevax) (Intramuscular) was unknown. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Concomitant and treatment medications were not reported. Company comment: This is a regulatory case concerning a 15 year-old, male patient with no relevant history, who experienced the unexpected serious events of chest pain, and the expected serious event of myocarditis. The event occurred approximately 3 days after the 1st dose of mRNA-1273 Moderna vaccine. The rechallenge was not applicable (information about 2nd dose was not provided). relevant lab data reported: Blood creatine phosphokinase: abnormal (High), Troponin: 24.815,6 pg/ml (High)	Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin; a causal relationship cannot be excluded due to the lack of other information.

		The benefit-risk relationship of mRNA-1273 Moderna vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 29-Oct-2021: Follow up received on 29-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 01-Oct-2021 and was forwarded to Moderna on 01-Oct-2021. 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. The patient's past medical history included Anxiety. Family history included Hypertension (Both parents have hypertension.) since an unknown date. On 01-Aug-2021, the patient received first dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. 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	37 years old male with medical history of anxiety and hypertension who reported having palpitations after the 1st dose and then next day after the 2nd dose with malaise, was hospitalized and was diagnosed with myocarditis. Lab results showed prolonged QTs in the EKG, and hypertension. ELevated troponin, elevated CRP, D-dimer. SARS-CoV-2 test negative. No other information was provided. Important information is missing in the report including patient's medical history, concomitant medications as well as any other laboratory test conducted, including testing for any infectious process. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and abnormal EKG; a causal relationship cannot be excluded due to the lack of other information.

		report, PALPITATIONS (palpitations), MALAISE (Generally unwell) and ELECTROCARDIOGRAM QT PROLONGED (qtc prolonged) had resolved and MYOCARDITIS (Myocarditis) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 28-Sep-2021, SARS-CoV-2 test: negative (Negative) No - Negative COVID-19 test. The action taken with mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown) was unknown. For mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. No concomitant product was reported. Patient previously had heavy alcohol during COVID lockdown but none recently and denied any drugs specifically cocaine. 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. 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. 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. This case concerns a 58-year-old female patient, with relevant medical history of hypertension and anxiety, who experienced the unexpected serious event of Palpitations, Malaise, Electrocardiogram QT prolonged and expected serious event myocarditis. Additionally, the unexpected serious event blood pressure increased is also reported. The events occurred on an unknown date after the second dose of Spikevax. The rechallenge was not applicable as the AEs occurred after the second dose and we are not expecting another dose. The medical history hypertension remains a confounder. 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. 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. Previously administered products included for Vaccination: Comirnaty.	37 years old female with unknown medical history, who received as her first dose the Cominarty vaccine at an unknown date, and was seeing in the doctor's office beacuse of reported chest pressure since July, and worsening 3 days after receiving the 2nd dose with Spikevax. At CV examination patient was found to have pericardial fluid, heart rate increased, chest pain, her Echo was abnormal and she was diagnosed with pericarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any laboratory test conducted, including testing for SARS-CoV-2, and any information related to her

		Past adverse reactions to the above products included Adverse event with Comirnaty. 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 [redacted] (seriousness criterion hospitalization). On 28-Aug-2021, the patient experienced CHEST PAIN [redacted] (seriousness criterion hospitalization) and PERICARDITIS [redacted] (seriousness criteria hospitalization and medically significant). On 18-Sep-2021, the patient experienced HEART RATE INCREASED [redacted]) (seriousness criterion hospitalization). At the time of the report, CHEST PAIN [redacted], HEART RATE INCREASED [redacted], COVID-19 IMMUNISATION [redacted]) and PERICARDITIS [redacted] was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 31-Aug-2021, Cardiovascular examination: abnormal (abnormal) A 1 cm fluid brake was detected behind the left ventricle. Interpreted as possible pericarditis.. On 18-Sep-2021, C-reactive protein: 5 (Inconclusive) 5. 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..	previous chest pain history. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, a causal relationship cannot be excluded due to the lack of other information.

		On 18-Sep-2021, Red blood cell sedimentation rate: 26 (slightly elevated) (High) 26 (slightly elevated). On 21-Sep-2021, Echocardiogram: abnormal (abnormal) Unchanged amount of pericardial fluid. For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered CHEST PAIN [redacted], HEART RATE INCREASED [redacted] and PERICARDITIS [redacted] to be possibly related. No further causality assessment was provided for COVID-19 IMMUNISATION [redacted]. No relevant concomitant medications were reported. 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. No treatment information was provided. 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. Most recent FOLLOW-UP information incorporated above includes:	

		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. 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. Previously administered products included for Vaccination: Comirnaty. 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. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In August 2021, Echocardiogram: findings compatible with perimyocarditis findings compatible with perimyocarditis. In August 2021, Magnetic resonance imaging heart: findings compatible with perimyocarditis findings compatible with perimyocarditis. In August 2021, Troponin: maximum at 1582 Maximum at 1582. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Concomitant product use was not provided by reporter.	31 years old male with unknown medical history who received Cominarty as the 1st dose of COVID-19 vaccination and 23 days after the 2nd dose of Spikevax was diagnosed with myocardits after laboratory showed elevated troponin, and Echo and cMRI findings compatible with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and Echo and cMRI findings. A causal relationship cannot be excluded due to the lack of other information.

		Treatment information was not provided. 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. Most recent FOLLOW-UP information incorporated above includes: On 04-Oct-2021: Translation document received on 06-Oct-2021 as live follow up included NNI.	
4.1(b) [redacted]	4.1(b) [redacted]	This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 04-Oct-2021 and was forwarded to Moderna on 04-Oct-2021. 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. Previously administered products included for Vaccination: COMIRNATY. Past adverse reactions to the above products included No adverse reaction with COMIRNATY. 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	37 years old male with unknown medical history who received Cominarty as the 1st dose of his COVID-19 vaccination and same day after the 2nd dose with SpikevXexpereinced acute myocardial infarction and was diagnosed with myocarditis. Lab results showed elevated troponin, abnormal catheterizarization and EKG. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and EKG and catheterization

		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. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 11-Sep-2021, Computerised tomogram thorax: abnormal (abnormal) Changes mostly suspect for interstitial alveolar edema, alt. infection less probable.. 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. On 13-Sep-2021, Ejection fraction: abnormal (abnormal) Completely normalized. In September 2021, C-reactive protein: 4-126 (abnormal) 4-126. In September 2021, Echocardiogram: abnormal (abnormal) Reduced cardiac function. In September 2021, Troponin T: high (High) Slightly elevated. 118-135-82.. 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). 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. Concomitant product usage were not provided.	results and a causal relationship cannot be excluded due to the lack of other information.

		The patient was hospitalized on 12 Sep 2021. Treatment details were not provided. Company comment 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. Most recent FOLLOW-UP information incorporated above includes: On 04-Oct-2021: Translation received on 06-Oct-2021 included hospitalization details updated in narrative. On 08-Oct-2021: Follow-up contains non-significant information.	
4.1(b) [redacted]	4.1(b) [redacted]	This case was initially received via 4.1(b) [redacted] (Reference number: 4.1(b) [redacted]) on 05-Oct-2021. The most recent information was received on 21-Oct-2021 and was forwarded to Moderna on 21-Oct-2021. 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. Concurrent medical conditions included Myocarditis. On 30-Sep-2021, the patient received second dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) .5 ml.	19 years old male with unknown medical history who 3 days after the 2nd dose experienced chest pain, pain in jaw, and heart rate increased and was diagnosed with myocarditis. Laboratory values showed elevated troponin, and abnormal cMRI. ECH and Echo were normal. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for any other infectious process that may had explained the cough and the malaise and the previous symptoms he was feeling for a week. According to

		On 03-Oct-2021, received dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. 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. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 03-Oct-2021, Troponin: high (High) Trop 1318 rise to 2370, 3 days after second vaccine. On 04-Oct-2021, Magnetic resonance imaging: abnormal (abnormal) Consultant confirmed myocarditis. On 04-Oct-2021, Troponin: 1700 (Low) Slightly decreased to 1700. On an unknown date, Blood pressure measurement: normal (normal) normal. On an unknown date, Echocardiogram: normal (normal) normal. On an unknown date, Electrocardiogram: normal (normal) normal. On an unknown date, Heart rate: inconclusive (Inconclusive) 90s. For mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. 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-	the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and cMRI results; a causal relationship cannot be excluded due to the lack of other information.

		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. Adverse reaction did not occur as a result of an exposure during pregnancy. 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 5 days after the second dose of mRNA-1273. The re-challenge is unknown as the adverse event occurred after second dose and the outcome is recovering.. The benefit-risk relationship of Moderna covid -19 vaccine, is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 21-Oct-2021: Significant Follow-up Appended, Events, Lab data, Product Information was updated.	
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. 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. The patient's past medical history included Anxiety and Depression. Concomitant products included ESCITALOPRAM OXALATE (LEXAPRO) for an unknown indication. On 15-Sep-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine)	24 years old male with medical history of anxiety and depression who 3 days after the 2nd dose experienced pain, and was admitted was found to have elevated troponin, abnormal ECG and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for any other infectious process. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and

		(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. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 18-Sep-2021, Electrocardiogram: abnormal (abnormal) abnormal. On 18-Sep-2021, Troponin: increased (High) increased. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. 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. Company Comment: 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.	ECG results; a causal relationship cannot be excluded due to the lack of other 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. 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. No Medical History information was reported. On 20-Sep-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. 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. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 20-Sep-2021, Troponin: increased (High) Troponin on arrival was 1.4 and peaked at 2.4.. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments.	33 years old male with unknown medical history who same day after the 2nd dose experienced dyspnoea and chest pain and was diagnosed with myocarditis. Laboratory values showed elevated troponin and normal ECH, Echo, and chest x-ray. Patient was admitted to hospital overnight. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events as well as elevated troponin. A causal relationship cannot be excluded due to the lack of other information.

		No concomitant medication was given. 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. On 20-Sep-2021 Chest X-ray, Echocardiogram and Electrocardiogram were performed and results were normal. Patient had short of breath a few hours later, and chest pain at evening and he was admitted to hospital overnight for myocarditis monitoring. 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 Takeda Pharmaceuticals (Reference number: 4.1(b)) on 02-Oct-2021 and was forwarded to Moderna on 06-Oct-2021. 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.	20 years old male with unknown medical history who 3 days after the 2nd dose experienced chest discomfort and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2.

		On an unknown date, body temperature before the vaccination: 36.4 degrees Celsius. On 28-Sep-2021, at 13:30, the patient received the 2nd dose of this vaccine. On 29-Sep-2021, pyrexia of 40 degrees Celsius developed. 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. The outcome of pyrexia and suspected myocarditis was unknown. Follow-up investigation will be made. Company Comment: The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events as well as elevated troponin. A causal relationship cannot be excluded due to the lack of other information.
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. 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 vaccination: 36.6 degrees Celsius. On 24-Sep-2021, at 17:00, the patient received the 2nd dose of this vaccine. On 25-Sep-2021, pyrexia of 38.0-38.9 degrees Celsius developed. On 26-Sep-2021, fever went down to 37 degrees Celsius. At 17:00, myocarditis developed. Chest pain and respiratory discomfort were noted.	28 years old male with unknown medical history who 3 days after the 2nd dose experienced chest pain and respiratory discomfort, and was diagnosed with myocarditis. Laboratory values showed elevated troponin and CK, and abnormal ECGNo other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as elevated troponin and

		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. Around 29-Sep-2021, ST tended to improve on ECG. Around 30-Sep-2021, subjective symptoms improved. On 01-Oct-2021, recovery of symptoms was confirmed. The patient was discharged from the hospital. The outcome of pyrexia and myocarditis was reported as recovered. Follow-up investigation will be made. Company Comment: The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	abnormal ECG. A causal relationship cannot be excluded due to the lack of other 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 05-Oct-2021 and was forwarded to Moderna on 05-Oct-2021. 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. Concurrent medical conditions included Allergy to vaccine (Pertussis Toxoid).	25 years old male with unknown medical history who same day after the 2nd doseexpereinced acute myocardial infarction and was diagnosed with myocarditis. Lab results showed elevated troponin, abnormal catheterizarization and EKG. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality

		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 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. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 19-Sep-2021, Electrocardiogram: st elevation (abnormal) ST elevation consider inferolateral injury or acute infarct. On 19-Sep-2021, Troponin: 869 (High) 869. On 20-Sep-2021, Catheterisation cardiac: acute st-elevation mi (abnormal) Acute ST-elevation myocardial infarction (MI). This appears to be related to myocarditis.. On 20-Sep-2021, Troponin: 1799 (High) 1799.	assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and EKG and catheterization results and a causal relationship cannot be excluded due to the lack of other information.

		For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Concomitant product use was not provided by the reporter. No treatment information was provided. Patient reported worsening chest pain (8 out of 10) and shortness of breath. On 17 Sep 2021, echocardiogram and magnetic resonance imaging heart was performed (results were pending). 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) [redacted]	4.1(b) [redacted]	This case was received via 4.1(b) [redacted] (Reference number: 4.1(b) [redacted]) on 06-Oct-2021 and was forwarded to Moderna on 06-Oct-2021. 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. No Medical History information was reported. 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	19 years old male with unknown medical history who 3 days after the 2nd dose experienced chest pain and pain was found to have elevated troponin, cMRI abnormal, that confirmed the diagnosis of myocarditis, with normal ECH and normal Echo. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the

		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. The action taken with mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown) was unknown. No concomitant medication was provided by reporter. 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, 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. No treatment drug was provided by reporter. 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	elevated troponin and cMRI results; a causal relationship cannot be excluded due to the lack of other information.

		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 initially received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 01-Oct-2021. The most recent information was received on 06-Oct-2021 and was forwarded to Moderna on 19-Oct-2021. 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) 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) 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) On 31-Aug-2021, the patient received the 1st dose of this vaccine. On 28-Sep-2021, the patient received the 2nd dose of this vaccine. On 30-Sep-2021, severe chest pain developed. It was considered that acute myocarditis developed. 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. Myocarditis after the vaccination with this vaccine was suspected. The patient was hospitalized in the reporting hospital.	21 years old male with unknown medical history who 3 days after the 2nd dose experienced chest pain and was found to have elevated troponin, Ck, NT-proBNP, abnormal EGC, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and ECG results; a causal relationship cannot be excluded due to the lack of other information.

		On an unknown date, after the hospitalization, follow-up was performed, and CK and NT-proBNP levels returned to normal. On 04-Oct-2021, the recovery was confirmed, and the patient was discharged from the hospital. The outcome of acute myocarditis was reported as recovered. No follow-up investigation will be made. Follow-up received on 06-OCT-2021 Updated: Lab Data, Product Information, Event Information, Narrative 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 04-Oct-2021 and was forwarded to Moderna on 08-Oct-2021. 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 20-Sep-2021, around 19:00, the patient received the 2nd dose of this vaccine. On 21-Sep-2021, pyrexia of 38.0 degrees Celsius developed and persisted for two days. On 22-Sep-2021, at 19:00, as chest pain developed and did not disappear with oral administration of loxoprofen sodium hydrate but slightly improving, the patient visited the reporting hospital. ST elevation on ECG and increase of in TnT, CK, and CKMB on blood test were observed. The patient was hospitalized with a diagnosis of acute epicarditis and	22 years old male with unknown medical history who next days after the 2nd dose experienced pyrexia, and the following day experienced chest pain, patient went to the hospital and was found to have elevated troponin, CK, abnormal EGC, abnormal cMRIand was diagnosed with myocarditis and acute epicarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and cMRI and ECG results; a

		myocarditis. CK/CKMB was 367/35 at the peak. On 23-Sep-2021, the symptoms were resolving, and ST tended to decrease. On 25-Sep-2021, T wave was negative, and electrocardiogram normalized. On 28-Sep-2021, MRI showed findings of myocarditis (delayed imaging on a plaque in the middle of the left ventricular wall). On 29-Sep-2021, the patient recovered from the symptoms and was discharged from the hospital. The outcome of pyrexia, acute epicarditis, and myocarditis was reported as recovered. Follow-up investigation will be made. Reporter comments continuation: Since myocardial enzyme elevation, ST elevation on ECG, and findings of myocarditis on MRI are present, pericarditis and myocarditis are also definite diagnosis. Company Comment: The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	causal relationship cannot be excluded due to the lack of other information.
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. 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. The patient's past medical history included Cholecystectomy. Concurrent medical conditions included Drug allergy (Mivacurium allergy).	27 years old male with medical history of cholecystectomy who 21 days after the 2nd dose experienced retrosternal chest pain and was found to have elevated troponin, and abnormal cMRI, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO

		On 16-Jun-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. 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. No relevant concomitant medications were reported. 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. 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. Most recent FOLLOW-UP information incorporated above includes: 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.	causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and cMRI results; a causal relationship cannot be excluded due to the lack of other information.
4.1(b) [redacted]	4.1(b) [redacted]	This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) [redacted]) on 04-Oct-2021 and was forwarded to Moderna on 08-Oct-2021.	20 years old male with unknown medical history who 2 days after the 2nd dose experienced chest pain and SOB was found

		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) On 02-Sep-2021, the patient received the 1st dose of this vaccine. On 30-Sep-2021, at 10:00, the patient received the 2nd dose of this vaccine. On 01-Oct-2021, the patient was aware of chest pain and breathlessness. 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. On 04-Oct-2021, the symptoms were ongoing. The outcome of acute myocarditis was reported as ongoing and unchanged. 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.	to have elevated troponin, and abnormal EGC, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and ECG results; a causal relationship cannot be excluded due to the lack of other 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. 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.	19 years old male with unknown medical history who 2 days after the 2nd dose experienced chest discomfort and was found to have elevated troponin, Ck, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test

		No Medical History information was reported. On 23-Jul-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. 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. Treatment information was not provided. 3 days after the second vaccination, Patient developed complaints of retrosternal pressure, tachycardia (206/min). 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. Company Comment: 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. Most recent FOLLOW-UP information incorporated above includes: On 07-Oct-2021: Translation received on 11-OCT-2021 contain significant information that include event verbatim updated and I narrative updated.	conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin ECG results; a causal relationship cannot be excluded due to the lack of other information.

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. 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) On 08-Sep-2021, the patient received the 1st dose of this vaccine. On 29-Sep-2021, at 18:00, the patient received the 2nd dose of this vaccine. Vomiting developed 3 times. 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. On 01-Oct-2021, pericarditis and myocarditis developed. The patient was hospitalized for pericarditis after the vaccination. On 05-Oct-2021, recovery was confirmed. The outcome of vomiting, pyrexia, malaise, pericarditis, and myocarditis was reported as resolved. Follow-up investigation will be made. Company Comment: The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	24 years old male with unknown medical history who 1 days after the 2nd dose experienced vomiting, pyrexia, chest discomfort, malaise, and was found to have elevated troponin, and abnormal EGC, and was diagnosed with myopericarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and ECG results; a causal relationship cannot be excluded due to the lack of other information.
4.1(b)	4.1(b)	This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b)	22 years old male with unknown medical history

		4.1(b)) on 06-Oct-2021 and was forwarded to Moderna on 11-Oct-2021. 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) Myocarditis was assessed as serious by the MAH. On an unknown date, the patient received the 1st dose of this vaccine. On 21-Sep-2021, the patient received the 2nd dose of this vaccine. 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. On 04-Oct-2021, recovery of symptoms was confirmed. The outcome of myocarditis was reported as recovered. 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.	who next days after the 2nd dose experienced chest pain and was found to have elevated troponin, and abnormal EGC, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and ECG results; a causal relationship cannot be excluded due to the lack of other 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. 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-	21 years old male with unknown medical history who 2 days after the 2nd dose was found to have ventricular dysfunction and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO

		1273 (Spikevax) for COVID-19 immunisation. The patient's past medical history included Smoker. 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. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 26-Sep-2021, Troponin I: 21704 (High) 21704 ng. On 26-Sep-2021, White blood cell count: 16840 (High) 16840 INTERNATIONAL UNIT(S)-(UNDER 100). On 27-Sep-2021, C-reactive protein: 6 (normal) 6 mg. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Concomitant medications was not reported. Treatment history was not reported. 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	causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the ventricular dysfunction and myocarditis diagnosis; a causal relationship cannot be excluded due to the lack of other information.

		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. Most recent FOLLOW-UP information incorporated above includes: On 08-Oct-2021: Follow up received contains No new information 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.	
4.1(b) [redacted]	4.1(b) [redacted]	This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 08-Oct-2021 and was forwarded to Moderna on 08-Oct-2021. 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. No Medical History information was reported. 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. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 26-Sep-2021, Echocardiogram: no signs of pericardial fluid, normal ventricular (normal) No signs of	25 years old male with unknown medical history who 5 days after the 2nd dose experienced dyspnoea and was found to have elevated troponin, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin; a causal relationship cannot be excluded due to the lack of other information.

		pericardial fluid, normal ventricular function. For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered DYSPNOEA (DYSPNEA) and MYOCARDITIS (MYOCARDITIS) to be possibly related. Concomitant product use was not provided by the reporter. Treatment information was not provided. On 26-Sep-2021, Troponin T: 401 (normal) Maximum measured value: 401 ng/L. 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 Most recent FOLLOW-UP information incorporated above includes: On 08-Oct-2021: Translation received on 12-Oct-2021, contains 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 12-Oct-2021 and was forwarded to Moderna on 12-Oct-2021. 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)	24 years old male with unknown medical history and Cominarty as the 1st dose of COVID019 vaccine who 28 days after the 2nd dose was found to have elevated troponin, and abnormal EGC, and was diagnosed with myopericarditis. No other information was provided.

		(batch no. 3003604) for Vaccination. The occurrence of additional non-serious events is detailed below. Previously administered products included for Vaccination: COMIRNATY. 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. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In 2021, C-reactive protein: crp elevation (High) CRP elevation.. In 2021, Electrocardiogram: abnormal (abnormal) Acute pericarditis with typical symptoms, ECG changes and CRP elevation.. In 2021, Troponin I: 7000 (High) Approx. 7000 at the highest. 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. Concomitant product use was not provided by the reporter. No treatment information was provided. Company Comment: This case concerns a 24-year-old male subject with no relevant medical history reported, who	Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and ECG results; a causal relationship cannot be excluded due to the lack of other information.

		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. Most recent FOLLOW-UP information incorporated above includes: 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 4.1(b) (Reference number: 4.1(b) on 12-Oct-2021 and was forwarded to Moderna on 12-Oct-2021. 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 (Moderna COVID-19 Vaccine) (batch no. 002F21A) for COVID-19 vaccination. No Medical History information was reported. 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),	33 years old male with unknown medical history who next day after the 2nd dose experienced chest discomfort, chest pain, influenza like-illness, chills, presyncope, vomiting, and was found to have elevated troponin, and abnormal EGC, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and ECG results; a causal relationship cannot be excluded due to the lack of other information.

		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. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 21-Sep-2021, Troponin: increased (High) Increased. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. 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. 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. 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.	

		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 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 Takeda Pharmaceuticals (Reference number: 4.1(b)) on 06-Oct-2021 and was forwarded to Moderna on 14-Oct-2021. 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: 36.2 degrees Celsius. On 29-Sep-2021, at 11:00, the patient received the 2nd dose of this vaccine. At around 23:00, pyrexia developed. On 30-Sep-2021, at around 03:00, chest pain developed. 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 and PR depression on an electrocardiogram. The patient was hospitalized. On 03-Oct-2021, the symptoms were resolving, and the patient was discharged from the hospital.	18 years old female with unknown medical history who next day after the 2nd dose experienced chest pain and was found to have and abndormal ECG and was diagnosed with pericarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events as well as the abnormal ECG. A causal relationship cannot be excluded due to the lack of other information.

		The outcome of pyrexia, chest pain, and acute pericarditis was reported as resolving. Follow-up investigation will be made. Company Comment: The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	
4.1(b) [redacted]	4.1(b) [redacted]	This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) [redacted]) on 07-Oct-2021 and was forwarded to Moderna on 14-Oct-2021. 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. No Medical History information was reported. On 27-Sep-2021, the patient received second dose of mRNA-1273 (COVID 19 Vaccine Moderna) (Intramuscular) dosage was changed to 1 dosage form. 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. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 29-Sep-2021, Alanine aminotransferase: 56 enzyme unit per litre 56. On 29-Sep-2021, Aspartate aminotransferase: 88 enzyme unit per litre 88. On 29-Sep-2021, Blood creatine phosphokinase: 770 Test Result:770.	18 years old male with unknown medical history who 2 days after the 2nd dose experienced have elevated troponin, CRP, abnormal ECG, SARS-ColoV-2 negative, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and ECH results; a causal relationship cannot be excluded due to the lack of other information.

		On 29-Sep-2021, Blood lactate dehydrogenase: 246 enzyme unit per litre 246. On 29-Sep-2021, Brain natriuretic peptide: 20.6 picogram per millilitre 20.6. On 29-Sep-2021, C-reactive protein increased: 1.17 milligram per decilitre 1.17. 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. On 29-Sep-2021, Electrocardiogram: st elevation in v2-6 Electrocardiogram showed ST elevation in V2-6.. On 29-Sep-2021, Polymerase chain reaction: negative (Negative) PCR test for SARS-CoV-2 was negative.. On 29-Sep-2021, Troponin: 10.2922 milliliter 10.2922. On 29-Sep-2021, White blood cell count: 6200 u/l U/L Test Result: 6,200 U/L. On 30-Sep-2021, Blood creatine phosphokinase: 988 Test Result:988 (CK-MB 84.2). For mRNA-1273 (COVID 19 Vaccine Moderna) (Intramuscular), the reporter considered MYOCARDITIS (Acute myocarditis) to be possibly related. 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) [redacted]	4.1(b) [redacted]	This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 14-Oct-2021 and was forwarded to Moderna on 14-Oct-2021. 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	29 years old male with unknown medical history who same day after the 2nd dose experienced chest pain and malaise and was found to have elevated troponin and CRP, ECG abnormal, and was diagnosed with myocarditis. No other information was provided.

		vaccination) in a 29-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 3004954 and 3004954) for COVID-19 immunisation. No Medical History information was reported. On 23-Aug-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. 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. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 23-Sep-2021, C-reactive protein: 18 (abnormal) 18 Unit not specified. On 23-Sep-2021, Electrocardiogram: unknown (abnormal) Compatible with perimyocarditis. On 23-Sep-2021, Troponin T: 243-465 (High) Increasing, unit not specified. On 23-Sep-2021, White blood cell count: 5.8 (abnormal) 5.8 Unit not specified. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medication provided. No treatment information mentioned. 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	Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and ECG results; a causal relationship cannot be excluded due to the lack of other information.

		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 Takeda Pharmaceuticals (Reference number: 4.1(b)) on 08-Oct-2021 and was forwarded to Moderna on 14-Oct-2021. This case, initially reported to the 4.1(b) by a pharmacist, 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 28-Sep-2021, the patient received the 2nd dose of this vaccine. Only on the same day, the patient had low-grade fever. 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. On 05-Oct-2021, the symptoms were resolving, and the patient was discharged from the hospital. The outcome of low-grade fever was reported as recovered. The outcome of myocarditis was reported as resolving. Follow-up investigation will be made.	18 years old male with unknown medical history who dveloped fever the same day after the 2nd dose of the vaccine and 3 days later experienced chest pain and was found to have abnormal ECG. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the ECG results; a causal relationship cannot be excluded due to the lack of other information.

		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 08-Oct-2021 and was forwarded to Moderna on 15-Oct-2021. This case, initially reported to the 4.1(b) by a (physician), was received via the 4.1(b) (Ref, 4.1(b) On 03-Sep-2021, the patient received the 1st dose of the vaccine. On an unknown date, body temperature before the vaccination: 36.4 degrees Celsius. On 01-Oct-2021, at 15:00, the patient received the 2nd dose of the vaccine. At night, pyrexia developed. On 02-Oct-2021, fever subsided. On 03-Oct-2021, the patient had chest pain. 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. On 05-Oct-2021, mild lymphocyte infiltration was found by myocardial biopsy, which led to definitive diagnosis of myocarditis. On 07-Oct-2021, steroid therapy was effective, and CK/CKMB were normalized with a decrease in troponin T	18 years old male with unknown medical history who developed pyrexia the same day after receiving the 2nd dose of Spikevax and 3 days later experienced chest pain and was found to have elevated troponin, CK, and CKMB, ECG abnormal, and was diagnosed with myopericarditis. Patient had a myocardial biopsy doen that showed mild lymphocyte inflitration. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as all the other well documented information; a causal relationship cannot be excluded due to the lack of other information.

		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. The outcome of pyrexia and perimyocarditis was reported as resolving. Follow-up investigation will be made. Reporter comments continuation: 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 vaccine is considered as highly possible cause of the event based on the timing of onset. Company Comment: The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	
4.1(b) [redacted]	4.1(b) [redacted]	This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 15-Oct-2021 and was forwarded to Moderna on 15-Oct-2021. 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. The patient's past medical history included Emergency care examination (No findings.), Chest pressure on 12-Jul-	39 years old male with medical history of chest discomfort and chest pressure a month before receiving the 2nd dose of Spikevax and his first dose was Cominarty who 41 days after the 2nd dose aggravation of his chest discomfort, and dizziness, and was admitted and found to have abnormal ultrasound scan and normal Echo. He was diagnosed with Pericarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted. This case is heavily confounded by the

		2021 and Chest discomfort on 12-Jul-2021. Previously administered products included for Vaccination: COMIRNATY. 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. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In September 2021, Emergency care examination: normal (normal) Normal No findings. On 23-Sep-2021, Ultrasound scan: abnormal (abnormal) Abnormal Diagnosed with PERICARDITIS.. On an unknown date, Electrocardiogram: normal (normal) Normal No findings. No concomitant medication was reported. No treatment medication was reported. Company Comment: 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	use of Cominarty as the 1st dose. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and Echo results; a causal relationship cannot be excluded due to the lack of other information.

		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. This case was linked to 4.1(b) [redacted] (E2B Linked Report). Most recent FOLLOW-UP information incorporated above includes: On 15-Oct-2021: Translation document received on 19-OCT-2021 contains no new information.	
4.1(b) [redacted]	4.1(b) [redacted]	This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) [redacted]) on 11-Oct-2021 and was forwarded to Moderna on 18-Oct-2021. This case, initially reported to the 4.1(b) [redacted] by a physician, was received via the 4.1(b) (Ref 4.1(b) [redacted] On an unknown date, the patient received the 1st dose of the vaccine. On 05-Oct-2021, the patient received the 2nd dose of the vaccine. On 06-Oct-2021, pyrexia developed. 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. On an unspecified date, the patient was hospitalized.	

		The outcome of pyrexia and myocarditis was unknown. Follow-up investigation will be made. 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 12-Oct-2021 and was forwarded to Moderna on 18-Oct-2021. This case, initially reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref, 4.1(b) Suspected myocarditis was assessed as serious by the MAH. On an unknown date, the patient received the 1st dose of this vaccine. On 03-Oct-2021, the patient received the 2nd dose of this vaccine. The patient had pyrexia of 38.0-38.9 degrees Celsius. 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. 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. On 07-Oct-2021, subjective symptoms subsided. The symptoms were confirmed to be resolving. The outcome of pyrexia, left precordial pain, dyspnoea, palpitations, and suspected myocarditis was reported as resolving. Follow-up investigation will be made. 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 European Medicines Agency (Reference number: 4.1(b)) on 18-Oct-2021 and was forwarded to Moderna on 18-Oct-2021. 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. No Medical History information was reported. On 06-Jul-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. 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. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 03-Aug-2021, Magnetic resonance imaging heart: abnormal (abnormal) myocarditis. On 12-Aug-2021, Troponin: negative (Negative) negative. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. No concomitant medications provided. No treatment medications provided.	
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. 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. On an unknown date, the patient received the 1st dose of this vaccine. On an unknown date, body temperature before vaccination: 35.8 degrees Celsius.	

		On 28-Sep-2021, the patient received the 2nd dose of this vaccine. 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. On 02-Oct-2021, left chest pain showed a tendency of improvement at return visit. On 07-Oct-2021, the patient visited another hospital. On an unknown date, the improvement of symptom was confirmed. 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 14-Oct-2021 and was forwarded to Moderna on 19-Oct-2021. 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: 36.3 degrees Celsius. On 05-Oct-2021, the patient received the 2nd dose of this vaccine. On 07-Oct-2021, around 19:00, chest pain developed, and the patient visited the reporting hospital. The patient was hospitalized with a diagnosis of acute myocarditis based on extensive ST elevation in electrocardiogram and elevation of cardiac enzymes in blood test. On an unknown date, there was no symptom of cardiac failure, and various examination findings improved. On 13-Oct-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 received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 14-Oct-2021 and was forwarded to Moderna on 19-Oct-2021. 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 the vaccine. On an unknown date, body temperature before the vaccination: 36.4 degrees Celsius. On 09-Oct-2021, the patient received the 2nd dose of the vaccine. On 10-Oct-2021, pyrexia of 39.0-39.9 degrees Celsius developed. On 11-Oct-2021, around 12:00, pericarditis and myocarditis developed. Chest pain was noted, and thus an emergency call was made. The patient was transported to the reporting hospital. An electrocardiogram showed ST elevations in I, II, aVL, aVF, and V2-6. Echocardiography showed mild encircling hypokinesis. Blood test showed an increase in troponin. The patient was hospitalized with a diagnosis of pericarditis and myocarditis. The outcome of pericarditis and myocarditis was unknown. Follow-up investigation will be made. Company Comment: The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	20 years old male with unknown medical history who developed fever the next day afetr the 2nd dose of the vaccine and the next day experienced chest pain, was admitted was found to have elevated troponin, abnormal Echo and ECG. He was diagnosed with myopericarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and ECG and Echo results; a causal relationship cannot be excluded due to the lack of other 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. This case, initially reported to the 4.1(b)	24 years old male with unknown medical history who developed 3 days after the 2nd dose experienced chest pain and was found to have elevated troponin, Ck, NT-

		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: 36.6 degrees Celsius. 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. 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. 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. 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. On 13-Oct-2021, respiratory discomfort remained but tended to improve.	proBNP, abnormal EGC, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and ECG results; a causal relationship cannot be excluded due to the lack of other information.

		The outcome of pyrexia, suspected acute pericarditis, respiratory discomfort, throbbing chest pain, chest tightness, cough, and pericardial effusion was reported as resolving. Follow-up investigation will be made. 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 4.1(b) (Reference number: 4.1(b) on 19-Oct-2021 and was forwarded to Moderna on 19-Oct-2021. 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), 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. No medical history was reported. Concurrent medical conditions included Asthma, Arthritis and Drug allergy. Concomitant products included BUDESONIDE, FORMOTEROL FUMARATE (SYMBICORT), ALBUTEROL [SALBUTAMOL], PARACETAMOL (TYLENOL) and IBUPROFEN for an unknown indication. 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	This case of a 38 years old male with acute myocarfial infarction and myocarditis 238 days after the 2nd dose of the vaccine is unlikely related to the vaccine. The TTO is to prolonged to be causally associated with the vaccine

		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. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 25-Sep-2021, Angiocardiogram: abnormal (abnormal) No occlusions found. Diagnosed with Focal Myocarditis.. On 25-Sep-2021, Electrocardiogram: abnormal (abnormal) Showed inferion MI. On 25-Sep-2021, Fibrin D dimer: high (High) EKG showed STEMI Troponins + d-dimer+.. On 25-Sep-2021, Troponin: high (High) EKG showed STEMI Troponins + d-dimer+.. On 27-Sep-2021, Electrocardiogram: abnormal (abnormal) EKG showed STEMI Troponins + d-dimer+..	

		For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. 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. Treatment information include patient took 1 gm Tylenol and 400 mg Ibuprofen. On 26-Sep-2021 21:00, patient had left upper chest pain which got resolved with 1gm Tylenol and a warm bath. 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. Again pain returned and EKG was done which showed STEMI Troponins + d-dimer+. Patient was then sent to Cath lab for cardiac catheterization. No occlusions found. Diagnosed with Focal Myocarditis. 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.	21 years old male with unknown medical history who next day after the 2nd dose experienced chest pain, chest discomfort,

		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. Concomitant products included FENTANYL for Pain, ACETYLSALICYLIC ACID (ASPIRIN (E.C.)), COLCHICINE, IBUPROFEN and METOPROLOL SUCCINATE for an unknown indication. On 24-Aug-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. 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	dyspnoea, and was found to have elevated troponin, pericardial effussion, ventricular hypokynesia, and abnormal EGC, and was diagnosed with myopericarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and ECG results; a causal relationship cannot be excluded due to the lack of other information.

		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 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. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 24-Sep-2021, Blood potassium: decreased (Low) decreased. On 24-Sep-2021, Cardiac imaging procedure: abnormal (abnormal) abnormal. On 27-Sep-2021, Electrocardiogram: st elevations (abnormal) ST elevations and st elevations (abnormal) ST elevations. 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. On 28-Sep-2021, Magnetic resonance imaging heart: normal lv cavity si (abnormal) Normal LV cavity si.	

		For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. 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. ON 27-SEP-2021 at 06.32 Chest X-Raywas done ,On same day at 10.56 Covid PCR was done,results not provided. 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). No treatment medications were provided. Company Comment: 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 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. 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	23 years old male with unknown medical history who 2 days after the 2nd dose experienced chest pain and dyspnoea and was found to have elevated troponin, and normal EGC, and was diagnosed with myocarditis. No other information was provided.

		mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 048F21A) for COVID-19 vaccination. No Medical History information was reported. 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. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 05-Oct-2021, Electrocardiogram: normal (normal) normal. On 05-Oct-2021, Laboratory test: normal (normal) normal. On 05-Oct-2021, Troponin (8000-10.3000): increased (High) Increased, high sensitivity troponins with value of 10,337. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. No concomitant medications were reported No treatment medications were reported. The patient had Myocarditis - developed chest pain, shortness of breath quite suddenly the morning of 10/5/2021. 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-	Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin; a causal relationship cannot be excluded due to the lack of other information.

		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 Takeda Pharmaceuticals (Reference number: 4.1(b) on 13-Oct-2021 and was forwarded to Moderna on 20-Oct-2021. This case, reported by a physician, was received by Takeda via Moderna's adverse reaction reporting site （ 4.1(b) On 03-Sep-2021, at 15:00, the patient received the 1st dose of this vaccine. On an unknown date, body temperature before the vaccination: 36.4 degrees Celsius. On 01-Oct-2021, at 15:00, the patient received the 2nd dose of this vaccine. Pyrexia developed at night. On 02-Oct-2021, pyrexia went down. On 03-Oct-2021, at 21:00, chest pain developed. 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. On 05-Oct-2021, myocardial biopsy showed mild lymphocytic infiltration, leading to a definitive diagnosis of myocarditis. On 07-Oct-2021, steroid treatment was effective, CK/CKMB were normalized, and troponin T decreased to 0.551 ng/mL.	18 years old male with unknown medical history who developed fever the same day after the 2nd dose of Spikevax and 2 days later experienced chest pain and was found to have elevated troponin, Ck, abnormal Echo, and myocardial biopsy showed mild lymphocytis infiltration and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and ECG results as well as the myocardial biopsy; a causal relationship cannot be excluded due to the lack of other information.

		On 12-Oct-2021, colchicine was additionally administered. The patient's general condition was stabilized thereafter. On 13-Oct-2021, the symptoms were resolving. The outcome of pyrexia was reported as recovered. The outcome of perimyocarditis and diffuse wall hypokinesis was reported as resolving. Follow-up investigation will be made. 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 13-Oct-2021 and was forwarded to Moderna on 20-Oct-2021. 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) On 02-Sep-2021, at 14:00, the patient received the 1st dose of this vaccine. On 30-Sep-2021, at 14:00, the patient received the 2nd dose of this vaccine. On 01-Oct-2021, chest pain developed. 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. On an unknown date, myocardial enzymes improved over time, and test values returned to normal.	

		On 13-Oct-2021, the patient recovered but remained hospitalized for examinations. The outcome of chest pain and suspected myocarditis was reported as resolved. Follow-up investigation will be made. 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 4.1(b) (Reference number: 4.1(b) on 19-Oct-2021 and was forwarded to Moderna on 19-Oct-2021. 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. No relevant medical history was provided by the reporter. Concomitant products included IBUPROFEN for an unknown indication. 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. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 02-Oct-2021, Chest X-ray: normal (normal) chest x-ray normal. On 02-Oct-2021, Echocardiogram: normal (normal) echocardiogram normal.	

		On 02-Oct-2021, Electrocardiogram: abnormal (abnormal) consistent with pericarditis. On 02-Oct-2021, Troponin: increased (High) Elevated. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. 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. No treatment medications were reported. 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)	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. 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. 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.	38 years old male with no relevant medical history who same day after the 2nd dose experienced influenza like illness, abdominal pain, and was was found to have elevated troponin, Ck, abnormal EGC and Echo, and was diagnosed with myopericarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the

		Concurrent medical conditions included Allergy (Dyshidrotic finger/hand eczema without spread; idiopathic, possible atopic diathesis). In July 2021, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 100 microgram. 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. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 05-Aug-2021, Angiocardiogram: abnormal (abnormal) Stenosis-free coronary vessels, LVEF 55%; mid-ventricular hypokinesis. 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.. 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. 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..	product and the start of the events, as well as the elevated troponin and ECG results; a causal relationship cannot be excluded due to the lack of other information.

		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.. 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. No concomitant medications reported 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 . 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 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. It was reported that Patient was hospitalized on 05AUG2021 and discharged on 07AUG2021 . Lab data included CK of 386 U/L, Troponin Most recent FOLLOW-UP information incorporated above includes: 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 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. No Medical History information was reported. On 03-Aug-2021, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) .5 milliliter. 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. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 14-Sep-2021, Echocardiogram: normal (normal) Normal echocardiographic findings with an EF of 61% were found in the TTE.. In addition	25 years old male with unknown medical history who 3 days after the 2nd dose experiencedfever, headache arthralgias and dyspnea and was found to have elevated troponin, abnormal EGC, Echo and cMRI, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and ECG results; a causal relationship cannot be excluded due to the lack of other information.

		there was no evidence of constrictive physiology or pericardial effusion.. 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.. 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).. On an unknown date, Electrocardiogram: normal (normal) Accentuated ST segments above V2-V5 were seen electrocardiographically. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered MYOCARDITIS (Acute perimyocarditis) to be possibly related. Patient had no other previous known diagnoses or allergies and it was unknown if patient was consuming nicotine or alcohol. The patients eGFR (MDRD) lab test was 93.58 mL/min. Based on lab examinations of patient acute peri-myocarditis was diagnosed. Concomitant medication details was reported. The patient was not taking any medications on admission. 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. 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. 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. Most recent FOLLOW-UP information incorporated above includes: 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.	
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. Concurrent medical conditions included Hashimoto's thyroiditis. Concomitant products included LEVOTHYROXINE SODIUM (EUTHYROX) for an unknown indication. On 20-Aug-2021, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 100 microgram. 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. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):	39 years old male with unknown medical history who 2 days after the 2nd dose experienced chest pain that increased with inspiration, and dyspnoea on exertion. Patient was hospitalized next day and was found to have elevated troponin, CRP and abnormal EGC, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and ECG results; a causal relationship cannot be

		On 20-Sep-2021, Blood creatine phosphokinase: 281 (High) 281 U/L high. On 20-Sep-2021, C-reactive protein increased: 132 (High) 132 mg/L increased. On 20-Sep-2021, Echocardiogram: normal (normal) Echocardiography revealed normal LVEF (60%) and no structural changes.. On 20-Sep-2021, Electrocardiogram: normal (normal) An ECG showed ST depressions in lead III and T-negativity in AVL and AVR;. On 20-Sep-2021, Troponin increased: 442 (High) 442 ng/L elevation. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered MYOCARDITIS (Myopericarditis) to be possibly related. 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). On 20-Sep-2021, the patient presented clinically and was hospitalized. 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. No treatment medication reported. 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:	excluded due to the lack of other information.

		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. Most recent FOLLOW-UP information incorporated above includes: 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. 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. The patient's past medical history included Adenoidectomy. Concurrent medical conditions included Obesity and Penicillin allergy. 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. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 03-Oct-2021, C-reactive protein (0-6): 22 (High) High-sensitivity C-reactive protein- 22 milligram per litre. On 03-Oct-2021, N-terminal prohormone brain natriuretic peptide (0-100): 62 (normal) 62 picogram per millilitre. On 03-Oct-2021, Troponin I (0-17.5): 2424 (High) High Sensitive troponin I- 2424 nanogram per litre.	29 years old male with medical history of adenoidectomy and obesity who next day after the 2nd dose was found to have elevated troponin, NT-proBNP, CRP, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin; a causal relationship cannot be excluded due to the lack of other information.

		On 04-Oct-2021, C-reactive protein (0-6): 18 (High) High-sensitivity C-reactive protein- 18 milligram per litre. On 04-Oct-2021, Troponin I (0-17.5): 1451 nanogram per litre (High) High Sensitive troponin I- 1451 nanogram per litre. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medication information provided by the reporter. No treatment medication information was provided. 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. Most recent FOLLOW-UP information incorporated above includes: 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. 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) 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 function	

		disorder was indicated in a medical checkup. The patient had a history of surgery. On 03-Sep-2021, the patient received the 1st dose of the vaccine. On an unknown date, acute enteritis developed. On 13-Sep-2021, the patient started taking an over-the-counter cold medicine for the treatment of acute enteritis. On 15-Sep-2021, the patient stopped taking the over-the-counter cold medicine. On 01-Oct-2021, at 11:30, the patient received the 2nd dose of the vaccine. Pyrexia developed. 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. 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. On 05-Oct-2021, transthoracic echocardiography was performed and showed no problems in the cardiac function. 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. 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 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. On 09-Oct-2021, the symptoms were resolving. 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. The outcome of acute enteritis was unknown. The outcome of acute myocarditis was reported as resolving. Follow-up investigation will be made.	

		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 20-Oct-2021 and was forwarded to Moderna on 26-Oct-2021. 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 26-Jul-2021, the patient received the 2nd dose of this vaccination. Pyrexia developed. On 28-Jul-2021, the patient visited another hospital with chest pain. 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. On an unknown date, after that, the patient rested, and no cardiac failure or fatal arrhythmia occurred with NSAIDs, and chest pain also improved. On 02-Aug-2021, the patient was discharged from the hospital. On 10-AUg-2021, the symptoms were resolving. The outcome of pyrexia and myocarditis was reported as resolving. Follow-up investigation will be made. Company Comment:	22 years old male with unknown medical history who 3 days after the 2nd dose experienced chest pain and was found to have elevated troponin, and abnormal EGC, myocardial biopsy was normal, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and ECG results; a causal relationship cannot be excluded due to the lack of other information.

		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. No Medical History information was reported. On 11-Oct-2021, the patient received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) dosage was changed to 1 dosage form. 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. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 14-Oct-2021, Blood creatine phosphokinase (47-222 international unit per litre): 514 international unit per litre	20 years old male with unknown medical history who 2 days after the 2nd dose experienced chest pain and wthe next day as found to have elevated troponin, Ck, CRP, abnormal EGC, SARS-CoV-2 negative, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and ECG results; a causal relationship cannot be excluded due to the lack of other information.

		(High) 514 iU/L and 909 international unit per litre (High) 909 iU/L. On 14-Oct-2021, C-reactive protein (0-10 milligram per litre): 55 milligram per litre (High) high. On 14-Oct-2021, Chest X-ray: normal (normal) Normal. On 14-Oct-2021, Electrocardiogram: abnormal (abnormal) Elevation in DII-III-aVF, V4-6 with descending PR interval DII-III-avF. On 14-Oct-2021, SARS-CoV-2 test: negative (Negative) Negative. On 14-Oct-2021, Troponin (Unknown-14 ng/L): 838 ng/L (High) 838 ng/L and 1096 ng/L (High) 1096 ng/L. On 14-Oct-2021, White blood cell count (4-11): 13 (High) high. 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. No concomitant medications were reported. 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. Lab data also included of, LDH 285 U/L, AST 101 U/L, remainder of liver and kidney function panel aligned. Analgesic therapy with Paracetamol was started, and a cardiac MRI was planned. Most recent FOLLOW-UP information incorporated above includes: On 25-Oct-2021: Translation document received on 27-Oct-2021: Lab data, event verbatim, narrative and senders comment updated.	
4.1(b)	4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b)) on 24-Oct-	COnsumer report on a 40 years old male with unknown medical history

		2021 and was forwarded to Moderna on 24-Oct-2021. 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. No Medical History information was reported. On 30-Jun-2021, the patient received first dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (Parenteral) 1 dosage form. 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. mRNA-1273 (Moderna CoviD-19 Vaccine) (Parenteral) dosing remained unchanged. No concomitant medications were reported. Treatment information was not provided. The patients past medical history included Beal's syndrome and was reported that it was recently confirmed. Patient lab data included Troponin high" , MRI result: confirmed pericarditis. 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.	who 8 days after the 2nd dose experienced chest pain and palpitations, and was found to have elevated troponin, and abnormal cMRI, and was diagnosed with pericarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and cMRI results; a causal relationship cannot be excluded due to the lack of other information.

		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. 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." Company comment: 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.	
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-Oct-2021 and was forwarded to Moderna on 26-Oct-2021. 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. No Medical History information was reported. 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	32 years old male with unknown medical history who 4 days after the 2nd dose experienced chest pain and was found to have elevated troponin, abnormal EGC, Echo and cMRI, and was diagnosed with myopericarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and ECG, Echo and cMRI results; a causal relationship cannot be

		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. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 07-Oct-2021, Cardiac imaging procedure: abnormal (abnormal) Cardiac MRI showed LGE indicative of myocarditis. On 07-Oct-2021, Catheterisation cardiac: normal (normal) normal. On 07-Oct-2021, Echocardiogram: abnormal (abnormal) focal WMA. On 07-Oct-2021, Electrocardiogram: abnormal (abnormal) abnormal. On 07-Oct-2021, Troponin: 1.31 (High) increased. On 07-Oct-2021, Wall motion score index: abnormal (abnormal) abnormal. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Concomitant medications was not reported.	excluded due to the lack of other information.
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. 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. No Medical History information was reported.	25 years old male with unknown medical history who 2 days after the 2nd dose experienced chest pain and was found to have elevated troponin, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based

		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. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 13-Oct-2021, Troponin: increased (High) High. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. No concomitant medications were reported No treatment information was provided	on temporal association between the use of the product and the start of the events, as well as the elevated troponin; a causal relationship cannot be excluded due to the lack of other information.
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. This regulatory authority case was reported by an other health care professional and describes the occurrence of CHEST PAIN (Chest pain), SENSORY DISTURBANCE (Sensory disturbance) and MYOCARDITIS (Myocarditis) in a 23-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 027A21A) for COVID-19 vaccination. No Medical History information was reported. 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 CHEST PAIN (Chest pain) (seriousness criterion hospitalization), SENSORY DISTURBANCE (Sensory disturbance) (seriousness criterion hospitalization) and MYOCARDITIS (Myocarditis)	23 years old male with unknown medical history who 2 days after the 2nd dose experienced chest pain and sensory disturbances, and was found to have elevated troponin, abnormal EGC,abnormal Echo and normal chest x-ray, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and ECG and Echo results; a

		(seriousness criteria hospitalization and medically significant). The patient was hospitalized for 2 days due to CHEST PAIN, MYOCARDITIS and SENSORY DISTURBANCE. The patient was treated with ASPIRIN [ACETYLSALICYLIC ACID] for Adverse event, at an unspecified dose and frequency. At the time of the report, CHEST PAIN (Chest pain), SENSORY DISTURBANCE (Sensory disturbance) and MYOCARDITIS (Myocarditis) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 07-Mar-2021, Blood test: abnormal (abnormal) Abnormal. On 07-Mar-2021, Catheterisation cardiac: diagnosed as myocarditis (abnormal) Officially diagnosed as myocarditis. On 07-Mar-2021, Chest X-ray: normal (normal) The chest x-ray came back fine.. On 07-Mar-2021, Echocardiogram: diagnosed as myocarditis (abnormal) Officially diagnosed as myocarditis. On 07-Mar-2021, Electrocardiogram: abnormal (abnormal) Slight abnormality. On 07-Mar-2021, Troponin: elevated (High) Elevated. In April 2021, Echocardiogram: 100 percent good to go (normal) 100 percent good to go. In April 2021, Electrocardiogram: 100 percent good to go (normal) 100 percent good to go. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. 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. On 07-Mar-2021, at the same location patient had the same feeling except time increased to a second and a half, a	causal relationship cannot be excluded due to the lack of other information.

		pinching sensation in the middle of the sternum. Patient reported to a clinic and was sent to hospital and had performed tests. 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). Treatment included Ace inhibitor, beta blocker and normal aspirin for 30 days. 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.	
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. 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. No Medical History information was reported. 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). 26-Apr-2021, the patient experienced CHEST PAIN (Excessive chest pain for 2 days and then chest pain off). On an unknown	34 years old female with unknown medical history who same day after the 2nd dose experienced chest pain and was found to have abnormal Echo and cMRI, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the Echo results; a causal relationship cannot be excluded due to the lack of other information.

		date, the patient experienced CHEST PAIN (Chest pain on for the next 4 months). On 28-Apr-2021, CHEST PAIN (Excessive chest pain for 2 days and then chest pain off) had resolved. At the time of the report, MYOCARDITIS (Myocarditis) and CHEST PAIN (Chest pain on for the next 4 months) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 26-Apr-2021, Chest X-ray: normal (normal) Normal. On 26-Apr-2021, Echocardiogram: normal (normal) Normal. On 26-Apr-2021, Magnetic resonance imaging: abnormal (abnormal) Cardiac MRI showing myocarditis. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Concomitant product use was not provided by the reporter. No treatment information was provided.	
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. 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. Concurrent medical conditions included Allergy to antibiotic (Moxifloxacin). On 24-Sep-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. Last menstrual period and	28 years old pregnant female with unknown medical history who next day after the 2nd dose of Spikevax experienced dyspnoea, was hospitalized and was found to have elevated inflammatory markers (not specified), elevated liver enzymes and abnormal Echo, and was diagnosed with pericarditis. Five days later labour was induced and she had a premature live baby 34 weeks and 5 days old. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. The reason for inducing labor, etc. According to

		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. 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. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 25-Sep-2021, Blood test: abnormal (abnormal) abnormal confirmed acute pericarditis. On 25-Sep-2021, Echocardiogram: abnormal (abnormal) abnormal confirmed acute pericarditis. On 25-Sep-2021, Hepatic enzyme: high (High) High, Liver enzymes with 100+ (AST/ALT). On 25-Sep-2021, Inflammatory marker test: high (High) High. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Was induced and gave birth on 4.1(b) to a baby 34 weeks and 5 days old.	the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated inflammatory markers and Echo results; a causal relationship cannot be excluded due to the lack of other information.
4.1(b)	4.1(b)	This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b)	31 years old male with unknown medical history

		[redacted] on 20-Oct-2021 and was forwarded to Moderna on 28-Oct-2021. 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 28-Oct-2021. This case, initially reported to the [redacted] by a pharmacist, was received via the [redacted] (Ref, [redacted] Myocarditis was assessed as serious by the MAH. On 26-Aug-2021, the patient received the 1st dose of this vaccine. On 30-Sep-2021, the patient received the 2nd dose of this vaccine. On 01-Oct-2021, pyrexia and chills developed. 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. 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. 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.	who next day after the 2nd dose experienced pyrexia and chills, and 2 days later experienced chest pain and was found to have elevated troponin, CRP, Ck, abnormal Echo, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and Echo results; a causal relationship cannot be excluded due to the lack of other information.

		On 05-Oct-2021, chest pain subsided. Recovery of the symptoms was confirmed. 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. The outcome of pyrexia, chills, myocarditis, feeling of tightness in the neck and upper arm from the left shoulder was reported as resolved. Follow-up investigation will be made. 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 15-Oct-2021 and was forwarded to Moderna on 28-Oct-2021. This case, initially reported to the 4.1(b) by a pharmacist, was received via the 4.1(b) (Ref, 4.1(b) The patient had a history of allergy to antibiotics and a history of urticaria due to faropenem sodium hydrate. On an unknown date, the patient received the 1st dose of the vaccine. On an unknown date, body temperature before the vaccination: 36.5 degrees Celsius. On 08-Oct-2021, at 11:00, the patient received the 2nd dose of the vaccine. 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.	22 years old male with unknown medical history who next day after the 2nd dose experienced chest pain and pyrexia and was hospitalized and found to have elevated troponin, Ck, and abnormal EGC, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and ECG results; a causal relationship cannot be excluded due to the lack of other information.

		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. 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. 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. On 14-Oct-2021, the symptoms improved. Resolution was confirmed, and the patient was discharged from the hospital. The outcome of myocarditis was reported as resolved. 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 23-Oct-2021 and was forwarded to Moderna on 29-Oct-2021. This case, initially reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref, 4.1(b) On 02-Sep-2021, the patient received the 1st dose of this vaccine. On 01-Oct-2021, the patient received the 2nd dose of this vaccine. 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. On 13-Oct-2021, the symptoms resolved, and the patient was discharged from the hospital.	

		The outcome of myocarditis was reported as resolved. 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-Oct-2021 and was forwarded to Moderna on 29-Oct-2021. 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 12-Oct-2021, the patient received the 2nd dose of this vaccine. On 16-Oct-2021, at 17:00, the patient was suddenly aware of chest pain and was raced to a hospital. After the visit, an electrocardiogram showed extensive ST elevation, and echocardiography showed hypokinesis of the apical wall. Emergency cardiac catheterization was performed. There was no stenosis in the coronary artery. Afterwards, LGE was noted predominantly in the epicardium by contrast-enhanced MRI, and it was considered as myocarditis. On 21-Oct-2021, the symptom was ongoing. The outcome of myocarditis was reported as ongoing and unchanged. 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.	27 years old male with unknown medical history who 4 days after the 2nd dose experienced chest pain and was found to have abnormal EGC, abnormal Echo and abnormal cMRI and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the ECG, Echo and cMRI results; a causal relationship cannot be excluded due to the lack of other information.
4.1(b)	4.1(b)	This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 23-Oct-2021 and	27 years old male with unknown medical history who the next day after the the 2nd dose developed

		was forwarded to Moderna on 29-Oct-2021. This case, initially reported to the 4.1(b) by a pharmacist, was received via the 4.1(b) (Ref, 4.1(b) On 19-Sep-2021, at 10:00, the patient received the 1st dose of this vaccine. On 17-Oct-2021, at 10:00, the patient received the 2nd dose of this vaccine. On 18-Oct-2021, at 01:00, pyrexia of 38 degrees Celsius or higher developed. At 13:00, myocarditis developed. The patient had chest discomfort. 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. The outcome of pyrexia, myocarditis was unknown. Follow-up investigation will be made. Company Comment: The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	pyrexia and chest discomfort and 2 days later experienced severe chest pain and was found to have elevated troponin, and abnormal EGC, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and ECG results; a causal relationship cannot be excluded due to the lack of other information.
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. This case, initially reported to the 4.1(b) by a (nurse), was received via the 4.1(b) (Ref, 4.1(b)	25 years old male with unknown medical history who the next day after the 2nd dose experienced pyrexia, and the next day after exercising experienced chest pain and dyspnoea, and was found to have elevated troponin, BPN, CRP, abnormal EGC, normal cMRI, and was diagnosed

		On an unknown date, the patient received the 1st dose of this vaccine. On 28-Sep-2021, the patient received the 2nd dose of this vaccine. On 29-Sep-2021, pyrexia of 39 degrees Celsius developed. 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. 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. On 03-Oct-2021, CPK peaked out. On 04-Oct-2021, cardiac MRI showed no problem, and acute myocarditis was diagnosed. On 06-Oct-2021, the patient was discharged from the hospital. On 11-Oct-2021, recovery of the symptoms was confirmed. The outcome of pyrexia, chest pain, and acute myocarditis was reported as resolved. Follow-up investigation will be made. Company Comment: The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and ECG results; a causal relationship cannot be excluded due to the lack of other information.
4.1(b)	4.1(b)	This case was initially received via an unknown source (no reference has been entered for a health authority or license partner) on 03-Sep-2021. The most recent information was received on 03-Sep-2021 and was forwarded to Moderna on 08-Sep-2021.	37 years old male with familial medical history of CV disorder who 3 days after the 2nd dose of the vaccine was diagnosed with myocarditis. Laboratory results showed elevated CRP, elevated

		This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (4.1(b) (Moderna), ED 27.07.2021) in a 37-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination. Family history included Family history of cardiovascular disorder (Father died at 51 years of age from myocardial infarction.). On 27-Jun-2021, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form. On 24-Jul-2021, received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) dosage was changed to 1 dosage form. On 27-Jul-2021, after starting mRNA-1273 (COVID-19 Vaccine Moderna), the patient experienced MYOCARDITIS (4.1(b) (Moderna), ED 27.07.2021) (seriousness criteria hospitalization and medically significant). The patient was hospitalized from 27-Jul-2021 to 30-Jul-2021 due to MYOCARDITIS. The patient was treated with ASA on 27-Jul-2021 for Adverse event, at an unspecified dose and frequency; BISOPROLOL FUMARATE (BISOPROLOLO) on 27-Jul-2021 for Adverse event, at an unspecified dose and frequency and RAMIPRIL on 27-Jul-2021 for Adverse event, at an unspecified dose and frequency. On 30-Jul-2021, MYOCARDITIS (4.1(b) (Moderna), ED 27.07.2021) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 27-Jul-2021, Catheterisation cardiac: normal (normal) Epicardial coronary arteries normal.. On 27-Jul-2021, Echocardiogram: slightly reduced systolic function (abnormal) Normal sized ventricle with slightly reduced systolic function (LVEF biplan 47% GLS with GE Vivid -14.1%) with mid inferolateral circumscribed hypokinesis..	troponin, elevated, abnormal EKG, cMRI, and Echo. No other information was provided. Important information is missing in this report including patient's medical history, as well as clinical course of the events, laboratory tests conducted and any results, including SARS-CoV2 test.

		On 27-Jul-2021, Electrocardiogram: abnormal (abnormal) nc SR, IT, no block image, discrete ST elevations in I, II, aVF, PQ depressions in I, II.. On 27-Jul-2021, Magnetic resonance imaging: abnormal (abnormal) Normal biventricular dimensions with slightly reduced left ventricular function (EF 51%). No evidence of myocardial infarction. Patchy subepicardial fibrosis at the midventricular and septal levels with evidence of related myocardial edema. Results compatible with myocarditis.. On 27-Jul-2021, N-terminal prohormone brain natriuretic peptide: 783 ng/l (Inconclusive) 783 ng/L Abnormal. On 27-Jul-2021, Troponin I: 1603 ng/l (Inconclusive) 1603 ng/L abnormal. On 27-Jul-2021, Troponin T: 195 ng/l (High) Troponin T hs 195 ng/l (Peak 484 ng/l). For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered MYOCARDITIS ([redacted] (Moderna), ED 27.07.2021) to be probably related. No concomitant medications were provided. The patient presented with chest pain radiating to the neck and left shoulder. Company Comment: Based on the current available information and temporal association between the use of the product and the onset date of the events, a causal relationship cannot be excluded. Therefore, causality is assessed as possibly related. Translation is being requested. Most recent FOLLOW-UP information incorporated above includes: On 03-Sep-2021: Translation received on 08-Sep-2021, patient past medical history, labs, hospitalization end date, treatment medications and inarrative updated.	
[redacted]	[redacted]	This case was initially received via European Medicines Agency (Reference number:[redacted]) on 04-Sep-2021. The	19 years old female with unknown medical history who same day after the 2nd dose of the vaccine

		most recent information was received on 28-Sep-2021 and was forwarded to Moderna on 28-Sep-2021. This regulatory authority case was reported by a physician and describes the occurrence of HYPERHIDROSIS (4.1(b) COUGH (4.1(b) CHEST DISCOMFORT (4.1(b) DYSPNOEA (4.1(b) HEADACHE (4.1(b) PYREXIA (4.1(b) and MYOCARDITIS (4.1(b) in a 19-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3002919) for COVID-19 vaccination. No Medical History information was reported. On 09-Aug-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 2 dosage form. On 09-Aug-2021, the patient experienced HYPERHIDROSIS (4.1(b) (seriousness criterion hospitalization), COUGH (4.1(b) (seriousness criterion hospitalization), CHEST DISCOMFORT (4.1(b) (seriousness criterion hospitalization), DYSPNOEA (4.1(b) (seriousness criterion hospitalization), HEADACHE (4.1(b) (seriousness criterion hospitalization), PYREXIA (4.1(b) (seriousness criterion hospitalization) and MYOCARDITIS (4.1(b) (seriousness criteria hospitalization and medically significant). At the time of the report, HYPERHIDROSIS 4.1(b) , COUGH , CHEST DISCOMFORT , DYSPNOEA , HEADACHE , PYREXIA and MYOCARDITIS was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In August 2021, Blood bilirubin: 31 (High) 31 umol/L (micromole per litre).	experienced hyperhydrosis, cough, chest discomfort, dypsnea, pyrexia, and was diagnosed with myocarditis. Laboratory results showed mild thrombocytopenia, elevated CRP, elevated troponin, abnormal Echo. No other information was provided. Important information is missing in this report including patient's medical history, as well as clinical course of the events, laboratory tests conducted and any results

		In August 2021, Blood creatinine: 87 (normal) 87 umol/L (micromole per litre) and 78 (normal) 78 umol/L (micromole per litre). In August 2021, C-reactive protein: 103 (High) 103 mg/L (milligram per litre) and 118 (High) 118 mg/L (milligram per litre). In August 2021, Chest X-ray: normal (normal) No pathology. In August 2021, Echocardiogram: abnormal (abnormal) Smal area with pericardial fluid outside of the right ventricle. Otherwise normal findings.. In August 2021, Haematocrit: 0.4 (abnormal) Hematocrit 0.4. In August 2021, Haemoglobin: 13.8 (normal) 13.8 g/dL (gram per decilitre). In August 2021, Platelet count: 129 (abnormal) 129 g/dL (gram per decilitre), 142 (abnormal) 142 g/dL (gram per decilitre) and 111 (abnormal) 111 g/dL (gram per decilitre). In August 2021, SARS-CoV-2 test: negative (Negative) Negative. In August 2021, Troponin T: 37 (High) 37 ng/L (nanogram per litre), 79 (High) 79 ng/L (nanogram per litre), 65 (High) 65 ng/L (nanogram per litre) and 79 (High) 79 ng/L (nanogram per litre). For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered HYPERHIDROSIS ([redacted]) COUGH ([redacted]) CHEST DISCOMFORT ([redacted]) DYSPNOEA ([redacted]) HEADACHE ([redacted]) PYREXIA ([redacted]) and MYOCARDITIS ([redacted]) to be possibly related. No relevant concomitant and treatment medications were reported. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Most recent FOLLOW-UP information incorporated above includes: On 04-Sep-2021: Non-significant follow up: Translation Document received on 08 Sep 2021 include translated Sender's	

		comments which contain no new information.	
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 35-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination. Concurrent medical conditions included Drug allergy (Aspirin), Drug allergy (Ibuprofen) and Alcoholism (Alcohol : rarely). In May 2021, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form. On 25-Jun-2021, received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) dosage was changed to 1 dosage form. On 26-Jun-2021, the patient experienced PERICARDITIS (4.1(b) (seriousness criterion medically significant). At the time of the report, PERICARDITIS (4.1(b) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In June 2021, C-reactive protein: 18 (High) C-reactive protein Elevated 18 mg/L. In June 2021, Electrocardiogram: abnormal (abnormal) ECG with pre-existing right bundle branch block and negative concordant T. In June 2021, Troponin: negative (Negative) Cardiac Troponin negative. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered PERICARDITIS (4.1(b) to be possibly related. Patient experienced pericarditis which was diagnosed following various laboratory and imaging investigations. The same evening of second vaccination patient also fever and chills. The following day there was an increased feeling of left side chest pressure without radiation. ECG with preexisting right bundle branch block and concordant	35 years old male with unknown medical history who same day after the 2nd dose of the vaccine pateint exoerience fever and chills. The following day there was an increased feeling of left side chest pressure without radiation. Laboratory results showed elevated CRP, and troponin. ECG with preexisting right bundle branch block and concordant negative. No other information was provided. Important information is missing in this report including patient's medical history, as well as clinical course of the events, laboratory tests conducted and any results, including SARS-CoV2 test.

		negative. Patient was under physical rest and NSAID therapy with celecoxic (allergic to Ibuprofen and aspirin). There was a marked improvement and patient had only few infrequent symptoms. Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. Most recent FOLLOW-UP information incorporated above includes: On 03-Sep-2021: Translation received on 08-Sep-2021: Narrative was updated with significant information.	
4.1(b)	4.1(b)	This case was initially received via European Medicines Agency (Reference number: 4.1(b)) on 03-Sep-2021. The most recent information was received on 07-Sep-2021 and was forwarded to Moderna on 08-Sep-2021. This regulatory authority case was reported by a pharmacist and describes the occurrence of CHEST DISCOMFORT (4.1(b)), ABDOMINAL PAIN UPPER (4.1(b)) and MYOCARDITIS (4.1(b)) in a 21-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 3005695 and 214010) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Asthma. On 26-Jul-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 23-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 DISCOMFORT 4.1(b) MALAISE (4.1(b) MUSCULOSKELETAL PAIN (4.1(b)	21 years old male with unknown medical history who 3 days after the 2nd dose of the vaccine experienced discomfort, malaise, musculoskeletal pain, pyrexia and was diagnosed with myocarditis. Laboratory results showed elevated CRP, elevated troponin. No other information was provided. Important information is missing in this report including patient's medical history, as well as clinical course of the events, laboratory tests conducted and any results, including SARS-CoV2 test.

		4.1(b) and PYREXIA (4.1(b) . On 25-Aug-2021, the patient experienced CHEST DISCOMFORT (4.1(b) (seriousness criteria hospitalization and medically significant) and ABDOMINAL PAIN UPPER (4.1(b)) (seriousness criteria hospitalization and medically significant). On 26-Aug-2021, the patient experienced MYOCARDITIS (4.1(b)) (seriousness criteria hospitalization and medically significant). The patient was treated with PARACETAMOL for Adverse event, at a dose of 1 dosage form. On 23-Aug-2021, MUSCULOSKELETAL PAIN 4.1(b) had resolved. On 24-Aug-2021, DISCOMFORT 4.1(b) , MALAISE (4.1(b) and PYREXIA (4.1(b) had resolved. At the time of the report, CHEST DISCOMFORT (4.1(b)), ABDOMINAL PAIN UPPER (4.1(b) and MYOCARDITIS (4.1(b) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 26-Aug-2021, Blood creatine phosphokinase (20-200): 371 (abnormal) 371 enzyme unit per litre, 382 (abnormal) 382 enzyme unit per litre, 371 371 enzyme unit per litre and 382 382 enzyme unit per litre. On 26-Aug-2021, Troponin T: 313 (abnormal) 313 nanogram per litre, 233	

		(abnormal) 233 nanogram per litre, 313 313 nanogram per litre and 233 233 nanogram per litre. On 27-Aug-2021, Blood creatine phosphokinase (20-200): 281 (abnormal) 281 enzyme unit per litre and 281 281 enzyme unit per litre. On 27-Aug-2021, Troponin T: 264 (abnormal) 264 nanogram per litre and 264 264 nanogram per litre. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. Concomitant medications were not reported. Treatment medications were not reported. Company Comment: This case concerns a 21 year old male patient, who experienced unexpected serious events of CHEST DISCOMFORT, ABDOMINAL PAIN UPPER, MYOCARDITIS. The serious events occurred 2-3 days after the second dose of mRNA-1273 vaccine. The patient also experienced non-serious events of discomfort, malaise, musculoskeletal pain, pyrexia. The non-serious events occurred on same day after the second dose of mRNA-1273 vaccine. Limited information regarding the events have been provided at this time. The benefit-risk relationship of the vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 07-Sep-2021: Follow-up document received and contain include patient height added. On 07-Sep-2021: Translation received on 08-SEP-2021 and description to be coded has change for event tightness in chest as tight Chest and general discomfort in place of initial general malaise.	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b) on 03-Sep-2021 and was forwarded to Moderna on 03-Sep-2021.	22 years old male with unknown medical history 4 days after the 2nd dose of the vaccine experienced chest pain, and was diagnosed with

		This regulatory authority case was reported by an other health care professional and describes the occurrence of CHEST PAIN (Chest pain) and MYOCARDITIS (Myopericarditis) in a 22-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. No Medical History information was reported. On 23-Jul-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 20-Aug-2021, received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. On 21-Aug-2021, the patient experienced CHEST PAIN (Chest pain) (seriousness criterion hospitalization). On 24-Aug-2021, the patient experienced MYOCARDITIS (Myopericarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, CHEST PAIN (Chest pain) and MYOCARDITIS (Myopericarditis) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In August 2021, Echocardiogram: abnormal (abnormal) Echocardiograph: preserved LVEF without segmental contractility alterations. RV with normal function and morphology. Mitral valve with minimal insufficiency. Tricuspid aortic valve, good opening. Tricuspid valve without impairment. No pericardial effusion, but increased enhancement of the pericardium.. In August 2021, Troponin: abnormal (abnormal) serial troponins 3302 ---› 3747 ---›2215.. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. No concomitant medication information was provided No treatment product information was provided	myocarditis. Laboratory results showed elevated troponin, and abnormal Echo. No other information was provided. Important information is missing in this report including patient's medical history, as well as clinical course of the events, laboratory tests conducted and any results, including SARS-CoV2 test.

		The action taken with mRNA-1273 (Spikevax) (unknown) was not applicable. Company comment: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Most recent FOLLOW-UP information incorporated above includes: On 03-Sep-2021: Translation document received on 07-Sep-2021, updated the lab investigation results	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 04-Sep-2021 and was forwarded to Moderna on 04-Sep-2021. This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myopericarditis) and PERICARDITIS (Chest pain worsened by lying flat consistent with pericarditis) in a 23-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 3004218 and 3002290) for COVID-19 immunisation. No Medical History information was reported. On 07-Jul-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 06-Aug-2021, received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. On 08-Aug-2021, the patient experienced MYOCARDITIS (Myopericarditis) (seriousness criteria hospitalization and medically significant). On an unknown date, the patient experienced PERICARDITIS (Chest pain worsened by lying flat consistent with pericarditis) (seriousness criteria disability and medically significant). At the time of the report, MYOCARDITIS (Myopericarditis) and PERICARDITIS (Chest pain worsened by lying flat consistent with pericarditis) had not resolved.	23 years old male with unknown medical history 2 days after the 2nd dose of the vaccine experienced chest pain, and was diagnosed with myopericarditis. Laboratory results showed elevated CRP, abnormal EKG. No other information was provided. Important information is missing in this report including patient's medical history, as well as clinical course of the events, laboratory tests conducted and any results, including SARS-CoV2 test.

		DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In August 2021, C-reactive protein: abnormal (abnormal) Raised inflammatory marker CRP = 115. In August 2021, Electrocardiogram: abnormal (abnormal) ECG changes - ST elevation and PR depression.. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. Concomitant product use was not provided by the reporter. Treatment information was not provided. Company Comment : Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.	
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 30-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) (batch nos. 3003188 and 3003188) for COVID-19 vaccination. No Medical History information was reported. On 06-Jul-2021, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 200 microgram. On 03-Aug-2021, received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) dosage was changed to 200 microgram. On 05-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. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Blood creatine phosphokinase: 456 456.	30 years old male with unkonw medical history who 2 days after the 2nd dose of the vaccine developed fever, retrosternal, extensive, oppressive chest pain, fatigue and mild exertional dyspnea on exertion. The patient was hospitalized and diagnosed with myopericarditis. Coronary angiography revealed stenosis-free coronary arteries with smooth walls. Echo revealed a normal systolic ejection fraction of 60% without regional kinetic disorders. Resting ECG revealed sinus rhythm with a heart rate of 61 bpm, a normal heart axis with normal PQ and QRS intervals, but ST elevations in leads I, aVL and V2-6, normal repolarization and a QTc interval of 380 ms. CRP elevated, elevated troponin, elevated CK. Important information is missing in the report

		On an unknown date, Blood creatinine: 83 83 umol/L. On an unknown date, Blood potassium: 3.74 3.74 mmol/L. On an unknown date, Blood sodium: 138 138mmol/L. On an unknown date, Blood thyroid stimulating hormone: 2.44 2.44. On an unknown date, C-reactive protein increased: 2.2 2.2mg/L. On an unknown date, Haemoglobin: 15.2 15.2 g/dL. On an unknown date, International normalised ratio: 1.06 1.06. On an unknown date, Troponin: 552 552. On an unknown date, White blood cell disorder: 6.2 6.2 G/L. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medication, treatment medication were provided. It was reported that on 05-Aug- 2021, patient developed fever as well as retrosternal, extensive, oppressive chest pain. In addition, the patient reported rapid fatigue and mild exertional dyspnea on exertion. The patient was hospitalized and diagnosed with Peri-myocarditis. Etiologically, a connection with the COVID vaccination (Moderna) was most likely seen. Reportes showed that coronary angiography on 06-Aug-2021 revealed stenosis-free coronary arteries with smooth walls. TTE revealed a normal systolic ejection fraction of 60% without regional kinetic disorders. The resting ECG revealed sinus rhythm with a heart rate of 61 bpm, a normal heart axis with normal PQ and QRS intervals, but ST elevations in leads I, aVL and V2-6, normal repolarization and a QTc interval of 380 ms. Laboratory chemistry results on 06-Aug-2021 revealed the following values: Leukocytes 6.2 G/L, CRP 2.2 mg/L, Hb 15.2 g/dL, platelets 129 G/L, INR 1.06, creatinine 83 umol/L, Na 138 mmol/L, K	including pateint's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2.

		3.74 mmol/L, troponin 552 ng/L, CK 456 U/L, TSH 2.44 mU/L. The patient was monitored on an inpatient basis due to initially increasing troponin and increasing CK. Over the course, the patient's symptoms were regressive. Was a non-smoker and did not consume alcohol. There were no known allergies or liver disorders. This case concerns a 30-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. The reporter assessed the event as related to the product. 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 events resulted in a persistent or permanent incapacity. Most recent FOLLOW-UP information incorporated above includes: On 17-Sep-2021: Translation Document Received on 21 Sep 2021 contains significant information - updated inarrative.	
4.1(b) [redacted]	4.1(b) [redacted]	This regulatory authority case was reported by a consumer and describes the occurrence of PYREXIA (Fever) and MYOCARDITIS (4.1(b) [redacted]) in a 37-year-old female patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination. Concurrent medical conditions included Palpitations (Arrhythmic pulse, partly tachycardic). On 07-Jul-2021, the patient received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form. On 07-Jul-2021, after starting mRNA-1273 (COVID-19 Vaccine Moderna), the patient experienced PYREXIA (Fever) (seriousness criterion medically significant). On 14-Jul-2021,	37 years old female with history of palpitations who the same day after the 2nd dose of the vaccine experience pyrexia, and 7 days later experienced exertional dypsnea, retrosternal chest pain and aggravation of palpitations. Pateint was diagnised with myopericarditis. Laboratory results showed increased troponin and minor pericardial efusion during sonography. No other information was provided. Important information is missing in the report including pateint's medical history as well as any other

		the patient experienced MYOCARDITIS (4.1(b)) (seriousness criterion medically significant). On 09-Jul-2021, PYREXIA (Fever) had resolved. At the time of the report, MYOCARDITIS (4.1(b)) had not resolved. No concomitant medication information was mentioned by reporter. No treatment medication information was mentioned by reporter. Patient experienced suspected perimyocarditis. It was reported that patient was presented in Emergency due to aggravation of known palpitations and new exertional dyspnea with retrosternal burning for 3 weeks (onset of symptoms 1 week after 2nd Covid vaccination with COVID-19 Vaccine Moderna, 07-Jul-2021). In this regard, a cardiological clarification took place approximately 1 year ago with ergometry and echocardiography. No pathologies were found. After the 2nd Covid vaccination, there was an increased temperature for 2 days. No cold symptoms since the 2nd Covid vaccination. No risk factors for thrombosis. Increased troponin in the laboratory (43 ng/L), minor pericardial effusion during sonography. Therapy of ADR: Analgesics. Company Comment: This case concerns a 37-year-old, female patient with medical history of palpitations, who experienced the serious expected event of myocarditis and unexpected event of pyrexia. The event pyrexia occurred approximately 1 day and myocarditis 8th day after the second dose of Spikevax. The rechallenge was unknown since no information about the first dose was disclosed. The benefit-risk relationship of Spikevax is not affected by this report. Event seriousness assessed as per Regulatory Authority reporting. Most recent FOLLOW-UP information incorporated above includes: On 17-Sep-2021: Translation received on 26-Sep-2021 included event verbatim	laboratory test conducted, including testing for SARS-CoV-2.

		translated and significant information from case narrative added.	
4.1(b)	4.1(b)	This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myoperikarditis) in a 35-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) (batch no. 3002541) for COVID-19 vaccination. 4.1(b) Concurrent medical conditions included Tobacco user (known tobacco use), Alcohol use (rare alcohol consumption.), Pollen allergy and Allergy to animal dander (animal hair). Concomitant products included DOXYCYCLINE HYCLATE (DOXYCLIN [DOXYCYCLINE HYCLATE]) for an unknown indication. On 25-May-2021, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (unknown route) 1 dosage form. On 22-Jun-2021, received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (unknown route) dosage was changed to 1 dosage form. On 24-Jun-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. For mRNA-1273 (COVID-19 Vaccine Moderna) (Unknown), the reporter considered MYOCARDITIS (4.1(b) to be possibly related. Patient received the vaccinations through intramuscular route immunization against COVID-19. From 24 Jun 2021, the patient developed increasing chest pain due to acute myopericarditis. Electrocardiogram (ECG) was initially unremarkable, over further course there were ST segment elevations in the	35 years old male with concomitant use of doxycicline for an imflamatory process in the testicles (no other infomration provided) who 2 days after the 2nd dose of the vaccine experienced chest pain and was diagnosed with myopericarditis. Laboratory results showed abnormal EKG (St segment elevations) and abnormal Echo. No other information was provided. No other information was provided. Important information is missing in the report including pateint's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2.

		inferior leads and in V2-5, without PQ depression, with “J wave”. Pericarditis or “early repolarization” was discussed as a differential diagnosis. Transthoracic echocardiogram (TTE) showed left ventricular ejection fraction of 50-55%, hypokinesia of the inferoinferoseptobasal region, and global longitudinal strain of 19%. Therapy with Irfen (ibuprofen) and colchicine was started. Over further course, the patient's condition improved. As concomitant medication, the patient was using doxycycline 200 mg/day due to testicular pain (19 Jun 2021 – 24 Jun 2021). Company comment: This case concerns a 35-year-old, male patient, known tobacco user with no relevant medical history, who experienced the expected event of Myocarditis. The event occurred approximately 2 days after the second dose of Moderna vaccine. The event was considered related to the product per the reporter’s assessment. 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. Most recent FOLLOW-UP information incorporated above includes: On 17-Sep-2021: Translation was received on 22-sep-2021, and the medical history was updated. The route of administration of vaccine, concomitant medicine information, event description, laboratory information, treatment medications were updated in I narrative.	
4.1(b)	4.1(b)	This regulatory authority case was reported by a physician and describes the occurrence of INFLUENZA LIKE ILLNESS (4.1(b)) and MYOCARDITIS (Perimyocarditis) in an 18-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) (batch nos. 3002912 and 3003185) for SARS-CoV-2 immunization. No Medical History information was reported.	18 year old male patient who is a landscaper and sporty who drinks alcohol occasionally. Patient's medical history included consultation for palpitations on unspecified date of 2020 and 2021. Same day after receiving 2nd dose of vaccine, patient experienced fever, chills, feeling hot, muscle pain, and abundant night

		On 11-Jun-2021, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) .5 milliliter. On 09-Jul-2021, received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) dosage was changed to .5 milliliter. On 09-Jul-2021, after starting mRNA-1273 (COVID-19 Vaccine Moderna), the patient experienced INFLUENZA LIKE ILLNESS (4.1(b)) (seriousness criterion hospitalization). On 11-Jul-2021, the patient experienced MYOCARDITIS (Perimyocarditis) (seriousness criteria hospitalization and medically significant). On 15-Jul-2021, INFLUENZA LIKE ILLNESS (4.1(b)) had resolved. At the time of the report, MYOCARDITIS (Perimyocarditis) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 15-Jul-2021, Echocardiogram: normal (normal) no pericardial effusion, LV systolic function normal. On 15-Jul-2021, Electrocardiogram: normal (normal) regular, normal rhythm, QRS narrow and regular with no signs of ischemia. In August 2021, Magnetic resonance imaging heart: normal (normal) Normal. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered INFLUENZA LIKE ILLNESS 4.1(b)) and MYOCARDITIS (Perimyocarditis) to be probably related. This case concerns an 18 year old male patient who is a landscaper and sporty who drinks alcohol occasionally. Patient's medical history reported included consultation for palpitations on unspecified date of 2020 and 2021. After receiving second dose of vaccine, on 09-Jul-2021 patient experienced fever with a temperature of 38.7°C, accompanied by chills, feeling hot, muscle pain, and abundant night sweats. Fever was recovered on 15-Jul-2021. Patient was hospitalized on 15-Jul-2021 due to lower chest pain with an intensity of 5/10 on the visual analogue scale. It was reported	sweats. 2 days later patien experienced lower oppressive chest pain and pain aggravated by deep inhalation, with the pain radiating towards the right flank. Patient was treated with analgesics but symptoms was not improved. Patient also experienced tachycardia, with no indication of malaise or loss of consciousness. Patient's lab data reported elevated troponins I and elevated CK. EKG, Echo and cMRI were all normal. No other information was provided. Important information is missing in the report including pateint's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. This case is heavily confounded by the negative imaging test results

		that pain was oppressive with progressive onset since 11-Jul-2021 and pain aggravated by deep inhalation, with the pain radiating towards the right flank. Patient was treated with analgesics but symptoms was not improved. Patient also experienced tachycardia, with no indication of malaise or loss of consciousness. Patient's lab data reported also included Ultra-sensitive troponins I (N <60 ng/L): 140 ng/L (15.07.2021); 124 ng/L (16.07.2021). CK: 61 U/L (15.07.2021); 38 U/L (16.07.2021) Patient was discharged from hospital on 16-Jul-2021 with nonsteroidal anti-inflammatory drugs (NSAID) prescribed for 10 days, combined with colchicine for 2 months. Vitals signs measurement at the time of discharge included blood pressure 133/65 mmHg, pulse 74 bpm, temperature 36.8°C, 98%saturation in ambient air. Patient also experienced short of breath when working and episodes of mild chest pain around 17-Aug-2021. It was reported that patient stopped taking colchicine based on the MRI result. This case concerns a 18-year-old, male patient with no relevant medical history, who experienced the unexpected event of influenza like illness and the expected event of myocarditis. The event influenza like illness occurred the same day with the second dose of mRNA-1273 vaccine administration, and the event myocarditis occurred 2 days after second dose of mRNA-1273 vaccine administration. The rechallenge was unknow Most recent FOLLOW-UP information incorporated above includes: On 17-Sep-2021: Translation received on 21-Sep-2021 included patient's medical history (palpitations), lab data results and additional events (fever, chills, feeling hot, muscle pain, night sweats).	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 17-Sep-2021 and was forwarded to Moderna on 17-Sep-2021. This regulatory authority case was reported by a pharmacist and describes the occurrence of CHEST PAIN (Chest pain), ABDOMINAL PAIN UPPER (epigastrialgia), PYREXIA (Fever),	21-year-old, male patient with unknown medical history, and who received the Janssen vaccine at an undetermine time and the next day after the 3?? dose of the Moderna vaccine experienced chest pain, adominal pain upper,

		MALAISE (Malaise), PALPITATIONS (Palpitation) and MYOCARDITIS (Perimyocarditis) in a 21-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 immunisation. Previously administered products included for an unreported indication: COVID-19 VACCINE JANSSEN (AD26.COV2.S) in 2021. On 17-Aug-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. In August 2021, the patient experienced CHEST PAIN (Chest pain) (seriousness criteria hospitalization and life threatening), ABDOMINAL PAIN UPPER (epigastrialgia) (seriousness criteria hospitalization and life threatening) and PALPITATIONS (Palpitation) (seriousness criteria hospitalization and life threatening). On 18-Aug-2021, the patient experienced PYREXIA (Fever) (seriousness criteria hospitalization and life threatening) and MALAISE (Malaise) (seriousness criteria hospitalization and life threatening). On 20-Aug-2021, the patient experienced MYOCARDITIS (Perimyocarditis) (seriousness criteria hospitalization, medically significant and life threatening). At the time of the report, CHEST PAIN (Chest pain) had not resolved and ABDOMINAL PAIN UPPER (epigastrialgia), PYREXIA (Fever), MALAISE (Malaise), PALPITATIONS (Palpitation) and MYOCARDITIS (Perimyocarditis) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In August 2021, Blood test: tnt 39 (abnormal) TNT 39 and was 13 when discharged. CRP: 53 and was 8 when discharged. BNP: 450 and is 10 when discharge. Platelets: 128 and was 152 when discharge.. In August 2021, Chest X-ray: no signs of air or fluid in the pleura. no infecti (normal) No signs of air or fluid in the pleura. No infection is demarcated. Heart size and blood vessel dimension within normal limits. Free air is not detected under the diaphragm.	pyrexia, malaise, palpitation and was diagnosed with mocarditis 2 days later. Laboratory results showed elevated troponin, CRP, and BNP; decreased platelet levels, normal chest x-rays; ECG and EKG were abnormal. No other information was provided. It is not clear how many doses this patient actually received give n that the Janssen vaccine is a one-dose COVID-19 vaccine, and it is also not clear if this was then a second Moderna vaccine dose or just one dose. This report is confounded by the administration of the other COVID-19 vaccine

		In August 2021, Echocardiogram: echocardiography. preserved left ventricular contr (abnormal) Insignificant echocardiography. Preserved left ventricular contraction, emission fraction 60%. Not to see motile lumps on the valves. There is mild calcification on the cordae on the tricuspid valve but no clear signs of vegetation. There is a mild leak in the tricuspid valve.. In August 2021, Electrocardiogram: sinus rhythm, hr 95. (abnormal) Sinus rhythm, HR 95. High take of ST-segment (V3-V6).. In August 2021, Urine analysis: negative (Negative) Negative. The action taken with mRNA-1273 (Spikevax) (Unknown) was unknown. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. Company Comment: This case concerns a 21-year-old, male patient with no previous relevant medical history, who experienced the unexpected events of chest pain, adominal pain upper, pyrexia, malaise, palpitation and expected events of mocarditis. Pyrexia and malaise occurred 1 day after, and myocarditis occurred 3 days after the first dose of mRNA-1273 (Moderna COVID-19 Vaccine). The rechallenge was not applicable since only information about the first dose was disclosed. The reporter assessed the events as possible. The benefit-risk relationship of mRNA-1273 (Moderna COVID-19 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 17-Sep-2021 and was forwarded to Moderna on 17-Sep-2021. This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (4.1(b) [redacted]) in a 20-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3003604) for Vaccination.	20 years old male with history of receiving the other mRNA vaccine as the 1st dose, and who 3 days after the 2nd dose was diagnosed with myopericarditis. Lab results showed elevated troponin and CRP. Echo normal and EKG abnormal. No other information was provided. Important information is missing in the report

		Co-suspect product included non-company product TOZINAMERAN (COMIRNATY) for COVID-19 vaccination. No Medical History information was reported. On 01-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On an unknown date, the patient started TOZINAMERAN (COMIRNATY) (unknown route) at an unspecified dose. On 04-Sep-2021, the patient experienced MYOCARDITIS (4.1(b) [redacted] (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (4.1(b) [redacted] was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 04-Sep-2021, C-reactive protein: high (High) Slightly increased. On 04-Sep-2021, Echocardiogram: normal (normal) Normal. On 04-Sep-2021, Electrocardiogram: perimyocarditis (abnormal) Findings consistent with perimyocarditis. On 04-Sep-2021, Troponin T: 378 (abnormal) 378. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No relevant concomitant medications were reported. The patient had Perimyocarditis, troponin-t increase to 378. No treatment information was provided. Company Comment: This case concerns a 20-year-old, male patient with no relevant medical history, 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 limited information was provided about the first dose. The event was considered related to the product per the reporter's	including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. This report is confounded by the adminstration of the other mRNA vaccine

		assessment. The event is consistent with the current understanding of the mechanism of action of the study medication The benefit-risk relationship of Moderna Covid-19 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 17-Sep-2021: Translation Received on 22-Sep-2021, Narration was updated.	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 17-Sep-2021 and was forwarded to Moderna on 17-Sep-2021. 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 25-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3004959) for Vaccination. Previously administered products included for Vaccination: Comirnaty. On 27-Aug-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 30-Aug-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) (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. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 30-Aug-2021, Cardiac telemetry: normal (normal) Normal. On 30-Aug-2021, Magnetic resonance imaging heart: abnormal (abnormal) Findings compatible with acute PERI MYOCARDITIS.	25 years old male with history of receiving the other mRNA vaccine as the 1st dose, and who 3 days after the 2nd dose was diagnosed with myopericarditis. Lab results showed elevated troponin. cMRI abnormal. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. This report is confounded by the adminstration of the other mRNA vaccine

		On 30-Aug-2021, Troponin: 500 (abnormal) Troponines max around 500. 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. No concomitant medication was reported. Treatment information was not provided by reporter. Company comment This is a case of revaccination with different COVID-19 vaccine concerning a 24-year-old female patient, with no reported medical history who experienced the unexpected event of myocarditis. The event occurred 3 days after the second dose of Spikevax. The rechallenge was unknown as no details about the first dose was provided. Causality assessment for the event was not provided by the reporter. The event is consistent with the current understanding of the mechanism of action 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 event is a medical important event. Most recent FOLLOW-UP information incorporated above includes: On 17-Sep-2021: Translation document received on 22-Sep-2021 include no newinformation.	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 17-Sep-2021 and was forwarded to Moderna on 17-Sep-2021. This regulatory authority case was reported by a physician and describes the occurrence of CHEST PAIN (4.1(b) COVID-19 IMMUNISATION (4.1(b) and PERICARDITIS (4.1(b) in a 33-year-old male patient who received mRNA-1273 (Spikevax)	33 years old male with history of receiving the other mRNA vaccine as the 1st dose, and who 1 days after the 2nd dose was diagnosed with myopericarditis. Abnormal EKG and normal Echo wihtout pericardial effusion. No other information was provided. Important information is missing in the report

		(batch no. 3004224) for COVID-19 vaccination. Previously administered products included for Vaccination: COMIRNATY. On 02-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 02-Sep-2021, the patient experienced CHEST PAIN (4.1(b) (seriousness criterion medically significant), COVID-19 IMMUNISATION (4.1(b) (seriousness criterion medically significant) and PERICARDITIS (4.1(b) (seriousness criterion medically significant). At the time of the report, CHEST PAIN (4.1(b) COVID-19 IMMUNISATION (4.1(b) and PERICARDITIS (4.1(b) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 03-Sep-2021, Electrocardiogram: abnormal (abnormal) ST elevations in most precordial leads and some extremity leads (do not have access to this). Suspected pericarditis.. In September 2021, Echocardiogram: normal (normal) Normal without pericardial effusion. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No relevant concomitant and treatment medications were reported. Company Comment: The case concerns a 33-year-old-male patient with previous relevant medical history of vaccination with COMIRNATY, who experienced the unexpected event of chest pain and the expected evet pericarditis. Revaccination with different COVID-19 vaccine was considered as an additional event. The event occurred the same day, after the first dose of Spikevax. The rechallenge was not applicable since only information about the first dose was disclosed. The medical history of vaccination with COMIRNATY	including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. This report is confounded by the adminstration of the other mRNA vaccine

		remains a confounder for the events pericarditis and chest pain. The events 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. Most recent FOLLOW-UP information incorporated above includes: On 17-Sep-2021: Translation Received on 22-SEP-2021, Narration & Event Verbatim is Translated	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 17-Sep-2021 and was forwarded to Moderna on 17-Sep-2021. This regulatory authority case was reported by a physician and describes the occurrence of COVID-19 IMMUNISATION (4.1(b) CHEST PAIN (4.1(b) and MYOCARDITIS (4.1(b) in a 19-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3003604) for COVID-19 vaccination. Previously administered products included for Vaccination: Comirnaty (5'capped mRNA encoding full length SARS-CoV-2 spike protein). On 03-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 05-Sep-2021, the patient experienced COVID-19 IMMUNISATION (4.1(b) (seriousness criterion hospitalization), 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, COVID-19 IMMUNISATION (4.1(b) CHEST PAIN (4.1(b) and MYOCARDITIS (4.1(b) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):	19 years old male with history of receiving the other mRNA vaccine as the 1st dose, and who 2 days after the 2nd dose experienced chest pain and was diagnosed with myocarditis. Lab results showed elevated troponin and abnormal EKG. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. This report is confounded by the administration of the other mRNA vaccine

		On 05-Sep-2021, Electrocardiogram: abnormal (abnormal) Electrocardiogram shows ST-depression.. On 05-Sep-2021, Troponin I: 400 (Inconclusive) inconclusive. In September 2021, Troponin I: 29633 (Inconclusive) inconclusive. For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered COVID-19 IMMUNISATION (4.1(b) CHEST PAIN (4.1(b) and MYOCARDITIS (4.1(b) to be possibly related. No concomitant medications were provided by the reporter No treatment information was provided by the reporter. This case concerns a 19-year-old, male patient with no relevant medical history, who experienced the unexpected events of chest pain and revaccination with different Covid vaccine and expected event of myocarditis. The events of chest pain and myocarditis occurred approximately 2 days after the dose of Moderna COVID-19 Vaccine. The patient received Comirnaty vaccine previously. The rechallenge was not applicable. 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. Chest pain could be the symptom of myocarditis. Most recent FOLLOW-UP information incorporated above includes: On 17-Sep-2021: Translated document received on 22-SEP-2021 included suspect drug related additional information and dosage form updated.	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 17-Sep-2021 and was forwarded to Moderna on 17-Sep-2021. 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	20 years old male with unknown medical history who next day after the 2nd dose was diagnosed with myocarditis. Lab results showed elevated troponin, abnormal Echo and EKG. No other information was provided. Important information is missing in

		(Spikevax) (batch no. 3004224) for COVID-19 vaccination. No Medical History information was reported. On 27-Aug-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 28-Aug-2021, the patient experienced MYOCARDITIS ([redacted]) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS ([redacted]) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 28-Aug-2021, Echocardiogram: abnormal (abnormal) Thickened pericardium.. On 28-Aug-2021, Electrocardiogram: abnormal (abnormal) Globalized ST elevations and abnormal (abnormal) PQ depressions.. On 28-Aug-2021, Troponin T: 757 nanogram per liter (High) 757 nanogram per liter. For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered MYOCARDITIS ([redacted]) to be possibly related. No concomitant medications were provided. No treatment information was provided. Company Comment : This case concerns a 20-year-old male subject with no reported relevant medical history, who experienced the expected event of Myocarditis (AESI). The event occurred 2 days after the second dose of Spikevax. The rechallenge was not applicable since only information about one dose was disclosed. The events were considered possibly related to Spikevax Vaccine per the reporter's assessment. The event is consistent with the current understanding of the mechanism of action of the study medication. The benefit-risk relationship	the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2.

		of Spikevax Vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 17-Sep-2021: Translation Received on 22-SEP-2021, No new information	
4.1(b)	4.1(b)	This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b)) on 11-Sep-2021 and was forwarded to Moderna on 11-Sep-2021. 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 18-Aug-2021, the patient received the 2nd dose of this vaccine. At night, pyrexia of 38.0 degrees Celsius developed and persisted up until 20-Aug-2021. On 21-Aug-2021, at the time of awakening, chest pain developed. The patient visited the reporting hospital. Electrocardiogram showed ST elevation in a wide range of lead, and Trop 1 was also positive (0.985 ng/mL). The patient was hospitalized with suspected pericarditis and myocarditis. Subsequent cardiac MRI showed LGE in the side of the epicardium. Myocarditis was diagnosed because there was also a high signal at 92 W. On 26-Aug-2021, the patient was discharged from the hospital. On 08-Sep-2021, it was confirmed 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.	22 years old male with unknown medical history who 2 days after the 2nd dose was diagnosed with myocarditis. Lab results showed elevated troponin, abnormal EKG and cMRI. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2.

4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 17-Sep-2021 and was forwarded to Moderna on 17-Sep-2021. This regulatory authority case was reported by a physician and describes the occurrence of the first episode of CHEST DISCOMFORT (4.1(b) the second episode of CHEST DISCOMFORT (4.1(b) and PERICARDITIS (4.1(b) in a 22-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 1601800) for Vaccination. The occurrence of additional non-serious events is detailed below. Co-suspect product included non-company product TOZINAMERAN (COMIRNATY) for Vaccination. No Medical History information was reported. On 08-Jul-2021 at 12:00 PM, the patient received first dose of TOZINAMERAN (COMIRNATY) (Intramuscular) 1 dosage form. On 25-Aug-2021 at 12:00 PM, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 29-Aug-2021, the patient experienced the first episode of CHEST DISCOMFORT (4.1(b) (seriousness criterion medically significant), the second episode of CHEST DISCOMFORT (4.1(b) (seriousness criterion medically significant) and PERICARDITIS (4.1(b) (seriousness criterion medically significant). On an unknown date, the patient experienced COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine). At the time of the report, last episode of CHEST DISCOMFORT (4.1(b) and PERICARDITIS (4.1(b) outcome was unknown and COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):	22 years old male with history of receiving the other mRNA vaccine as the 1st dose, and who 4 days after the 2nd dose was diagnosed with pericarditis. Lab results showed elevated troponin and CRP but normal Echo amd EKG. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. This report is confounded by the administration of the other mRNA vaccine

		In August 2021, C-reactive protein: 19 (High) 19 mg/L. In August 2021, Echocardiogram: normal (normal) No finding of pathological amounts of pericardial fluid, only subnormal systolic function at rest.. In August 2021, Electrocardiogram: normal (normal) Normal. In August 2021, Troponin: 20 (High) 20 ng/L. In August 2021, White blood cell count: normal (normal) Normal. For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered CHEST DISCOMFORT (4.1(b) CHEST DISCOMFORT (4.1(b) and PERICARDITIS (4.1(b) to be possibly related. No further causality assessment was provided for COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine). Concomitant medications were not provided by the reporter. Treatment information was not provided. Company Comment: This case concerns a 22-year-old, male patient with no known medical history, who experienced the unexpected events of chest discomfort, chest pressure and revaccination with different covid 19 vaccine and and expected event of pericarditis. The events occurred approximately 5 days after the dose of Spikevax and had an unknown outcome. The patient received one dose of Cominarty prior to Spikevax. The rechallenge is not applicable, as another dose of spikevax is not expected. The event was considered related to the product per the reporter's assessment. The event pericarditis is consistent with the current understanding of the mechanism of action of the study medication. The product Cominarty vaccine remains as a confounding factor to the events. The benefit-risk relationship of Spikevax is not affected by this report. Most recent FOLLOW-UP information incorporated above includes:	

		On 17-Sep-2021: Translation document received on 23-SEP-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 16-Sep-2021 and was forwarded to Moderna on 16-Sep-2021. This regulatory authority case was reported by a physician and describes the occurrence of CHEST PAIN (4.1(b) , TACHYCARDIA (4.1(b) and MYOCARDITIS (4.1(b) in a 22-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 3002916 and 3002916) for COVID-19 vaccination. The patient's past medical history included Bronchial asthma since an unknown date. Concomitant products included CICLESONIDE (ALVESCO) and CETIRIZINE HYDROCHLORIDE (ZODAC) for Bronchial asthma. On 25-Jun-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 06-Aug-2021, received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to 1 dosage form. On 10-Aug-2021, the patient experienced CHEST PAIN (4.1(b)) (seriousness criteria hospitalization, medically significant and life threatening), TACHYCARDIA (4.1(b) (seriousness criteria hospitalization, medically significant and life threatening) and MYOCARDITIS (4.1(b) (seriousness criteria hospitalization, disability, medically significant and life threatening). At the time of the report, CHEST PAIN (4.1(b)), TACHYCARDIA (4.1(b) and MYOCARDITIS (4.1(b) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 10-Aug-2021, Angiogram: abnormal (abnormal) Coronary arteries without any pathology. On 10-Aug-2021, Echocardiogram: abnormal (abnormal) borderline dilatation of the left ventricle and borderline	22 years old male with medical history of asthma who 4 days after the 2nd dose experienced chest pain and tachycardia and was diagnosed with myocarditis. Lab results showed elevated troponin, abnormal Echo and cMRI. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2.

		ejection fraction, no kinetic disturbance, minimal pericardial effusion. On 10-Aug-2021, Ejection fraction: borderline (Borderline) Borderline. On 10-Aug-2021, Magnetic resonance imaging heart: abnormal (abnormal) acute myocarditis with oedema and late saturation, mildly reduced systolic function of the borderline large left ventricle, mildly reduced systolic function of the slightly enlarged right ventricle. In August 2021, Troponin T: 1147 ng/l; 1744 ng/l (abnormal) highly sensitive Troponin T. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Lab tests were conducted on an unknown date in Aug,2021 to rule out an autoimmune or infectious cause of peri myocarditis (results not provided). Treatment information was not provided. Company Comment : This case concerns a 22-year-old, male patient with no relevant medical history, who experienced the unexpected events of Chest pain, Tachycardia, and the expected event of Myocarditis. The events occurred around 5 days after second dose of Spikevax. The rechallenge was not applicable since no events were reported after the first dose. 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.	
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 22-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination. No Medical History information was reported. On 14-Jul-2021, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 100 microgram.	22 years old male with unknown medical history who 2 days after the 2nd dose experienced fatigue and chest pain and discomfort and was diagnosed with myocarditis. Lab results showed elevated troponin, CPK, and abnormal EKG. No other information was provided. Important information is missing in the report including patient's medical history

		On 11-Aug-2021, received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) dosage was changed to 100 microgram. On 13-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. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 14-Aug-2021, Blood creatine phosphokinase: 1100 1100 IU/L, taken at 10:00 am, 1333 1333 IU/l MB 103 IU/L and 1690 1690 IU/L, CK MB 150 IU/L taken at 11:00pm. On 14-Aug-2021, Electrocardiogram: normal (normal) Normal rate sinus rhythm. PQ depressions I, V5, V5 [sic], ST segment elevation II, V4-V6. Ejection fraction was visually 65%.. On 14-Aug-2021, Heart rate: 70 70 BPM. On 14-Aug-2021, Troponin: 1176 1176 ng/L, Taken at 10:00 am, 1245 hs T 1245 ng/L, Taken at 5:00 pm and 1346 1346 ng/L, Taken at 11:00pm. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered MYOCARDITIS (4.1(b) to be possibly related. No concomitant medication was reported. No treatment medication was reported. After the second vaccination, patient developed sever fatigue and chest pain and discomfort when bending on the left side. Was hospitalized for possible acute coronary syndrome or myocarditis. Cardiac ultrasound showed normal results and no pericardial effusions. company comment: This case concerns a 22-year-old, male patient with no relevant medical history, who experienced the expected events of Myocarditis. The events occurred approximately 3 days after the second dose of Spikevax. The rechallenge was unknown since no event about the first	as well as any other laboratory test conducted, including testing for SARS-CoV-2.

		dose was disclosed. 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 events resulted in a persistent or permanent incapacity Most recent FOLLOW-UP information incorporated above includes: On 21-Sep-2021: Translation document received on 23-Sep-2021, laboratory tests and findings updated.	
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. This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCARDITIS (Myocarditis), CHEST DISCOMFORT (Chest discomfort) and PAIN IN JAW (Pain in jaw) in a 26-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 051C21A) for COVID-19 vaccination. Concomitant products included MULTIVITAMIN [VITAMINS NOS] for an unknown indication. On 29-Jul-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 01-Aug-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant), CHEST DISCOMFORT (Chest discomfort) (seriousness criterion hospitalization) and PAIN IN JAW (Pain in jaw) (seriousness criterion hospitalization). The patient was hospitalized on 02-Aug-2021 due to CHEST DISCOMFORT, MYOCARDITIS and PAIN IN JAW. At the time of the report, MYOCARDITIS (Myocarditis), CHEST DISCOMFORT (Chest discomfort) and PAIN IN JAW (Pain in jaw) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):	26 years old female with unknown medical history and taking contraceptives for an unknown time who 2 days after the 2nd dose experienced chest discomfort and pain in the jaw and was diagnosed with myocarditis. Lab results showed elevated troponin and CRP, and abnormal MRI. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2.

		On 01-Aug-2021, C-reactive protein: increased (High) increased. On 01-Aug-2021, Magnetic resonance imaging thoracic: abnormal (abnormal) abnormal. On 01-Aug-2021, Red blood cell sedimentation rate: increased (High) increased. On 01-Aug-2021, Troponin: 3.2 (High) 3.2. On 02-Aug-2021, Magnetic resonance imaging: abnormal (abnormal) revealed inflammation in the myocardium.. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter considered MYOCARDITIS (Myocarditis) to be related. No further causality assessments were provided for CHEST DISCOMFORT (Chest discomfort) and PAIN IN JAW (Pain in jaw). Patient received an echo, EKG, and was attached to a holter monitor,Electrocardiogram ambulatory. concomitant medications :birth control pill. No treatment medication details was reported. Company Comment: This case concerns a 26-year old, female subject with no relevant medical history, who experienced the expected event of Myocarditis and the unexpected events of Chest discomfort and Pain in jaw. The events occurred approximately 3 days after the second dose of MODERNA COVID-19 VACCINE. The reporter assessed the event Myocarditis as likely related to the product. The benefit-risk relationship of MODERNA COVID-19 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 21-Sep-2021 and was forwarded to Moderna on 21-Sep-2021. This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (4.1(b) [redacted]) in a 22-year-old male patient who received mRNA-1273 (Spikevax) (batch no. FE9174) for	22 years old male with history of receiving the other mRNA vaccine as the 1st dose, and who 2 days after the 2nd dose experienced abdominal pain upper, cold sweat, nausea and vomiting and was diagnosed with myocarditis. Lab results showed elevated troponin and CRP and abnormal

		Vaccination. The occurrence of additional non-serious events is detailed below. Previously administered products included for Vaccination: Comirnaty. On 08-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 10-Sep-2021, the patient experienced MYOCARDITIS (4.1(b) (seriousness criteria hospitalization and medically significant), ABDOMINAL PAIN UPPER (EPIGASTRIC PAIN), COLD SWEAT (COLD SWEAT), INFLUENZA LIKE ILLNESS (INFLUENZA-LIKE SYMPTOMS), NAUSEA (NAUSEA) and VOMITING (VOMITING). 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) ABDOMINAL PAIN UPPER (EPIGASTRIC PAIN), COLD SWEAT (COLD SWEAT), INFLUENZA LIKE ILLNESS (INFLUENZA-LIKE SYMPTOMS), NAUSEA (NAUSEA) and VOMITING (VOMITING) was resolving and COVID-19 IMMUNISATION (REVACCINATION WITH DIFFERENT COVID-19 VACCINE) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 10-Sep-2021, C-reactive protein: slightly elevated (High) Slightly elevated (not specified). On 10-Sep-2021, Cardiac telemetry: abnormal (abnormal) VT-complexes. On 10-Sep-2021, Electrocardiogram: abnormal (abnormal) Global ST-elevations and PR-depressions.. On 10-Sep-2021, Troponin I: abnormal (abnormal) 25000 Fluctuating troponins on day 2 in hospital. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Patient was hospitalized 2 days after vaccination with Spikevax. First dose	EKG. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. This report is confounded by the administration of the other mRNA vaccine

		was Comirnaty. No concomitant medications were reported. Patient exhibited clinical improvement on the 2nd day of hospitalization. No treatment medications were reported. Company comment: This case concerns a 22-year-old male patient with no relevant medical history, who experienced serious, listed event of myocarditis. The serious event occurred after 3 days of 2nd dose of Moderna COVID-19 Vaccine. The rechallenge was not applicable as the event occurred after 2nd dose of Moderna COVID-19 Vaccine. The benefit-risk relationship of Moderna COVID-19 Vaccine is not affected by this report. Previously well Hospitalized 2 days after COVID-19 vaccination with Spikevax, 1st dose Comirnaty Severe epigastric pain, nausea, vomiting, cold sweats and prodromal influenza-like symptoms Clinically and biochemically diagnosed with perimyocarditis, considered vaccination related. Clinical improvement on the 2nd day of hospitalization. Most recent FOLLOW-UP information incorporated above includes: On 21-Sep-2021: Translation received on 24-Sep-21 contains no significant information. Sender's comments were updated.	
4.1(b) [redacted]	4.1(b) [redacted]	This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted] on 21-Sep-2021 and was forwarded to Moderna on 21-Sep-2021. This regulatory authority case was reported by a physician and describes the occurrence of PERICARDITIS (PERICARDITIS) in a 35-year-old male patient who received mRNA-1273 (Spikevax) (batch no. FE9174) for Vaccination. The occurrence of additional non-serious events is detailed below. Previously administered products included for Vaccination: Comirnaty. On 01-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax)	35 years old male with history of receiving the other mRNA vaccine as the 1st dose, and who 3 days after the 2nd dose experienced burning chest pain and was diagnosed with pericarditis. Lab results showed elevated troponin, CRP and NTp-BNP, and abnormal cMRI. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. This report

		(Intramuscular) 1 dosage form. On 04-Sep-2021, the patient experienced PERICARDITIS (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 (PERICARDITIS) and COVID-19 IMMUNISATION (REVACCINATION WITH DIFFERENT COVID-19 VACCINE) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 04-Sep-2021, C-reactive protein: 79 (abnormal) 79/milligram per litre. On 04-Sep-2021, N-terminal prohormone brain natriuretic peptide: 954 nanogram per litre (abnormal) Maximum of 954 ng/L. On 04-Sep-2021, Troponin I: 770 (abnormal) Maximum of 770. On 07-Sep-2021, Ejection fraction: 49 (abnormal) 49%. On 07-Sep-2021, Magnetic resonance imaging heart: abnormal (abnormal) Weak intermediary contrast uptake epicardially in parts of left ventricle. Slightly reduced systolic function of left ventricle.. For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered PERICARDITIS (PERICARDITIS) to be possibly related. No further causality assessment was provided for COVID-19 IMMUNISATION (REVACCINATION WITH DIFFERENT COVID-19 VACCINE). Concomitant product use was not provided by the reporter. Treatment medications included were Colchicine, Ibuprofen and Paracetamol for the pain. Patient was hospitalized with central burning chest pain, worsening when standing upright and deep inspiration. Patient was diagnosed with pericarditis, which has been uncomplicated up to point of reporting.	is confounded by the administration of the other mRNA vaccine

		Company comment: This case concerns a 35 year-old male patient with no reported medical history, who experienced the unexpected serious event of Pericarditis and the non-serious event of Revaccination with different COVID-19 vaccine. The event of Pericarditis occurred 4 days after the second dose of mRNA-1273 vaccine. The event of Revaccination with different COVID-19 vaccine occurred when patient was initially dosed with Comirnaty followed by the second dose with Spikevax. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 21-Sep-2021: Translation received on 24-Sep-2021 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 22-Sep-2021 and was forwarded to Moderna on 22-Sep-2021. 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. Previously administered products included for Vaccination: COMIRNATY. 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. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):	18 years old male with history of receiving the other mRNA vaccine as the 1st dose, and who 3 days after the 2nd dose experienced chest pain was diagnosed with myocarditis. Lab results showed elevated troponin and normal Echo. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. This report is confounded by the administration of the other mRNA vaccine

		On 31-Aug-2021, Echocardiogram: normal (normal) Normal. On 31-Aug-2021, Troponin: 250 (High) 250 ng/L (nanogram per litre). For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered CHEST PAIN (4.1(b)) and MYOCARDITIS (4.1(b)) to be possibly related. No concomitant medication was reported. No treatment was reported. Company comment: 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.	
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. This regulatory authority case was reported by a physician and describes the occurrence of CHEST PAIN (CHEST PAIN) and MYOCARDITIS (myocarditis) 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. Co-suspect product included non-company product TOZINAMERAN (COMIRNATY) for Vaccination. No Medical History information was reported. On 19-Jul-2021, the patient started TOZINAMERAN (COMIRNATY) (Intramuscular) 1 dosage form.	33 years old male with history of receiving the other mRNA vaccine as the 1st dose, and who 3 days after the 2nd dose expereinced chest pain and was diagnosed with myocarditis. Lab results showed elevated troponin and CRP. Echo was normal, but EKG and cMRI were abnormal. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. This report is confounded by the administration of the other mRNA vaccine

		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 (CHEST PAIN) (seriousness criterion hospitalization). On 04-Sep-2021, the patient experienced MYOCARDITIS (myocarditis) (seriousness criterion hospitalization). On an unknown date, the patient experienced COVID-19 IMMUNISATION (REVACCINATION WITH DIFFERENT COVID-19 VACCINE). At the time of the report, CHEST PAIN (CHEST PAIN) and MYOCARDITIS (myocarditis) had not resolved and COVID-19 IMMUNISATION (REVACCINATION WITH DIFFERENT COVID-19 VACCINE) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 03-Sep-2021, C-reactive protein: 40 (abnormal) 40 and 40 milligram per litre. On 03-Sep-2021, Echocardiogram: normal No pathological findings and no pathological findings (normal) No pathological findings. On 03-Sep-2021, Electrocardiogram: abnormal (abnormal) Global ST-elvations and global st-elvations (abnormal) Global ST-elvations. On 03-Sep-2021, Magnetic resonance imaging heart: abnormal (abnormal) Findings compatible with myocarditis. On 03-Sep-2021, Troponin I: 2000 - 3000 - 2000 ng/l (abnormal) 2000 - 3000 - 2000 ng/L. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medication listed No treatment medications provided It was originally reported perimyocarditis, but the after receiving results from cardiac MRI, the diagnosis was changed to myocarditis Most recent FOLLOW-UP information incorporated above includes:	

		On 23-Sep-2021: Translated document received on 29-sep-2021 contain no new information On 29-Sep-2021: Significant follow up received on 29-sep-2021,comirnanty updated from historical vaccine to suspect vaccineand event perimyocarditis updated to myocarditis.	
4.1(b) [redacted]	4.1(b) [redacted]	This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 23-Sep-2021 and was forwarded to Moderna on 23-Sep-2021. 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. Previously administered products included for Vaccination: Comirnaty. Concurrent medical conditions included Childhood asthma. On 09-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 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 11-Sep-2021, the patient experienced MYOCARDITIS (PERIMYOCARDITIS) (seriousness criteria hospitalization and medically significant). On an unknown date, the patient experienced the first episode of COVID-19 IMMUNISATION (REVACCINATION WITH DIFFERENT COVID-19 VACCINE), INCORRECT DOSE ADMINISTERED (Inappropriate dose of vaccine administered), the second episode of COVID-19 IMMUNISATION (REVACCINATION WITH DIFFERENT COVID-19 VACCINE) and CHEST PAIN (chest pain). At the time of the report, MYOCARDITIS (PERIMYOCARDITIS) was resolving, INCORRECT DOSE ADMINISTERED (Inappropriate dose of vaccine administered) had resolved and last episode of COVID-19	24 years old male with history of receiving the other mRNA vaccine as the 1st dose, and who 2 days after the 2nd dose exoerienced chest pain was diagnosed with myocarditis. Lab results showed elevated troponin, CRP, and abnormal Echo, but normal EKG. A cMRI performed 4 days later showed sparse perimyocarditis changes basal inferolateral. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. This report is confounded by the administration of the other mRNA vaccine

		IMMUNISATION (REVACCINATION WITH DIFFERENT COVID-19 VACCINE) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 11-Sep-2021, C-reactive protein: 100 (High) 100. On 11-Sep-2021, Echocardiogram: abnormal (abnormal) Small amount of pericardial fluid. On 11-Sep-2021, Electrocardiogram: normal (normal) No distinct abnormality. On 11-Sep-2021, Pain assessment: nrs3 (High) NRS 3. On 11-Sep-2021, Troponin T: high (High) 620. On 12-Sep-2021, Echocardiogram: normal (normal) Done by cardiologist. No pericardial fluid. Fine contractility.. On 12-Sep-2021, White blood cell count: abnormal (abnormal) Slight leucopenia, monocytopenia and neutropenia.. On 14-Sep-2021, Troponin T: 709 (High) high. On 15-Sep-2021, C-reactive protein: 18 (abnormal) 18. In September 2021, Electrocardiogram: abnormal (abnormal) 11.9 No distinct abnormality 16.9 ECG was normal at first, but development of global ST-elevations during one of the episodes with chest pain.(New reporter, duplicate report). In September 2021, Magnetic resonance imaging heart: abnormal (abnormal) 15.9 Sparse perimyocarditis changes basal inferolateral. 16.9 Perimyocarditis changes detected as well as reduced contractility in affected myocardium (New reporter, duplicate reportab and. On 15-Sep-2021, Magnetic resonance imaging heart abnormal (abnormal) Sparse perimyocarditis changes basal inferolateral.. On an unknown date, Troponin T: low (Low) 498 (lowest value). For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. No concomitant medications were provided by the reporter.	

		No treatment information was provided by the reporter. Most recent FOLLOW-UP information incorporated above includes: On 24-Sep-2021: follow-up received on 24-SEP-2021, significant follow-up lab data information updated.	
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. 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. No Medical History information was reported. On 09-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 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 10-Sep-2021, the patient 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. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In September 2021, C-reactive protein: 66 (High) 66. In September 2021, Troponin: 109 (High) 109. In September 2021, White blood cell count: 11.05 (High) 11.05. For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered CHEST PAIN (4.1(b) and	29 years old male with unknown medical history who next day after the 2nd dose experienced chest pain and was diagnosed with myocarditis. Lab results showed elevated troponin and CRP. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2.

		MYOCARDITIS (4.1(b) to be possibly related. No concomitant medications reported by reporter. No treatment medications provided by the reporter. Follow-up received on 23-SEP-2021 included no new information Most recent FOLLOW-UP information incorporated above includes: 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 European Medicines Agency (Reference number: 4.1(b)) on 23-Sep-2021 and was forwarded to Moderna on 23-Sep-2021. 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. None. On 28-Jul-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. 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	22 years old male with unknown medical history who next day after the 2nd dose experienced chest discomfort and was diagnosed with myopericarditis. Lab results showed elevated troponin and CRP, abnormal EKG and normal Echo. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2.

		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. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In August 2021, Electrocardiogram: inconclusive (Inconclusive) ECG wide spread concave upwards ST elevation. On 27-Aug-2021, C-reactive protein: 66 (abnormal) Admission CRP 66. On 27-Aug-2021, Echocardiogram: normal (normal) No pericardial effusion. Normal LV function. On 27-Aug-2021, Troponin: 893 (abnormal) Admission Troponin 893. On 30-Aug-2021, C-reactive protein: 10 (normal) normal. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. No treatment information was provided. No relevant concomitant medications were reported. 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 33-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination. Concurrent medical conditions included Alcohol use and Tobacco user. On 10-Jun-2021, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 200 microgram. On 08-Jul-2021, received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) dosage was changed to 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. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 20-Aug-2021, Echocardiogram: abnormal (abnormal) abnormal. On an unknown date, Angiogram: normal (normal) normal. On an unknown date, Blood creatine phosphokinase: 1506 peak: 1707 (High) 1506 peak: 1707. On an unknown date, Electrocardiogram: abnormal (abnormal) abnormal. On an unknown date, Troponin T: 2251 peak: 4441 (High) 2251 peak: 4441. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered MYOCARDITIS (4.1(b) to be possibly related.	33 years old male with unknown medical history who 42 days after the 2nd dose experienced left thoracic pain and was diagnosed with myocarditis. Lab results showed elevated troponin and CPK, abnormal Echo and EKG. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2.

		patient took moderna covid-19 vaccine on 08-JUL-2021 and on 19-AUG-2021 patient had complained of left thoracic pain without any previous symptoms of infection. Concomitant product use was not provided by the reporter. No treatment information was provided. Most recent FOLLOW-UP information incorporated above includes: 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. No Medical History information was reported. On 03-May-2021, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form. 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 CHEST PAIN (4.1(b) (seriousness criteria	37 years old male with unknown medical history who 4 days after the 2nd dose experienced chest pain was diagnosed with myocarditis. Lab results showed abnormal angiogram and abnormal EKG. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2.

		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. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 04-Apr-2021, Angiocardiogram: abnormal (abnormal) Bland coronary arteries with smooth walls,Apical hypokinesia, LVEF 45-50%. 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. 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. Concomitant products were not provided. Treatment medication were not reported. 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. The patient had a family history of myocarditis for his uncle at age of 60. 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. Most recent FOLLOW-UP information incorporated above includes: 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. No Medical History information was reported. 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))	28 years old male with unknown medical history who next day after the 2nd dose experienced respire-dependent retrosternal pain, radiating to the jaw and was diagnosed with pericarditis. Lab results showed ultrasensitive troponin assay negative, elevated CRP with normal EKG and chest x-ray. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted,

		(seriousness criterion medically significant). At the time of the report, PERICARDITIS (4.1(b)) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 14-Jul-2021, Chest X-ray: normal (normal) no infected site. On 14-Jul-2021, Electrocardiogram: normal (normal) Regular sinus rhythm. On 14-Jul-2021, Electrocardiogram ST segment: normal (normal) normal. On 14-Jul-2021, Sinus rhythm: 70 (normal) 70 bpm. On 14-Jul-2021, Troponin: high High sensitive. On 15-Jul-2021, Troponin: high High sensitive. On an unknown date, Blood pressure measurement: 122/71 mmHg 122/71. On an unknown date, C-reactive protein: 38.6 mg/l 38.6 mg/L. On an unknown date, Heart rate: 75 75 bpm. On an unknown date, Oxygen saturation: 98 percent 98%. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered PERICARDITIS (4.1(b)) to be probably related. Concomitant medications were not provided. Treatment medications included were NSAIDs for one week 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. Patient was received second dose after few hr later chills without a measured fever. 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.	including testing for SARS-CoV-2. Report confounded by the normal tests including the chest x-raym the EKG and the ultrasensitive troponin assay.

		Physical examination BP 122/71mmhg, pulse 75bpm, saturation 98% on room air On 14-Jul-2021, patient undergone High sensitive troponin I, C-reactive protein, Leukocyte count, Electrocardiogram, Thorax X-ray and results were unknown. On 15-Jul-2021, patient undergone C-reactive protein, High sensitive troponin I, Creatine kinase and results were unknown. 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. 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. No Medical History information was reported. On 13-Aug-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) .5 milliliter. 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. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 13-Sep-2021, C-reactive protein (0-5): 55 (High) 55 ng/L. On 13-Sep-2021, Electrocardiogram: abnormal (abnormal) patient ECG on	24 years old male with unknown medical history who 3 day2 after the 2nd dose was diagnosed with myocarditis. Lab results showed elevated troponin, elevated CRP and abnormal EKG. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2.

		admission (no pain): Sinus rhythm 75 lpm, axis 40°, decreased PR in V3-V6 peri cordials, incomplete RBBB, early repolarization. On 13-Sep-2021, Troponin T (0-5 ng/L): 318 ng/L (High) Increased. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Concomitant medications was not provided by the reporter Treatment information was not provided. Action taken with mRNA-1273 (Spikevax) was Not Applicable. Most recent FOLLOW-UP information incorporated above includes: On 24-Sep-2021: Translation received on 29-Sep-2021 and included patient lab data.	
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. 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 1st dose of the vaccine. On an unknown date, body temperature before vaccination: 36.2 degrees Celsius. On 11-Sep-2021, at 11:30, the patient received 2nd dose of the vaccine. 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. On 13-Sep-2021, the patient was hospitalized due to acute pericarditis.	28 years old male with unknown medical history who next day after the 2nd dose experienced chest pain and was diagnosed with pericarditis. Lab results showed elevated cardiac enzimes and abnormal EKG. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2.

		On 14-Sep-2021, it was confirmed that the symptom resolved. The outcome of acute pericarditis was reported as resolved. 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 17-Sep-2021 and was forwarded to Moderna on 28-Sep-2021. 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: 36.6 degrees Celsius. On 18-Aug-2021, the patient received the 2nd dose of this vaccine. On 19-Aug-2021, chest pain occurred. Acute pericarditis 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. Elevated myocardial enzyme was noted. Electrocardiogram showed ST elevation in chest leads. The patient was hospitalized with a diagnosis of myocarditis. Late gadolinium enhancement (LGE) was observed in lateral wall on contrast-enhanced MRI. On an unknown date, the symptoms showed an improving tendency.	26 years old male with unknown medical history who next day after the 2nd dose experienced chest pain. The following day patient went to the hospital were he was diagnosed with myocarditis. Lab results showed elevated cardiac enzymes, and abnormal EKG and cMRI. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2.

		On 25-Aug-2021, improvement of symptoms was confirmed. The patient was discharged home. The outcome of acute pericarditis and myocarditis was reported as resolving. Follow-up investigation will be made. 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 17-Sep-2021 and was forwarded to Moderna on 28-Sep-2021. 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: 36.6 degrees Celsius. On 18-Aug-2021, the patient received the 2nd dose of this vaccine. On 19-Aug-2021, chest pain occurred. Acute pericarditis 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. Elevated myocardial enzyme was noted. Electrocardiogram showed ST elevation in chest leads. The patient was hospitalized with a diagnosis of myocarditis. Late gadolinium enhancement (LGE) was observed in lateral wall on contrast-enhanced MRI. On an unknown date, the symptoms showed an improving tendency.	26 years old male with unknown medical history who next day after the 2nd dose experienced chest pain. The following day patient went to the hospital were he was diagnosed with myocarditis. Lab results showed elevated cardiac enzymes, and abnormal EKG and cMRI. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2.

		On 25-Aug-2021, improvement of symptoms was confirmed. The patient was discharged home. The outcome of acute pericarditis and myocarditis was reported as resolving. Follow-up investigation will be made. 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 17-Sep-2021 and was forwarded to Moderna on 28-Sep-2021. This case, initially reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref, 4.1(b) On 27-Jul-2021, the patient received the 1st dose of this vaccine. On an unknown date, body temperature before vaccination: 36.0 degrees Celsius. On 27-Aug-2021, at 13:00, the patient received the 2nd dose of this vaccine. The patient had pyrexia at night. On 29-Aug-2021, at 00:00, chest pain developed. The patient consulted a previous physician. There was extensive ST elevation in the electrocardiogram and myocardial enzyme elevation in the blood examination. On 30-Aug-2021, the patient was referred to our hospital and was admitted with acute myocarditis. On an unknown date, though there was the cardiac hypofunction temporarily, it was improved. On 04-Sep-2021, the patient's symptoms were considered to be improved. The patient was discharged from the hospital.	20 years old male with unknown medical history who 2 day after the 2nd dose experienced chest pain and pyrexia and was diagnosed the next day with myocarditis. Lab results showed elevated myocardial enzymes, and abnormal EKG. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2.

		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 received via Takeda Pharmaceuticals (Reference number: 4.1(b)) on 17-Sep-2021 and was forwarded to Moderna on 28-Sep-2021. This case, initially reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref, 4.1(b) 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 persisted from night (until the morning of 25-Aug-2021). On 25-Aug-2021, at 04:00, the patient visited the reporting hospital for subjective symptoms of chest pain and cold sweat. In the blood test, elevated cardiac enzymes and inflammatory reaction were found, and in the electrocardiogram, the ST elevation was noted. There was no coronary artery lesion in coronary ST, and the diagnosis of acute myocarditis was made. The patient was hospitalized. The patient was followed up, and the symtoms improved conservatively. On 31-Aug-2021, the remission of the symptom was confirmed. The patient was discharged from the hospital. The outcome of acute myocarditis was reported as resolving. Follow-up investigation will be made. Company Comment:	25 years old male with unknown medical history who 3 day after the 2nd dose experienced chest pain and cold sweat and was diagnosed with myocarditis. Lab results showed elevated myocardial enzymes, and abnormal EKG. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2.

		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 26-Sep-2021 and was forwarded to Moderna on 26-Sep-2021. This regulatory authority case was reported by a pharmacist and describes the occurrence of MYOCARDITIS (Perimyocarditis), DYSPNOEA (Shortness of breath), CHEST PAIN (Chest pain), 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. No Medical History information was reported. On 23-Jul-2021, the patient received first dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. 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. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):	19 years old male with unknown medical history who next day after the 2nd dose expereinced chest pain, dyspnea, and was diagnosed with myocarditis. Lab results showed elevated troponin, and abnormal EKG. Pateint had a postive SARS-Co_V test. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted. This case is heavily confounded by the positive SARS-CoV-2 test.

		On 29-Jun-2021, SARS-CoV-2 test: positive (Positive) Positive COVID-19 test. The action taken with mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown) was unknown. For mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Concomitant medications were not provided by the reporter. Treatment information was not provided.	
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. This case, initially reported to the 4.1(b) (4.1(b) by a pharmacist, was received via the 4.1(b) (Ref, 4.1(b) 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. On an unknown date, the patient received the 1st dose of the vaccine. 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. On 02-Sep-2021, in the morning, pyrexia and breathlessness developed. The patient was considered to experience acute myocarditis. 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	18 years old male with medical history of hemophilia B who next day after the 2nd dose experienced pyrexia and dyspnea. Next day pateint experienced chest pain and was diagnosed with myocarditis. Lab results showed elevated myocardial markers, abnormal EKG and abnormal MRI. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2.

		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. 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. 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. 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.	

		On 07-Sep-2021, chest pain disappeared. BP: 104/58 mmHg, HR: 62, and SpO2: 98% (room) without cardiac murmur. 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. On 10-Sep-2021, BP: 120/61 mmHg, HR: 68, and UCG: eyeball EF was 61%. On 11-Sep-2021, as cardiac function recovered and the clinical course was good, the patient was discharged from the hospital. On 16-Sep-2021, a coronary CT was performed to show no significant stenosis. 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. The outcome of acute myocarditis was reposted as resolved. 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 21-Sep-2021 and was forwarded to Moderna on 29-Sep-2021. This case was reported by a physician via the Drug Information Center.	23 years old male with unknown medical history who 2 days after the 2nd dose experienced chest pain and pyrexia was diagnosed with myocarditis. Lab results

		On 30-Aug-2021, the patient received the 1st dose of this vaccine. The patient experienced pyrexia. On an unknown date, pyrexia went down, and the patient recovered from pyrexia. On 15-Sep-2021, the patient received the 2nd dose of this vaccine. 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. On an unknown date, the patient was hospitalized. On 21-Sep-2021, the patient's chest pain disappeared without medication. On 22-Sep-2021, the patient was scheduled to be discharged. The outcome of pyrexia after the 1st dose of this vaccine was reported as resolved. The outcome of pyrexia and myocarditis after the 2nd dose of this vaccine was unknown. Follow-up investigation will be made. Company Comment: The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	showed elevated troponin, and abnormal EKG. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2.
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. This regulatory authority case was reported by an other health care professional and describes the occurrence of ABDOMINAL DISTENSION (bloating), C-REACTIVE	30 years old male with medical history of dyslipidemia who next day after the 2nd experienced chest discomfort, abdominal distension, chest pain, cough, dizziness, dypsnea, pain in extremities, peripheral

		PROTEIN INCREASED (C-reactive protein increased), CHEST DISCOMFORT (cracking chest pressure), CHEST PAIN (Chest pain), COUGH (Cough), DISCOMFORT (uncomfortable lying flat), DIZZINESS (lightheadedness), DYSPNOEA (SOB), EJECTION FRACTION DECREASED (Ejection fraction decreased), HYPERHIDROSIS (diaphoresis), MYOCARDITIS (Myocarditis), PAIN (Pain), PERICARDIAL EFFUSION (Pericardial effusion), PERICARDIAL FIBROSIS (Pericardial fibrosis), PERICARDITIS (Pericarditis), PYREXIA (Pyrexia), RED BLOOD CELL SEDIMENTATION RATE INCREASED (Red blood cell sedimentation rate increased), TROPONIN INCREASED (Troponin increased), MYALGIA (severe body aches), DEEP VEIN THROMBOSIS (unprovoked DVT), PAIN IN EXTREMITY (Pain of lower extremities) and PERIPHERAL SWELLING (swelling in his left lower extremity) in a 30-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 046C21A and 036C21A) for COVID-19 vaccination. The patient's past medical history included Dyslipidemia. On 10-Sep-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 10-Sep-2021, received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 11-Sep-2021, the patient experienced ABDOMINAL DISTENSION (bloating) (seriousness criterion hospitalization), C-REACTIVE PROTEIN INCREASED (C-reactive protein increased) (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) (seriousness criterion hospitalization), DIZZINESS (lightheadedness) (seriousness criterion	swealling, and was diagnosed with myopericarditis as well as DVT. Lab results showed elevated troponin, elevated CRP, abnormal Echo and EKG. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2.

		hospitalization), DYSPNOEA (SOB) (seriousness criterion hospitalization), EJECTION FRACTION DECREASED (Ejection fraction decreased) (seriousness criterion hospitalization), HYPERHIDROSIS (diaphoresis) (seriousness criterion hospitalization), MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant), PAIN (Pain) (seriousness criterion hospitalization), PERICARDIAL EFFUSION (Pericardial effusion) (seriousness criteria hospitalization and medically significant), PERICARDIAL FIBROSIS (Pericardial fibrosis) (seriousness criteria hospitalization and medically significant), PERICARDITIS (Pericarditis) (seriousness criteria hospitalization and medically significant), PYREXIA (Pyrexia) (seriousness criterion hospitalization), RED BLOOD CELL SEDIMENTATION RATE INCREASED (Red blood cell sedimentation rate increased) (seriousness criterion hospitalization) and TROPONIN INCREASED (Troponin increased) (seriousness criterion hospitalization). On an unknown date, the patient experienced MYALGIA (severe body aches) (seriousness criterion hospitalization), DEEP VEIN THROMBOSIS (unprovoked DVT) (seriousness criteria hospitalization and medically significant), PAIN IN EXTREMITY (Pain of lower extremities) (seriousness criterion hospitalization) and PERIPHERAL SWELLING (swelling in his left lower extremity) (seriousness criterion hospitalization). At the time of the report, ABDOMINAL DISTENSION (bloating), C-REACTIVE PROTEIN INCREASED (C-reactive protein increased), CHEST DISCOMFORT (cracking chest pressure), CHEST PAIN (Chest pain), COUGH (Cough), DISCOMFORT (uncomfortable lying flat), DIZZINESS (lightheadedness), DYSPNOEA (SOB), EJECTION FRACTION DECREASED (Ejection fraction decreased), HYPERHIDROSIS (diaphoresis), MYOCARDITIS (Myocarditis), PAIN (Pain), PERICARDIAL EFFUSION (Pericardial effusion), PERICARDIAL FIBROSIS (Pericardial fibrosis), PERICARDITIS	

		(Pericarditis), PYREXIA (Pyrexia), RED BLOOD CELL SEDIMENTATION RATE INCREASED (Red blood cell sedimentation rate increased) and TROPONIN INCREASED (Troponin increased) had not resolved and MYALGIA (severe body aches), DEEP VEIN THROMBOSIS (unprovoked DVT), PAIN IN EXTREMITY (Pain of lower extremities) and PERIPHERAL SWELLING (swelling in his left lower extremity) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Cardiac imaging procedure: abnormal (abnormal) abnormal. On an unknown date, Electrocardiogram: pr segment depression (abnormal) pr segment depression and st segment elevation (abnormal) st segment elevation. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Allergies: Sulfa antibiotics Other Meds : Xarelto Pt negative for covid. LFTs normal	
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. This regulatory authority case was reported by an other health care professional and describes the occurrence of ABDOMINAL DISTENSION (bloating), C-REACTIVE PROTEIN INCREASED (C-reactive protein increased), CHEST DISCOMFORT (cracking chest pressure), CHEST PAIN (Chest pain), COUGH (Cough), DISCOMFORT (uncomfortable lying flat), DIZZINESS (lightheadedness), DYSPNOEA (SOB), EJECTION FRACTION DECREASED (Ejection fraction decreased), HYPERHIDROSIS (diaphoresis), MYOCARDITIS (Myocarditis), PAIN (Pain), PERICARDIAL EFFUSION (Pericardial effusion), PERICARDIAL FIBROSIS (Pericardial fibrosis), PERICARDITIS (Pericarditis), PYREXIA	30 years old male with medical history of dyslipidemia who next day after the 2nd experienced chest discomfort, abdominal distension, chest pain, cough, dizziness, dypsnea, pain in extremities, peripheral swealling, and was diagnosed with myopericarditis as well as DVT. Lab results showed elevated troponin, elevated CRP, abnormal Echo and EKG. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2.

		(Pyrexia), RED BLOOD CELL SEDIMENTATION RATE INCREASED (Red blood cell sedimentation rate increased), TROPONIN INCREASED (Troponin increased), MYALGIA (severe body aches), DEEP VEIN THROMBOSIS (unprovoked DVT), PAIN IN EXTREMITY (Pain of lower extremities) and PERIPHERAL SWELLING (swelling in his left lower extremity) in a 30-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 046C21A and 036C21A) for COVID-19 vaccination. The patient's past medical history included Dyslipidemia. On 10-Sep-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 10-Sep-2021, received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 11-Sep-2021, the patient experienced ABDOMINAL DISTENSION (bloating) (seriousness criterion hospitalization), C-REACTIVE PROTEIN INCREASED (C-reactive protein increased) (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) (seriousness criterion hospitalization), DIZZINESS (lightheadedness) (seriousness criterion hospitalization), DYSPNOEA (SOB) (seriousness criterion hospitalization), EJECTION FRACTION DECREASED (Ejection fraction decreased) (seriousness criterion hospitalization), HYPERHIDROSIS (diaphoresis) (seriousness criterion hospitalization), MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant), PAIN (Pain) (seriousness criterion hospitalization), PERICARDIAL EFFUSION (Pericardial effusion) (seriousness criteria hospitalization and medically significant), PERICARDIAL FIBROSIS (Pericardial	

		fibrosis) (seriousness criteria hospitalization and medically significant), PERICARDITIS (Pericarditis) (seriousness criteria hospitalization and medically significant), PYREXIA (Pyrexia) (seriousness criterion hospitalization), RED BLOOD CELL SEDIMENTATION RATE INCREASED (Red blood cell sedimentation rate increased) (seriousness criterion hospitalization) and TROPONIN INCREASED (Troponin increased) (seriousness criterion hospitalization). On an unknown date, the patient experienced MYALGIA (severe body aches) (seriousness criterion hospitalization), DEEP VEIN THROMBOSIS (unprovoked DVT) (seriousness criteria hospitalization and medically significant), PAIN IN EXTREMITY (Pain of lower extremities) (seriousness criterion hospitalization) and PERIPHERAL SWELLING (swelling in his left lower extremity) (seriousness criterion hospitalization). At the time of the report, ABDOMINAL DISTENSION (bloating), C-REACTIVE PROTEIN INCREASED (C-reactive protein increased), CHEST DISCOMFORT (cracking chest pressure), CHEST PAIN (Chest pain), COUGH (Cough), DISCOMFORT (uncomfortable lying flat), DIZZINESS (lightheadedness), DYSPNOEA (SOB), EJECTION FRACTION DECREASED (Ejection fraction decreased), HYPERHIDROSIS (diaphoresis), MYOCARDITIS (Myocarditis), PAIN (Pain), PERICARDIAL EFFUSION (Pericardial effusion), PERICARDIAL FIBROSIS (Pericardial fibrosis), PERICARDITIS (Pericarditis), PYREXIA (Pyrexia), RED BLOOD CELL SEDIMENTATION RATE INCREASED (Red blood cell sedimentation rate increased) and TROPONIN INCREASED (Troponin increased) had not resolved and MYALGIA (severe body aches), DEEP VEIN THROMBOSIS (unprovoked DVT), PAIN IN EXTREMITY (Pain of lower extremities) and PERIPHERAL SWELLING (swelling in his left lower extremity) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):	

		On an unknown date, Cardiac imaging procedure: abnormal (abnormal) abnormal. On an unknown date, Electrocardiogram: pr segment depression (abnormal) pr segment depression and st segment elevation (abnormal) st segment elevation. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Allergies: Sulfa antibiotics Other Meds : Xarelto Pt negative for covid. LFTs normal	
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. 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. Concurrent medical conditions included Food allergy. 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), 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. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):	35 years old female with unknown medical history who 111 days after the 2nd dose expereinced chest pain and pal[itations and was diagnosed with myopericarditis. Lab results showed elevated troponin, elevated Fibrin D-dimer. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. The TTO in this report is considered too long for a possible associatiom with the vaccine.

		On 06-Jul-2021, Fibrin D dimer: high (High) high. On 06-Jul-2021, Heart rate: high (High) high. On 06-Jul-2021, Troponin: high (High) high. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. No concomitant medications were not reported. No treatment medications were not provided. Patient lab data includes Cardiac stress test, Chest X-ray, Echocardiogram, Electrocardiogram , Laboratory test on 06-JUL-2021 and the results were unknown.	
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. 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. Concurrent medical conditions included Food allergy. 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), 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.	35 years old female with unknown medical history who 111 days after the 2nd dose expereinced chest pain and pal[itations and was diagnosed with myopericarditis. Lab results showed elevated troponin, elevated Fibrin D-dimer. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. The TTO in this report is considered too long for a possible associatiom with the vaccine.

		DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 06-Jul-2021, Fibrin D dimer: high (High) high. On 06-Jul-2021, Heart rate: high (High) high. On 06-Jul-2021, Troponin: high (High) high. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. No concomitant medications were not reported. No treatment medications were not provided. Patient lab data includes Cardiac stress test, Chest X-ray, Echocardiogram, Electrocardiogram , Laboratory test on 06-JUL-2021 and the results were unknown.	
4.1(b) [redacted]	4.1(b) [redacted]	This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 29-Sep-2021 and was forwarded to Moderna on 29-Sep-2021. 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 Vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Migraine and Revaccination with different COVID-19 vaccine. Previously administered products included for Vaccination: COMIRNATY. Concomitant products included VERAPAMIL (ISOPTIN [VERAPAMIL]) for Migraine. On 06-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. 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	25 years old male with history of receiving the other mRNA vaccine as the 1st dose, and who 2 days after the 2nd dose experienced chest pain was diagnosed with myopericarditis. Lab results showed elevated troponin, and abnormal EKG and cMRI; Echo was normal. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. This report is confounded by the administration of the other mRNA vaccine

		experienced MYOCARDITIS (PERIMYOCARDITIS) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (PERIMYOCARDITIS) was resolving and MALAISE (MALAISE), CHEST PAIN (CHEST PAIN) and PYREXIA (FEVER) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 09-Sep-2021, Echocardiogram: normal (normal) No pathology.. On 09-Sep-2021, Electrocardiogram: abnormal (abnormal) Typical changes as seen in pericarditis.. On 09-Sep-2021, Magnetic resonance imaging heart: abnormal (abnormal) Typical changes as seen in myocarditis, oedema and T1/T2 mapping, preserved ventricular function.. On 09-Sep-2021, Troponin T: 3962 (High) nanogram per litre. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Treatment information was not provided.	
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. 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 12-Sep-2021, the patient received the 2nd dose of this vaccine. On 13-Sep-2021, pyrexia developed. On 14-Sep-2021, pyrexia persisted. On 15-Sep-2021, the patient was aware of pain in the chest and queasy in the morning and took pain relief. 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	20 years old male with unknown medical history who 4 days after the 2nd dose experienced pyrexia and chest pain and was diagnosed with myocarditis. Lab results showed elevated troponin, elevated CK. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2.

		patient was diagnosed with acute myocarditis. The patient was hospitalized on the purpose of follow-up. On 17-Sep-2021, symptom recovery was confirmed. The patient was discharged from the hospital. The outcome of acute myocarditis was reported as recovered. Follow-up investigation will be made. Reporter comments continuation: 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. Company Comment: The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	
4.1(b) [redacted]	4.1(b) [redacted]	This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) [redacted]) on 27-Sep-2021 and was forwarded to Moderna on 01-Oct-2021. This case, reported by a physician, was received by Takeda via Moderna's adverse reaction reporting site (4.1(b) [redacted] and reported to the 4.1(b) [redacted] by a physician, was received via the 4.1(b) (Ref, 4.1(b) [redacted] On 26-Aug-2021, the patient received the 1st dose of the vaccine. On 21-Sep-2021, the patient received the 2nd dose of the vaccine. 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	20 years old male with unknown medical history who 2 days after the 2nd dose experienced chest pain and was diagnosed with myocarditis. Lab results showed elevated troponin, abnormal EKG. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2.

		positive and 12-leads electrocardiogram showed negative T wave with the precordial lead. On 27-Sep-2021, resolution of the symptom was confirmed. The outcome of myocarditis was reported as resolved. 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) [redacted]		This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Acute myocarditis) in a 24-year-old male patient who received mRNA-1273 (COVID 19 Vaccine Moderna) (batch no. 3003187) for COVID-19 vaccination. Concurrent medical conditions included Tobacco user. On 16-Jul-2021, the patient received second dose of mRNA-1273 (COVID 19 Vaccine Moderna) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (COVID 19 Vaccine Moderna) (unknown route) 1 dosage form. On 18-Jul-2021, after starting mRNA-1273 (COVID 19 Vaccine Moderna), the patient experienced MYOCARDITIS (Acute myocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Acute myocarditis) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 19-Jul-2021, Angiocardiogram: normal (normal) normale. On 19-Jul-2021, C-reactive protein (Unknown-5): 19.3 (High) 19.3 milligram per litre. On 19-Jul-2021, Echocardiogram: normal (normal) Normal left ventricular kinetics, 56% ejection fraction, no heart valve disease, no sign of PAH, no myocardial hypertrophy, no dilation of the aortic root, clear pericardium.. On 19-Jul-2021, Electrocardiogram: normal (normal) No ST elevation. On 19-Jul-2021, Fibrin D dimer (Unknown-500): 280 (normal) 280 nanogram per millliiter. On 19-Jul-2021, Glomerular filtration rate: 105 (normal) 105 millilitre per minute. On 19-Jul-2021, Magnetic resonance imaging heart: abnormal (abnormal) Areas of basal inferolateral myocardial inflammation. Left and right cardiac ventricular functions considered normal. No pleural or pericardial effusion. No indirect sign of a mitro- aortic heart valve disease. After gadolinium injection, no transmural endocardial sequelae of infarction. Slight basal inferolateral subepicardial contrast and on lateral side of the LV, consistent with small inflammatory areas of myocarditis. (Fiesta MRI cine sequences.	

		On 19-Jul-2021, Myoglobin blood (Unknown-72): 31 (normal) 31 nanogram per millliiter. On 19-Jul-2021, Troponin T (Unknown-15): 64 (High) 64 nanogram per litre. On 19-Jul-2021, White blood cell count (4000-9000): 10150 (High) 10150 per cubic millimetre. For mRNA-1273 (COVID 19 Vaccine Moderna) (Unknown), the reporter did not provide any causality assessments. Concomitant product use was not provided by the reporter. Patient experienced acute myocarditis with precordial pain after 2 days of receiving 2nd moderna vaccine and diagnosis made the next day on MRI. Managed with medication. Patient currently recovering. He was hospitalized for 2 days No treatment information was provided. 4.1(b) Sender's Case Safety Report Unique Identifier is 4.1(b) Company comment Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. Most recent FOLLOW-UP information incorporated above includes: On 02-Aug-2021: Follow-up received on 06-Aug-2021 and laboratory data was added.
4.1(b)		This case was initially received via European Medicines Agency (Reference number: 4.1(b)) on 03-Aug-2021. The most recent information was received on 04-Aug-2021 and was forwarded to Moderna on 04-Aug-2021. This regulatory authority case was reported by a physician and describes the occurrence of DYSPNOEA (4.1(b) PALPITATIONS (4.1(b) and MYOCARDITIS (4.1(b) in a 27-year-old male patient who received mRNA-1273 (Spikevax) for Prophylactic vaccination. No Medical History information was reported. On 24-Jun-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 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 26-Jun-2021, the patient experienced DYSPNOEA (4.1(b) (seriousness criterion hospitalization), PALPITATIONS (4.1(b) (seriousness criterion hospitalization) and MYOCARDITIS (4.1(b) (seriousness criteria hospitalization and medically significant). At the time of the report, DYSPNOEA (4.1(b) and PALPITATIONS (4.1(b) outcome was unknown and MYOCARDITIS (4.1(b) had not resolved. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.

		No concomitant medications were reported. No treatment details were reported. Patient has taken Inpatient admission in the case of dyspnea and heart palpitations, which occurred one day after the second vaccination. Electrocardiography showed ST elevations in leads II, III, V2- V6; the laboratory showed troponinemia. Suspected myocarditis was proposed and, on 14/07/2021, confirmed with a cardiac MRI. The following differential diagnoses were ruled out: Acute coronary syndrome. Was outpatient treatment required?: No. Test: 20210714 MRI result Myocarditis. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Most recent FOLLOW-UP information incorporated above includes: On 04-Aug-2021: Follow up information was received , Vaccine indicated changed to Prophylactic vaccination and listedness for Myocarditis was updated. On 25-Aug-2021: Follow up received and contains no newinformation.
4.1(b)		This case was received via 4.1(b) (Reference number: 4.1(b) on 03-Aug-2021 and was forwarded to Moderna on 03-Aug-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of CHEST PAIN (Chest pain), PAIN (Pain), PYREXIA (Pyrexia) and MYOCARDITIS (Myocarditis) in a 25-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 025C217) for COVID-19 vaccination. No Medical History information was reported. On 17-Jul-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 19-Jul-2021, the patient experienced CHEST PAIN (Chest pain) (seriousness criterion hospitalization), PAIN (Pain) (seriousness criterion hospitalization), PYREXIA (Pyrexia) (seriousness criterion hospitalization) and MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). The patient was hospitalized on sometime in July 2021 due to CHEST PAIN, MYOCARDITIS, PAIN and PYREXIA. At the time of the report, CHEST PAIN (Chest pain) and MYOCARDITIS (Myocarditis) had not resolved and PAIN (Pain) and PYREXIA (Pyrexia) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 19-Jul-2021, Alanine aminotransferase: increased (High) 54 IU/L. On 19-Jul-2021, Aspartate aminotransferase: increased (High) 163 IU/L. On 19-Jul-2021, Catheterisation cardiac: normal (normal) Normal.

		On 19-Jul-2021, Ejection fraction: normal (normal) Normal. On 19-Jul-2021, Electrocardiogram: normal (normal) Normal and abnormal (abnormal) Mildly abnormal. On 19-Jul-2021, Liver function test: increased (High) Mildly elevated. On 19-Jul-2021, Troponin: high (High) Increased. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medications were reported. Treatment information is not given. The patient developed chest pain starting 48 hours after the 2nd dose of Moderna vaccine. Progressively worsened. Presented to the hospital 72 hours after the vaccine with mildly abnormal ECG and elevated troponin level. Underwent cardiac catheterization without coronary artery disease. Diagnosis of myocarditis made. No treatment information was provided. Based on the current available information and temporal association between the use of the product and the events, a causal relationship cannot be excluded. Most recent FOLLOW-UP information incorporated above includes: On 03-Aug-2021: Follow-up received contains additional laboratory data and events.
4.1(b)		This case was received via 4.1(b) (Reference number: 4.1(b) on 03-Aug-2021 and was forwarded to Moderna on 03-Aug-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of CHEST CRUSHING (Chest crushing), HYPERDYNAMIC LEFT VENTRICLE (Hyperdynamic left ventricle), CHEST DISCOMFORT (Chest discomfort), CHEST PAIN (Chest pain), MYALGIA (Myalgia), PAINFUL RESPIRATION (Painful respiration), PLEURITIC PAIN (Pleuritic pain), PYREXIA (Pyrexia) and MYOCARDITIS (Myocarditis) in a 21-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 045C21A and 004C21A) for COVID-19 vaccination. Concurrent medical conditions included Asthma and Depression. On 20-Jul-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 20-Jul-2021, received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 22-Jul-2021, the patient experienced CHEST CRUSHING (Chest crushing) (seriousness criteria hospitalization and medically significant), HYPERDYNAMIC LEFT VENTRICLE (Hyperdynamic left ventricle) (seriousness criteria hospitalization and medically significant), CHEST DISCOMFORT (Chest discomfort) (seriousness criterion hospitalization), CHEST PAIN (Chest pain) (seriousness criterion hospitalization), MYALGIA (Myalgia) (seriousness criterion

		hospitalization), PAINFUL RESPIRATION (Painful respiration) (seriousness criterion hospitalization), PLEURITIC PAIN (Pleuritic pain) (seriousness criterion hospitalization), PYREXIA (Pyrexia) (seriousness criterion hospitalization) and MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, CHEST CRUSHING (Chest crushing), HYPERDYNAMIC LEFT VENTRICLE (Hyperdynamic left ventricle), CHEST DISCOMFORT (Chest discomfort), CHEST PAIN (Chest pain), MYALGIA (Myalgia), PAINFUL RESPIRATION (Painful respiration), PLEURITIC PAIN (Pleuritic pain), PYREXIA (Pyrexia) and MYOCARDITIS (Myocarditis) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 22-Jul-2021, Angiocardiogram: normal (normal) Arteriogram coronary normal. On 22-Jul-2021, C-reactive protein: 108.69 (High) C-reactive protein increased. On 22-Jul-2021, Cardiac ventriculogram left: abnormal (abnormal) Cardiac ventriculogram left abnormal. On 22-Jul-2021, Catheterisation cardiac: normal (normal) Catheterisation cardiac normal. On 22-Jul-2021, Red blood cell sedimentation rate: 25 (High) Red blood cell sedimentation rate increased. On 22-Jul-2021, Troponin: 18.70 (High) Troponin increased. On 22-Jul-2021, White blood cell count: 14.5 (High) White blood cell count increased. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Patient reported that the chest pain was substernal, got worse with deep breaths, when he laid on his back and felt better when he sits up. It was diagnosed that he did not have any significant coronary artery disease or thrombotic occlusions. LV gram shown hyperdynamic, LV systolic function. His symptoms were consistent with myocarditis. No concomitant medications were reported. Treatment information was not provided. Company Comment: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.
4.1(b) [redacted]	4.1(b) [redacted]	This case was initially received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 04-Aug-2021. The most recent information was received on 04-Aug-2021 and was forwarded to Moderna on 10-Aug-2021. 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. 214012 and 3002620) for Prophylactic vaccination. No Medical History information was reported.

		On 25-Jun-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 17-Jul-2021, received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to 1 dosage form. On 20-Jul-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Myocarditis) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Troponin: 0.9 (Positive) Positive, the value was 0.9 ng/ml.. Concomitant medication was not reported. Treatment medications was not given. Lab data includes ECG: ST elevations II, III, aVF, positive troponin 0.9ng/mL and MRI: hypertensive change in rear wall TIRM sequence was reported. Myocardial infarction was excluded using a heart catheter was reported. Company Comment: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Awaiting SD Translation. Most recent FOLLOW-UP information incorporated above includes: On 04-Aug-2021: Translation includes sender comment 1st dose information updated, lab data added On 25-Aug-2021: Follow-up information 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 04-Aug-2021. The most recent information was received on 25-Aug-2021 and was forwarded to Moderna on 25-Aug-2021. This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (Myocarditis) in a 20-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3002183) for Prophylactic vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Pollen allergy. On 01-Jul-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 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 05-Jul-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant), CHEST DISCOMFORT (Chest pressure sensation of), MALAISE (General malaise), ARTHRALGIA (Joint ache) and HEADACHE (Head pain). The patient was hospitalized from 07-Jul-2021 to 12-Jul-2021 due to MYOCARDITIS. On 12-Jul-2021, MYOCARDITIS (Myocarditis), CHEST DISCOMFORT (Chest pressure sensation of), MALAISE

		(General malaise), ARTHRALGIA (Joint ache) and HEADACHE (Head pain) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 07-Jul-2021, Blood creatine phosphokinase: 200u/i (abnormal) 200 U/l. On 07-Jul-2021, Troponin T: 201.50 (abnormal) 201.50 pg/ml. On 08-Jul-2021, Magnetic resonance imaging heart: subacute myocarditis, good lv function, mild infer (abnormal) Subacute myocarditis, good LV function, mild inferolateral basal myocardial edema, subepicardial scar, maculopapular scar (inferolateral basal and medial).. No concomitant medications were provided by the reporter. No treatment information was provided by the reporter. Company comment: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. FU containing additional information does not change company comment. Most recent FOLLOW-UP information incorporated above includes: On 25-Aug-2021: Indication of suspect, details of concomitant medication and lab test details were updated.
4.1(b)	4.1(b)	This case was initially received via European Medicines Agency (Reference number: 4.1(b)) on 04-Aug-2021. The most recent information was received on 04-Aug-2021 and was forwarded to Moderna on 30-Aug-2021. This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (4.1(b) , CHEST PAIN (Thoracic pain), HEADACHE (4.1(b) 19.07.2021) and CHILLS (4.1(b) 19.07.2021) in a 26-year-old male patient who received mRNA-1273 (COVID 19 Vaccine Moderna) (batch no. 214007) for Prophylactic vaccination. No Medical History information was reported. On 17-Jul-2021, the patient received second dose of mRNA-1273 (COVID 19 Vaccine Moderna) (Intramuscular) 1 dosage form. On 18-Jul-2021, the patient experienced HEADACHE (4.1(b) 19.07.2021) (seriousness criterion hospitalization). On 19-Jul-2021, the patient experienced MYOCARDITIS (4.1(b) (seriousness criteria hospitalization and medically significant), CHEST PAIN (Thoracic pain) (seriousness criterion hospitalization) and CHILLS (4.1(b) 19.07.2021) (seriousness criterion hospitalization). On 21-Jul-2021, MYOCARDITIS (4.1(b) and CHEST PAIN (Thoracic pain) had resolved. At the time of the report, HEADACHE (4.1(b) 19.07.2021) had not resolved and CHILLS (4.1(b) 19.07.2021) outcome was unknown.

		DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In 2021, Magnetic resonance imaging: myocarditis confirmed (abnormal) myocarditis confirmed. In 2021, Troponin: elevated (abnormal) Elevated. Concomitant product use was not provided by the reporter. Patient Occasionally some alcohol consumption, a glass of wine 2 days before vaccination. Laboratory detail was elevated troponin levels, myocarditis confirmed in the MRI scan. No treatment information was provided. Company Comment: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Most recent FOLLOW-UP information incorporated above includes: On 04-Aug-2021: Translation received on 30-Aug-21 included events and narrative were translated to English with elevated troponin levels and myocarditis confirmed in the MRI scan. On 25-Aug-2021: Follow up contains no new information.
4.1(b) [redacted]	4.1(b) [redacted]	This case was initially received via 4.1(b) [redacted] (Reference number: 4.1(b) [redacted]) on 05-Aug-2021. The most recent information was received on 25-Aug-2021 and was forwarded to Moderna on 25-Aug-2021. This regulatory authority case was reported by a physician and describes the occurrence of CHEST PAIN (chest pain) and MYOCARDITIS (Myocarditis) in a 28-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for COVID-19 vaccination. Concurrent medical conditions included Smoker. Concomitant products included SERTRALINE from August 2021 to an unknown date for an unknown indication. On 07-May-2021, the patient received first dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 28-Jul-2021, received second dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 31-Jul-2021, the patient experienced CHEST PAIN (chest pain) (seriousness criterion medically significant). 31-Jul-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criterion medically significant). At the time of the report, CHEST PAIN (chest pain) and MYOCARDITIS (Myocarditis) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):

		On an unknown date, Angiocardiogram: normal (normal) Normal coronaries. On an unknown date, Blood creatine: 90 90. On an unknown date, Chest X-ray: normal (normal) normal. On an unknown date, Echocardiogram: normal (normal) normal. On an unknown date, Electrocardiogram: abnormal (abnormal) showed minor inferior ST elevation. On an unknown date, Glomerular filtration rate: >90 >90. On an unknown date, Haemoglobin: 156 (normal) normal. On an unknown date, Magnetic resonance imaging heart: abnormal (abnormal) Myocarditis, preserved LV function, Low grade scar. On an unknown date, Platelet count: 391 (normal) normal. On an unknown date, Staphylococcal infection: positive (Positive) positive. On an unknown date, Staphylococcus test: positive (Positive) Positive. On an unknown date, Troponin: 991 troponin value of 991, 499 499 and 205 (High) 205. On an unknown date, White blood cell count: 7.8 (normal) normal. For mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. No treatment information was reported. Patient had not tested positive for COVID-19 since having the vaccine. Lab data also include Cardiac troponin:991, 499, 205 on an unknown date. Concomitant medication started on 06 Aug 2021. Patient was also hospitalized. Most recent FOLLOW-UP information incorporated above includes: On 25-Aug-2021: Follow-up received on 25 Aug 2021, contains updated information on medical history, lab data, dose details, concomitant medication, event start date and event outcome: updated outcome from recovering to recovered for chest pain and myocarditis.
4.1(b) [redacted]		This regulatory authority case was reported by a physician and describes the occurrence of CHEST PAIN (chest pain) and MYOCARDITIS (Myocarditis) 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. Concurrent medical conditions included Myocarditis and Chest pain. On 07-May-2021, the patient received first dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 28-Jul-2021, received second dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 28-Jul-2021, the patient experienced INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (Inappropriate schedule of vaccine administered). On 31-Jul-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). At the time of the report, CHEST PAIN (chest pain) had resolved, MYOCARDITIS (Myocarditis) was resolving and INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (Inappropriate schedule of vaccine administered) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Angiogram: angiogram (normal) Normal coronary arteries on angiogram. On an unknown date, Magnetic resonance imaging heart: cardiac mri (abnormal) Cardiac MRI showed likely myocarditis. On an unknown date, SARS-CoV-2 test: sars-cov-2 test (Negative) negative. On an unknown date, Troponin: troponin (Positive) Troponin positive in blood tests. For mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Concomitant product information was not provided by the reporter. Patient was received first dose of vaccine on 07-May-2021 and second dose on 28-Jul-2021 Patient was hospitalized with chest pain and checked troponin level in blood it was found to be 991 (positive). Had normal coronary arteries on angiogram. Showed myocarditis on cardiac MRI scan. Treatment information was not provided by the reporter. Company Comment This report refers to a case of Inappropriate schedule of product administration for mRNA-1273, lot # unknown with AEs. Based on the current available information and temporal association between the use of the product and the start date of the events Myocarditis and Chest pain, a causal relationship cannot be excluded.
4.1(b)	4.1(b)	This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 03-Aug-2021 and was forwarded to Moderna on 06-Aug-2021. 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, body temperature before the vaccination: 36.5 degrees Celsius. On 26-Jul-2021, the patient received the 2nd dose of this vaccine in the afternoon. On 27-Jul-2021, the patient became aware of pyrexia in the 38 degrees Celsius range and chest discomfort. On 28-Jul-2021, the patient's symptoms did not improve, and the patient was rushed to a hospital. On arrival at the hospital, the patient

		was diagnosed with acute myocarditis, with pyrexia of 38.8 degrees Celsius, chest discomfort, widespread ST-segment elevation on electrocardiography, elevated myocardial enzymes on blood test, and decreased wall motion on echocardiography. The outcome of acute myocarditis (pyrexia, chest discomfort, ST elevated, elevation of cardiac enzymes, decreased wall motion) was unknown. 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)		This regulatory authority case was reported by a physician and describes the occurrence of SINUS BRADYCARDIA (4.1(b) 42 bpm), CARDIOVASCULAR DISORDER (4.1(b)), CHILLS (4.1(b) NAUSEA (4.1(b) and MYOCARDITIS (4.1(b) e) in an 18-year-old male patient who received mRNA-1273 (COVID 19 Vaccine Moderna) for COVID-19 vaccination. No Medical History information was reported. On 22-Jul-2021, the patient received second dose of mRNA-1273 (COVID 19 Vaccine Moderna) (unknown route) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (COVID 19 Vaccine Moderna) (unknown route) 1 dosage form. On 25-Jul-2021, the patient experienced SINUS BRADYCARDIA (4.1(b) 42 bpm) (seriousness criteria hospitalization and medically significant), CARDIOVASCULAR DISORDER (4.1(b)) (seriousness criterion hospitalization), CHILLS (4.1(b) (seriousness criterion hospitalization), NAUSEA (4.1(b) (seriousness criterion hospitalization) and MYOCARDITIS (4.1(b)) (seriousness criteria hospitalization and medically significant). On 28-Jul-2021, SINUS BRADYCARDIA (4.1(b) 42 bpm), CARDIOVASCULAR DISORDER (4.1(b)), CHILLS (4.1(b) NAUSEA (4.1(b) and MYOCARDITIS (4.1(b)) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 25-Jul-2021, Electrocardiogram ST segment elevation: elevated (High) Elevated. For mRNA-1273 (COVID 19 Vaccine Moderna) (Unknown), the reporter did not provide any causality assessments. No concomitant medication was reported. Treatment -4.1(b) colchicine. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (unknown) was not applicable.

		Company comment: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Event onset and stop dates are provided however the outcome are still inaccurately reported as Recovering/Resolving.
4.1(b)		This case was initially received via European Medicines Agency (Reference number: 4.1(b)) on 12-Aug-2021. The most recent information was received on 17-Aug-2021 and was forwarded to Moderna on 27-Aug-2021. This regulatory authority case was reported by a physician and describes the occurrence of CHILLS (4.1(b) the first episode of PAIN (4.1(b)), PAIN IN JAW (4.1(b)), PAINFUL RESPIRATION (4.1(b)), CHEST PAIN (4.1(b)), VENTRICULAR TACHYCARDIA (Tachycardia ventricular), the second episode of PAIN (4.1(b)) and MYOCARDITIS (Perimyocarditis) in a 21-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3003606) for COVID-19 immunisation. No Medical History information was reported. On 22-Jul-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-Jul-2021, the patient experienced VENTRICULAR TACHYCARDIA (Tachycardia ventricular) (seriousness criteria hospitalization and medically significant) and MYOCARDITIS (Perimyocarditis) (seriousness criteria hospitalization and medically significant). On 25-Jul-2021 at 5:00 AM, the patient experienced CHILLS (4.1(b) (seriousness criterion hospitalization), the first episode of PAIN (4.1(b)) (seriousness criterion hospitalization), PAIN IN JAW (4.1(b)) (seriousness criterion hospitalization), PAINFUL RESPIRATION (4.1(b)) (seriousness criterion hospitalization), CHEST PAIN (4.1(b)) (seriousness criterion hospitalization) and the second episode of PAIN (4.1(b)) (seriousness criterion hospitalization). At the time of the report, CHILLS (4.1(b) PAIN IN JAW (4.1(b)), PAINFUL RESPIRATION (4.1(b)), CHEST PAIN (4.1(b)), VENTRICULAR TACHYCARDIA (Tachycardia ventricular), the last episode of PAIN (4.1(b)) and MYOCARDITIS (Perimyocarditis) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 25-Jul-2021, Troponin: 1016 (High) 1016 pg/ml reference range 14.0, 1059 (High) 1059 pg/ml reference range14.0, 960 (High) 960

		pg/ml reference range 14.0 and 949 (High) 949 pg/ml reference range 14.0. On 26-Jul-2021, C-reactive protein: 1.58mg/dl (Low) 1.58mg/dl, then normalized CRP am 26.7.2021: 1.58mg/dl, then normalized. On 26-Jul-2021, Troponin: 935 (High) 935 pg/ml reference range 14.0. On 27-Jul-2021, N-terminal prohormone brain natriuretic peptide: 426 (High) 426pg/ml. On 27-Jul-2021, Troponin: 1507 (High) 1507 pg/ml reference range 14.0. On 29-Jul-2021, Troponin: 45 (High) 45 pg/ml reference range 14.0. On an unknown date, C-reactive protein: under control (Inconclusive) Under control. On an unknown date, Electrocardiogram ambulatory: slow ventricular tachycardia (Inconclusive) Slow ventricular tachycardia. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. Concomitant drug was not reported. Treatment medication was not reported. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Most recent FOLLOW-UP information incorporated above includes: On 17-Aug-2021: Translation received on 27-Aug-2021, Lab data results updated.
4.1(b) [redacted]		This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Perimyocarditis) in a 21-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) (batch nos. 3003188 and 3003188) for COVID-19 vaccination. The patient's past medical history included Non-smoker. On 22-Jun-2021, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form. On 20-Jul-2021, received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) dosage was changed to 1 dosage form. On 21-Jul-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. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 24-Jul-2021, Blood creatine phosphokinase: high (High) 75mmol/L. On 24-Jul-2021, Echocardiogram: inconclusive (Inconclusive) widespread disorders in the movement of the wall, with slightly limited systolic pump function.

		On 24-Jul-2021, Magnetic resonance imaging: inconclusive (Inconclusive) findings consistent with myocarditis; function of the systolic pump still slightly compromised (47%). On 24-Jul-2021, Troponin I: high (High) High. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter did not provide any causality assessments. Concomitant products were not provided. Treatment medication were not reported. Company Comment: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. Case awaiting translation. FU translation received with additional information does not change the company comment. Most recent FOLLOW-UP information incorporated above includes: On 13-Aug-2021: Translation document received on 25-AUG-2021included sender's comment, relevant medical history and test result updated
4.1(b)		This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 07-Aug-2021 and was forwarded to Moderna on 16-Aug-2021. 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: 36.1 degrees Celsius. On 02-Aug-2021, at 10:00, the patient received the 2nd dose of this vaccine. On 05-Aug-2021, at 03:24, chest pain developed, and the patient visited an emergency department. Blood collection showed increase in cardiac enzymes (CK, CK-MB) including troponin I, and echocardiography showed mildly decreased wall motion. The patient was hospitalized for treatment on suspicion of myocarditis. On an unknown date, the patient underwent coronary angiography on the 2nd day of the hospitalization and was diagnosed with myocarditis without coronary artery stenosis. Chest pain developed during inspiration, and comorbid pericarditis was observed. The possibility of viral myocarditis could not be denied as another factor. The outcome of myocarditis (chest pain) and pericarditis (chest pain) was reported as ongoing and unchanged.

		Follow-up investigation will be made. 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 initially received via 4.1(b) (Reference number: 4.1(b)) on 13-Aug-2021. The most recent information was received on 25-Aug-2021 and was forwarded to Moderna on 25-Aug-2021. This regulatory authority case was reported by a physician and describes the occurrence of CHEST PAIN (severe chest pain, and pain subsided after 4 hours.), MYOCARDITIS (Acute myocarditis) and INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (Moderna vaccine, 1st dose on 22/7/2021 and 2nd dose on 6/8/2021 (FIFTEEN DAYS BETWEEN TWO DOSES).) in a 25-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) (batch nos. 3002621 and 3003608) for COVID-19 vaccination. No Medical History information was reported. On 22-Jul-2021, the patient received first dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (Intramuscular) 1 dosage form. On 06-Aug-2021, received second dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 09-Aug-2021, the patient experienced MYOCARDITIS (Acute myocarditis) (seriousness criteria hospitalization and medically significant). On 09-Aug-2021 at 4:00 AM, the patient experienced CHEST PAIN (severe chest pain, and pain subsided after 4 hours.) (seriousness criterion hospitalization). On an unknown date, the patient experienced INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (Moderna vaccine, 1st dose on 22/7/2021 and 2nd dose on 6/8/2021 (FIFTEEN DAYS BETWEEN TWO DOSES).) (seriousness criterion hospitalization). At the time of the report, CHEST PAIN (severe chest pain, and pain subsided after 4 hours.) had not resolved, MYOCARDITIS (Acute myocarditis) was resolving and INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (Moderna vaccine, 1st dose on 22/7/2021 and 2nd dose on 6/8/2021 (FIFTEEN DAYS BETWEEN TWO DOSES).) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 09-Aug-2021, Echocardiogram: normal (normal) normal. On 09-Aug-2021, SARS-CoV-2 test: no - negative covid-19 test (Negative) No - Negative COVID-19 test. On 09-Aug-2021, Troponin: high (High) Serum troponin-I on admission was 3143 ng/l and it rose to 3956 ng/l.. The action taken with mRNA-1273 (Moderna CoviD-19 Vaccine) (Intramuscular) was unknown. For mRNA-1273 (Moderna CoviD-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments.

		Concomitant information was not provided. Treatment information was not provided. Patient has not tested positive for COVID-19 since having the vaccine Patient is not enrolled in clinical trial Company Comment - Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Most recent FOLLOW-UP information incorporated above includes: On 25-Aug-2021: Seriousness criteria Hospitalization added and case upgraded to serious, reporter added.
4.1(b)	4.1(b)	This case was initially received via European Medicines Agency (Reference number: 4.1(b) on 16-Aug-2021. The most recent information was received on 16-Aug-2021 and was forwarded to Moderna on 19-Aug-2021. 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) for COVID-19 vaccination. No Medical History information was reported. On 03-Jul-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 30-Jul-2021, received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to 1 dosage form. On 01-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. Concomitant medications were not reported. Treatment history was not reported . Patient had respiratory dependent chest pain. Heart enzymes (troponin, CK, CK-MB) was elevated in hospital. Company comment: Based on the current available information and temporal association between the use of the product and the event, a causal relationship cannot be excluded. Event term, onset date and outcome captured per SD Authority reporting. Event seriousness per assessment by Authority and per IME list. FU received with lab data does not change the company comment. Most recent FOLLOW-UP information incorporated above includes: On 16-Aug-2021: Translated document received on 19-AUG-2021. Lab data updated in narrative supplement. On 25-Aug-2021: Non-significant follow-up Added as same document as initial
4.1(b)	4.1(b)	This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 11-Aug-2021 and was forwarded to Moderna on 17-Aug-2021.

		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) for COVID-19 vaccination. No Medical History information was reported. On 05-Aug-2021 at 2:00 PM, the patient received second dose of mRNA-1273 (COVID 19 Vaccine Moderna) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (COVID 19 Vaccine Moderna) (Intramuscular) 1 dosage form. On 07-Aug-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Myocarditis) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 05-Aug-2021, Body temperature: 38 (High) Pyrexia over 38 degrees Celsius. On 07-Aug-2021, Echocardiogram: circumferential wall motion decreased (abnormal) circumferential wall motion decreased. On 07-Aug-2021, Electrocardiogram: st elevation (abnormal) extensive ST elevation. On an unknown date, Computerised tomogram aorta: normal (normal) Coronary artery stenosis was not noted in coronary artery CT. For mRNA-1273 (COVID 19 Vaccine Moderna) (Intramuscular), the reporter considered MYOCARDITIS (Myocarditis) to be possibly related. No concomitant medication was provided by the reporter On an unknown date, the patient received the 1st dose of this vaccine. On an unknown date, body temperature before the vaccination: 36.2 degrees Celsius. On 05-Aug-2021, at 14:00, the patient received the 2nd dose of this vaccine. After the vaccination, pyrexia over 38 degrees Celsius developed. On 07-Aug-2021, at 18:00, the patient was aware of precordial pain and was raced to a hospital. An electrocardiogram showed extensive ST elevation. Echocardiography showed circumferential wall motion decreased. Cardiac deviation enzymes increased. The patient was admitted to a hospital. Coronary artery stenosis was not noted in coronary artery CT. Thereafter, cardiac deviation enzymes decreased spontaneously. It could not be ruled out the possibility that other viral infections occurred coincidentally by chance. 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. EU Method of Assessment was given as Reasonable possibility. The treatment information was not provided. Company Comment Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.
4.1(b)		This case was received via 4.1(b) (Reference number: 4.1(b) on 17-Aug-2021 and was forwarded to Moderna on 17-Aug-2021. 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) for COVID-19 vaccination. No Medical History information was reported. On 29-Jul-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 01-Aug-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) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 01-Aug-2021, Blood creatine phosphokinase: 634 (High) increased. On 01-Aug-2021, Blood creatine phosphokinase MB: 35.1 (High) increased. On 01-Aug-2021, C-reactive protein: 7.5 (High) increased. On 01-Aug-2021, Electrocardiogram: abnormal (abnormal) abnormal. On 01-Aug-2021, Myocardial necrosis marker: increased (High) increased. On 01-Aug-2021, Prohormone brain natriuretic peptide: 328 (High) Increased. On 01-Aug-2021, Troponin: 0.38 (High) increased.

		For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medication information was provided. No treatment information was provided. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.
4.1(b)		This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 11-Aug-2021 and was forwarded to Moderna on 18-Aug-2021. This case, initially reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref, 4.1(b) On 26-Jun-2021, the patient received the 1st dose of this vaccine. On an unknown date, body temperature before vaccination: 36.5 degrees Celsius. On 31-Jul-2021, at 16:00, the patient received the 2nd dose of this vaccine. On 01-Aug-2021, pyrexia in the 38 degrees Celsius range developed. On 02-Aug-2021, at 10:00, the patient developed chest pain upon awakening. The patient visited a nearby hospital, and an electrocardiogram showed ST elevation; thus, the patient visited another hospital, and an electrocardiogram showed ST elevation in IIaVF and ST depression in V1. Blood test showed increased troponin I, creatine kinase (CK) of 70 U/L, and CK-MB of 35 U/L. The patient was diagnosed with myopericarditis and required hospitalization. Because the patient tested positive for SARS-CoV-2 antigen, the patient was transported to the hospital with a referral. All the items of multi-item nucleic acid tests were negative at the time of admission, and the coronary arteries were free of stenosis on coronary angiography (CAG). The patient received the diagnosis of myocarditis. The outcome of myocarditis and SARS-CoV-2 antigen positive was reported as resolving. Follow-up investigation will be made. 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 13-Aug-2021 and was forwarded to Moderna on 19-Aug-2021. This case, reported by a physician, was received by Takeda Pharmaceutical Company Limited via Modernas adverse reaction reporting site (4.1(b)

		On 10-Jul-2021, at 09:00, the patient received the 1st dose of the vaccine. On 31-Jul-2021, at 14:00, the patient received the 2nd dose of the vaccine. On 01-Aug-2021, at 08:00, the patient experienced pyrexia and chest pain. On 02-Aug-2021, the area of chest pain moved from median to left, and the symptom was worsened. At night, the patient visited the hospital. As there were elevated cardiac enzymes, ST elevation in various leads of electrocardiogram, and decreased cardiac function in echocardiography, the patient was hospitalized suspecting acute myocarditis. Cardiac catheterization that was performed after admission found no significant stenosis in the coronary artery, and the diagnosis of acute myocarditis was made based on various test results. On 12-Aug-2021, acute myocarditis subsided. The outcome of acute myocarditis was reported as resolving. No 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 regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (4.1(b) PYREXIA (4.1(b) , CHILLS (4.1(b)) and NIGHT SWEATS (4.1(b) in a 27-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination. Concurrent medical conditions included GERD. In 2021, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form. On 07-Jul-2021, received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) dosage was changed to 1 dosage form. On 08-Jul-2021, the patient experienced PYREXIA (4.1(b) (seriousness criterion hospitalization), CHILLS (4.1(b)) (seriousness criterion hospitalization) and NIGHT SWEATS (4.1(b)) (seriousness criterion hospitalization). On 09-Jul-2021, the patient experienced MYOCARDITIS (4.1(b) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (4.1(b) PYREXIA 4.1(b) CHILLS and

		NIGHT SWEATS (4.1(b)) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 11-Jul-2021, C-reactive protein: 10.3 mg/l (High) High. On 11-Jul-2021, Troponin T: 131 ng/l (High) High. On 12-Jul-2021, C-reactive protein: 6.6 mg/l (High) High. On 12-Jul-2021, Troponin T: 196 ng/l (High) High and 168 ng/l (High) High. On 13-Jul-2021, C-reactive protein: 2.6 mg/l (High) High. On 13-Jul-2021, Troponin T: 211 ng/l (High) High. On 14-Jul-2021, Troponin T: 127 ng/l (High) High. In July 2021, Echocardiogram: normal (normal) Normal. In July 2021, Electrocardiogram: normal (normal) Normal. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered PYREXIA (4.1(b) , CHILLS (4.1(b)) and NIGHT SWEATS (4.1(b) to be probably related and MYOCARDITIS (4.1(b) to be possibly related. No concomitant medications or treatment details were reported. Very limited translated information regarding these events has been provided at this time.
4.1(b)	4.1(b)	This regulatory authority case was reported by a physician and describes the occurrence of PERICARDITIS (Pericarditis), MYOCARDITIS (4.1(b) HEADACHE (4.1(b)), CHILLS (4.1(b)) and NAUSEA (4.1(b)) in an 18-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) (batch nos. 30380777700688 and 30380777700688) for COVID-19 vaccination. Concurrent medical conditions included Asthma (4.1(b)). On 28-Jun-2021, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form. On 26-Jul-2021, received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) dosage was changed to 1 dosage form. On 26-Jul-2021 at 3:00 PM, after starting mRNA-1273 (COVID-19 Vaccine Moderna), the patient experienced HEADACHE (4.1(b)) (seriousness criterion hospitalization). On 26-Jul-2021 at 6:00 PM, the patient experienced CHILLS (4.1(b)) (seriousness criterion hospitalization) and NAUSEA (4.1(b)) (seriousness criterion hospitalization). On 28-Jul-2021, the patient experienced PERICARDITIS (Pericarditis) (seriousness criteria hospitalization and medically significant) and MYOCARDITIS (4.1(b) (seriousness criteria hospitalization and medically significant). At the time of the report, PERICARDITIS (Pericarditis) and MYOCARDITIS (4.1(b) had not resolved and HEADACHE (4.1(b)

		4.1(b)), CHILLS (4.1(b)) and NAUSEA (4.1(b)) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 28-Jul-2021, Electrocardiogram: sinusrhythmus, hf 76/min, pq 171ms, qrs 94ms, q... Sinusrhythmus, HF 76/min, PQ 171ms, QRS 94ms, Q.... On 29-Jul-2021, Blood creatine phosphokinase: 1092 iu/l 1092 IU/l and 1052 iu/l 1052 IU/l. On 29-Jul-2021, C-reactive protein: 42.3mg/l 42.3mg/l. On 29-Jul-2021, Echocardiogram: normal (normal) Normal dimensionierter linker Ventrikel mit nor.... On 29-Jul-2021, Troponin T: 1116ng/l 1116ng/l and 1208 ng/l 1208 ng/l. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered PERICARDITIS (Pericarditis), HEADACHE (4.1(b)), CHILLS (4.1(b) and NAUSEA (4.1(b)) to be probably related and MYOCARDITIS (4.1(b) to be possibly related. No concomitant medications were provided. No treatment information was provided. 4.1(b) [redacted] company comment:Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Translation has been requested.
4.1(b)		This regulatory authority case was reported by a physician and describes the occurrence of MYALGIA (4.1(b) PYREXIA (4.1(b)) and MYOCARDITIS (4.1(b)) in a 21-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) (batch no. 3004215) for COVID-19 vaccination. Concurrent medical conditions included Tobacco user (1 pack per day). In 2021, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form. On 23-Jul-2021, received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) dosage was changed to 1 dosage

		form. On 23-Jul-2021, the patient experienced MYALGIA (4.1(b) (seriousness criterion hospitalization) and PYREXIA (4.1(b)) (seriousness criterion hospitalization). On 27-Jul-2021, after starting mRNA-1273 (COVID-19 Vaccine Moderna), the patient experienced MYOCARDITIS (4.1(b)) (seriousness criteria hospitalization and medically significant). On 26-Jul-2021, MYALGIA (4.1(b) and PYREXIA 4.1(b)) had resolved. At the time of the report, MYOCARDITIS (4.1(b)) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 27-Jul-2021, Echocardiogram: normal (normal) normal. On 27-Jul-2021, Electrocardiogram: normal (normal) With Non-abnormalities. On 27-Jul-2021, Magnetic resonance imaging: abnormal (abnormal) Visible lesion, suggestive of myocarditis. On 27-Jul-2021, Troponin: 1000 (abnormal) 1000 ng/mL. On 27-Jul-2021, Viral test: negative (Negative) Negative. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter did not provide any causality assessments. The concomitant medications were not reported. The treatment information was not provided. Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. Most recent FOLLOW-UP information incorporated above includes: On 19-Aug-2021: Translation received on 24-AUG-21 and had significant information. Updated the lab results.
4.1(b)		This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 13-Aug-2021 and was forwarded to Moderna on 22-Aug-2021. This case, initially reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref, 4.1(b) On 29-Jun-2021, the patient received the 1st dose of the vaccine. On an unknown date, body temperature before the vaccination: 36.6 degrees Celsius. On 28-Jul-2021, the patient received the 2nd dose of the vaccine. On 29-Jul-2021, pyrexia developed. On 31-Jul-2021, chest pain developed. On 01-Aug-2021, at 05:02, as the symptoms continued, the patient visited this hospital. A wide range of ST elevation was shown in the electrocardiogram and increases in myocardial markers and inflammatory response were found as CK: 1120 U/L, troponin I: 19642 pg/mL, and CRP: 4.96 mg/dL. Echocardiography revealed no wall

		motion abnormality. The patient was diagnosed with myocarditis based on the symptoms and course of the disease and was admitted to the hospital to receive treatments. On 07-Aug-2021, the symptoms improved. The patient was discharged from the hospital. The outcome of myocarditis was reported as recovered. 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. Sender's comments : The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.
4.1(b) [redacted]		This case was received via 4.1(b) [redacted] (Reference number: 4.1(b) [redacted] on 24-Aug-2021 and was forwarded to Moderna on 24-Aug-2021. This regulatory authority case was reported by a health care professional and describes the occurrence of CHEST DISCOMFORT (Chest discomfort), CHEST PAIN (Chest pain), LEFT VENTRICULAR DYSFUNCTION (Left ventricular dysfunction), NASOPHARYNGITIS (Nasopharyngitis), SLEEP DISORDER (Sleep disorder), STRESS (Stress), MYOCARDITIS (Myocarditis) and PERICARDITIS (Pericarditis) in a 23-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The patient's past medical history included Depression. Concurrent medical conditions included Dyspnea (Three days prior to vaccine patient had slightly more than expected dyspnea trying to restart running after a hiatus of several months, attributed it to stress and deconditioning.) and Asthma (Mild). Concomitant products included ALBUTEROL [SALBUTAMOL] for an unknown indication. On 03-Apr-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 05-Apr-2021, the patient experienced CHEST DISCOMFORT (Chest discomfort) (seriousness criterion hospitalization), CHEST PAIN (Chest pain) (seriousness criterion hospitalization), LEFT VENTRICULAR DYSFUNCTION (Left ventricular dysfunction) (seriousness criterion hospitalization), NASOPHARYNGITIS (Nasopharyngitis) (seriousness criterion hospitalization), SLEEP DISORDER (Sleep disorder) (seriousness criterion hospitalization), STRESS (Stress) (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 KETOROLAC TROMETHAMINE (TORADOL) at an unspecified dose and frequency and ASPIRIN [ACETYLSALICYLIC ACID] at an unspecified dose and frequency. At the time of the report, CHEST DISCOMFORT (Chest discomfort), CHEST PAIN (Chest pain), LEFT VENTRICULAR DYSFUNCTION (Left ventricular dysfunction), NASOPHARYNGITIS (Nasopharyngitis), SLEEP DISORDER (Sleep disorder), STRESS (Stress), MYOCARDITIS (Myocarditis) and PERICARDITIS (Pericarditis) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 05-Apr-2021, Aspartate aminotransferase: 51 (High) Increased. On 05-Apr-2021, Blood bilirubin: 1.6 (High) Increased. On 05-Apr-2021, C-reactive protein: 6.8 (High) Increased. On 05-Apr-2021, Cardiac imaging procedure: abnormal (abnormal) Demonstrated consistent with myopericarditis. On 05-Apr-2021, Chest X-ray: normal (normal) Normal. On 05-Apr-2021, Echocardiogram: abnormal (abnormal) Echocardiogram demonstrated mildly reduced LV systolic function.. On 05-Apr-2021, Haemoglobin: normal (normal) Normal. On 05-Apr-2021, Inflammatory marker test: increased (High) Increased. On 05-Apr-2021, Red blood cell sedimentation rate: 23 (High) increased. On 05-Apr-2021, SARS-CoV-2 test: negative (Negative) Negative. On 05-Apr-2021, Sinus rhythm: 57 (abnormal) 57 abnormal. On 05-Apr-2021, Troponin: increased ng/L (High) Troponin level at 6473 with a repeat of 8989, (reference range less than 45 ng/L). On 05-Apr-2021, White blood cell count: normal (normal) Normal. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Company comment: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.
4.1(b) [redacted]	4.1(b) [redacted]	This case was received via 4.1(b) [redacted] (Reference number: 4.1(b) [redacted] on 24-Aug-2021 and was forwarded to Moderna on 24-Aug-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCARDITIS (Myocarditis), CHEST PAIN (Chest pain), CHILLS (Chills), FATIGUE (Fatigue), MYALGIA (Myalgia) and NAUSEA (Nausea) in a 27-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. Concurrent medical conditions included Allergy to nuts. Concomitant products included BUPROPION for an unknown indication. On 15-Jun-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 19-

		Jun-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant), CHILLS (Chills) (seriousness criterion hospitalization), FATIGUE (Fatigue) (seriousness criterion hospitalization) and MYALGIA (Myalgia) (seriousness criterion hospitalization). On 19-Jun-2021 at 6:00 AM, the patient experienced CHEST PAIN (Chest pain) (seriousness criterion hospitalization) and NAUSEA (Nausea) (seriousness criterion hospitalization). At the time of the report, MYOCARDITIS (Myocarditis), CHEST PAIN (Chest pain), CHILLS (Chills), FATIGUE (Fatigue), MYALGIA (Myalgia) and NAUSEA (Nausea) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 19-Jun-2021, Catheterisation cardiac: normal (normal) resulted in no blockage. On 19-Jun-2021, Ejection fraction: decreased abnormal (Low) Ejection fraction deceased. On 19-Jun-2021, Electrocardiogram: abnormal (abnormal) ejection fraction between 40 and 45 %. On 19-Jun-2021, Magnetic resonance imaging heart: unknown (Inconclusive) unknown. On 19-Jun-2021, Scan with contrast: abnormal (abnormal) abnormal. On 19-Jul-2021, Magnetic resonance imaging heart: abnormal (abnormal) with and without contrast indicating ejection fraction of 41%. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. No Treatment information was received by the patient. After vaccination, initially the patient had symptoms of chills, fatigue, and muscle pain throughout body. These symptoms lasted about two days following his second dose of the Moderna vaccination. Symptoms subsided on the third day. On the fourth day following the vaccination he woke up at 6 am with nausea and chest pain. As a result patient was taken to the emergency room (ER) where he discovered that he had myocarditis. Company Comment: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.
4.1(b)		This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 18-Aug-2021 and was forwarded to Moderna on 26-Aug-2021. 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: Unknown.

		On 10-Aug-2021, the patient received the 2nd dose of this vaccine. At night, pyrexia of 38.0 degrees Celsius and headache developed. On 11-Aug-2021, in the morning, pyrexia persisted. Body temperature was 38.0 degrees Celsius. On 12-Aug-2021, at 06:30, body temperature was 36.6 degrees Celsius. At around 10:10, the patient was found lying unconscious on the floor. At 10:23, emergency call was made, and the patient was raced to a hospital in a state of cardio-respiratory arrest. Initial waveform was ventricular fibrillation. VA ECMO was introduced in ER, and cardiac catheterization was performed. There were no abnormal findings in the coronary artery. Elevated cardiac enzymes were observed, and the possibility that the patient developed myocarditis could not be ruled out. The patient was admitted to the hospital. The outcome of pyrexia, headache, cardio-respiratory arrest, elevated cardiac enzymes, ventricular fibrillation, and myocarditis was reported as ongoing and unchanged. Follow-up investigation will be made. 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 initially received via European Medicines Agency (Reference number: 4.1(b)) on 25-Aug-2021. The most recent information was received on 25-Aug-2021 and was forwarded to Moderna on 28-Aug-2021. This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (4.1(b) in a 29-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 214007) for Prophylactic vaccination. No Medical History information was reported. On 06-Jul-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 26-Jul-2021, received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to 1 dosage form. On 30-Jul-2021, the patient experienced MYOCARDITIS (4.1(b) (seriousness criteria hospitalization, medically significant and life threatening). At the time of the report, MYOCARDITIS (4.1(b) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Biopsy heart: abnormal The result was still excluded and has STEMI (acute ST-elevation myocardial infarction).. No relevant concomitant medications were reported.

		Treatment medication was not provided by the reporter. Lab data provided MRI Myocardial biopsy result is still excluded STEMI (acute ST-elevation myocardial infarction). Most recent FOLLOW-UP information incorporated above includes: On 25-Aug-2021: Follow Up received has no new information. On 25-Aug-2021: Translation received on 28-Aug-2021 and I narrative updated
4.1(b)		This case was received via European Medicines Agency (Reference number: 4.1(b)) on 26-Aug-2021 and was forwarded to Moderna on 26-Aug-2021. This regulatory authority case was reported by a physician and describes the occurrence of CHEST PAIN (Chest pain) and MYOCARDITIS (Myocarditis) in a 28-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3004494) for COVID-19 vaccination. The patient's past medical history included Myocarditis (Admitted hospital June 2019 due to mild myocarditis, TnT max 396. Presumed virology. No arrhythmia. CT cor normal. Echocardiography with mild hypokinesia posterioapical, small MI. No pericardial fluid. Normalization of ventricular function at ctr after 1 month.) in June 2019 and Family history of cardiovascular disorder (Brother got myocarditis 6-7 years ago). Concurrent medical conditions included Pollen allergy (No drug allergy) and Non-smoker. On 07-Aug-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 10-Aug-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) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 10-Aug-2021, Blood pressure measurement: 115/64 (Low) 115/64. On 10-Aug-2021, Body temperature: 36.6 (normal) 36.6. On 10-Aug-2021, C-reactive protein: 21 - 11 (High) 21 - 11 High. On 10-Aug-2021, Cardiac telemetry: sr 50-96, mostly < 70 (Low) SR 50-96, mostly < 70. On 10-Aug-2021, Echocardiogram: normal (normal) VV systolic function in the lower normal range, EF estimated 50%. Otherwise normal findings.. On 10-Aug-2021, Electrocardiogram: high (High) SR 58 / min. Incomplete right branch block. High ST-departure globally.. On 10-Aug-2021, Haemoglobin: 14.2 (normal) 14.2 Normal. On 10-Aug-2021, Heart rate: 60 (normal) 60. On 10-Aug-2021, Platelet count: 196 (normal) 196 Normal. On 10-Aug-2021, Respiratory rate: 16 (normal) 16 Normal. On 10-Aug-2021, Troponin T: 181-182-135-173 (High) 181 - 182 - 135 - 173 High. On 10-Aug-2021, Visual analogue scale: 4-5 (High) 4 - 5.

		For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered CHEST PAIN (Chest pain) and MYOCARDITIS (Myocarditis) to be possibly related. No concomitant medication details was provided. No treatment medication details was provided. Most recent FOLLOW-UP information incorporated above includes: On 26-Aug-2021: Additional translation information received does not contain any new information (NNI)
4.1(b)		This case was received via European Medicines Agency (Reference number: 4.1(b)) on 26-Aug-2021 and was forwarded to Moderna on 26-Aug-2021. This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myocarditis), HYPERSENSITIVITY (Rash on right arm), PYREXIA (Fever), CHEST PAIN (Chest pain) and VACCINATION SITE LYMPHADENOPATHY (Vaccination site lymphadenopathy) in a 29-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3002623) for Routine childhood immunisation. No Medical History information was reported. On 04-Jun-2021 at 5:37 PM, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 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 05-Jun-2021 at 6:06 AM, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant), HYPERSENSITIVITY (Rash on right arm) (seriousness criterion hospitalization), PYREXIA (Fever) (seriousness criterion hospitalization), CHEST PAIN (Chest pain) (seriousness criterion hospitalization) and VACCINATION SITE LYMPHADENOPATHY (Vaccination site lymphadenopathy) (seriousness criterion hospitalization). At the time of the report, MYOCARDITIS (Myocarditis), HYPERSENSITIVITY (Rash on right arm), PYREXIA (Fever), CHEST PAIN (Chest pain) and VACCINATION SITE LYMPHADENOPATHY (Vaccination site lymphadenopathy) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In June 2021, Body temperature: 39,0-39,4 (High) 39,0-39,4. In June 2021, Magnetic resonance imaging: abnormal (abnormal) myocarditis. For mRNA-1273 (Spikevax) (Unknown), the reporter considered MYOCARDITIS (Myocarditis) to be probably related and HYPERSENSITIVITY (Rash on right arm), PYREXIA (Fever), CHEST PAIN (Chest pain) and VACCINATION SITE LYMPHADENOPATHY (Vaccination site lymphadenopathy) to be possibly related. No concomitant medications are reported.

		No treatment medications are reported. Most recent FOLLOW-UP information incorporated above includes: On 26-Aug-2021: Translated doc received on 30AUG2021 includes no new information
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 27-Aug-2021 and was forwarded to Moderna on 27-Aug-2021. This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (Acute myocarditis) in a 21-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. No Medical History information was reported. On 10-Aug-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) dosage form. On 14-Aug-2021, the patient experienced MYOCARDITIS (Acute myocarditis) (seriousness criteria hospitalization and medically significant). The patient was treated with IBUPROFEN at an unspecified dose and frequency. On 16-Aug-2021, MYOCARDITIS (Acute myocarditis) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Blood creatine phosphokinase: high (High) INCREASED. Action taken with mRNA-1273 (Moderna COVID-19 Vaccine) in response to the event was not applicable. Troponin and CKMB increased. Treatment with ACE inhibitors Most recent FOLLOW-UP information incorporated above includes: On 27-Aug-2021: Translation received for initial source document: treatment details and lab ,initials updated
4.1(b)		This case was received via European Medicines Agency (Reference number: 4.1(b)) on 26-Aug-2021 and was forwarded to Moderna on 26-Aug-2021. This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (Perimyocarditis) in an 18-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3004235) for Prophylactic vaccination. No Medical History information was reported. On 09-Aug-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 12-Aug-2021, the patient experienced MYOCARDITIS (Perimyocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Perimyocarditis) had not resolved.

		No Concomitant medication was mentioned. No Treatment medication was mentioned.
4.1(b)		This case was received via European Medicines Agency (Reference number: 4.1(b)) on 27-Aug-2021 and was forwarded to Moderna on 27-Aug-2021. This regulatory authority case was reported by a pharmacist and describes the occurrence of DYSPNOEA EXERTIONAL (Dyspnea exertional), CHEST PAIN (Chest pain), FATIGUE (Fatigue), PYREXIA (Fever) and MYOCARDITIS (Myocarditis) in a 21-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 3003659 and 3003606) for COVID-19 immunisation. Concurrent medical conditions included Pollen allergy, Food allergy (peanut allergy) and Tobacco user. Concomitant products included DESLORATADINE (AERIUS [DESLORATADINE]) for an unknown indication. On 08-Jul-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 05-Aug-2021, received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to 1 dosage form. On 05-Aug-2021, the patient experienced FATIGUE (Fatigue) (seriousness criterion hospitalization) and PYREXIA (Fever) (seriousness criterion hospitalization). On 06-Aug-2021, the patient experienced DYSPNOEA EXERTIONAL (Dyspnea exertional) (seriousness criterion hospitalization) and MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). On 07-Aug-2021, the patient experienced CHEST PAIN (Chest pain) (seriousness criterion hospitalization). At the time of the report, DYSPNOEA EXERTIONAL (Dyspnea exertional), CHEST PAIN (Chest pain), FATIGUE (Fatigue), PYREXIA (Fever) and MYOCARDITIS (Myocarditis) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 05-Aug-2021, Body temperature: (High) fever. On 06-Aug-2021, Body temperature: (High) fever. On 07-Aug-2021, Angiocardiogram: Angiographically normal coronaries except for a discrete low flow of the tip of the IVA. No coronary disease. On 07-Aug-2021, Blood creatine phosphokinase (Unknown-190): 397. On 07-Aug-2021, Electrocardiogram: regular sinus rhythm with HR 80 beats/min, no conduction disorder, fine QRS, no repolarisation disorder, few changes with only a discrete concave ST elevation in V7-V9. On 07-Aug-2021, Troponin T (Unknown-0.014 nanogram per millliiter): 0.832 nanogram per millliiter. On 08-Aug-2021, Blood creatine phosphokinase (Unknown-190): 1650. On 08-Aug-2021, Electrocardiogram: regular sinus rhythm with HR 80 beats/min, no conduction disorder, fine QRS, no repolarisation disorder, with a discrete overshoot..

		On 08-Aug-2021, Troponin T (Unknown-0.014 nanogram per millliiter): 4.47 nanogram per millliiter. On 09-Aug-2021, Blood creatine phosphokinase (Unknown-190): 361. On 09-Aug-2021, Electrocardiogram: regular sinus rhythm with HR 80 beats/min, no conduction disorder, fine QRS, no repolarisation disorder.. On 09-Aug-2021, Troponin T (Unknown-0.014 nanogram per millliiter): 3.9 nanogram per millliiter and 4.5 nanogram per millliiter. On 10-Aug-2021, Blood creatine phosphokinase (Unknown-190): 141. On 10-Aug-2021, Troponin T (Unknown-0.014 nanogram per millliiter): 2.91 nanogram per millliiter. In August 2021, Echocardiogram: non-dilated, non-hypertrophied left ventricle with moderate hypokinesia of the posterior wall and minimal hypokinesia of the inferobasal wall. LVEF 51%.. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No treatment medications were reported.
4.1(b)		This case was received via 4.1(b) (Reference number: 4.1(b) on 29-Aug-2021 and was forwarded to Moderna on 29-Aug-2021. This regulatory authority case was reported by a non-health professional and describes the occurrence of FATIGUE (fatigue), MYOCARDIAL INFARCTION (heart attack), HYPERTENSION (hypertension), TREMOR (shaking), PAIN (pain), VOMITING (vomiting) and MYOCARDITIS (Myocarditis) in a 21-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) (batch no. 3003651) for COVID-19 vaccination. The patient's past medical history included Mood change and Pregnancy. Concurrent medical conditions included Hypertension. On 16-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 MYOCARDITIS (Myocarditis) (seriousness criterion medically significant). On an unknown date, the patient experienced FATIGUE (fatigue) (seriousness criterion life threatening), MYOCARDIAL INFARCTION (heart attack) (seriousness criteria medically significant and life threatening), HYPERTENSION (hypertension) (seriousness criterion life threatening), TREMOR (shaking) (seriousness criterion life threatening), PAIN (pain) (seriousness criterion life threatening) and VOMITING (vomiting) (seriousness criterion life threatening). At the time of the report, FATIGUE (fatigue), MYOCARDIAL INFARCTION (heart attack), HYPERTENSION (hypertension), TREMOR (shaking), PAIN (pain), VOMITING (vomiting) and MYOCARDITIS (Myocarditis) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, SARS-CoV-2 test: negative Negative.

		The action taken with mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown Route) was unknown. Lab reports:the enzyme Tropin was reported at 7000 rising to 12000,Had x rays, many blood tests,CT scan, ultra sound scan. patient isnow on 3 types of medication for hypertension.	
4.1(b) [redacted]		This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (4.1(b) [redacted] and CHEST PAIN 4.1(b) [redacted] in a 17-year-old male patient who received mRNA-1273 (COVID 19 Vaccine Moderna) (batch no. 3001946) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Type I diabetes mellitus without mention of complication. Concomitant products included INSULIN for Type I diabetes mellitus without mention of complication. On 14-May-2021, the patient received second dose of mRNA-1273 (COVID 19 Vaccine Moderna) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (COVID 19 Vaccine Moderna) (unknown route) 1 dosage form. On 14-May-2021, the patient experienced PRODUCT ADMINISTERED TO PATIENT OF INAPPROPRIATE AGE (inappropriate age at vaccination (17 years)). On 15-May-2021, the patient experienced MYOCARDITIS (4.1(b) [redacted] (seriousness criteria hospitalization and medically significant) and CHEST PAIN (4.1(b) [redacted] (seriousness	This is a 17 years old male with history if Diabetes Type 1 who the next day after the second dose of Spikevax developed chest pain and was diagnosed with myocarditis. Patient had abnormal echocardiogram and elevated troponin levels. Type 1 and type 2 diabetic patients are at increased risk of cardiomyopathy and heart failure is a major cause of death for these patients. Cardiomyopathy in diabetes is associated with a cluster of features including decreased diastolic compliance, interstitial fibrosis and myocyte hypertrophy. The mechanisms leading to diabetic cardiomyopathy remain uncertain. Diabetes is associated with most known risk factors for cardiac failure seen in the overall population, including obesity, dyslipidemia, thrombosis, infarction, hypertension, activation of multiple hormone and cytokine systems, autonomic neuropathy, endothelial dysfunction and coronary artery disease. This case is classify as Level 2 of diagnostic certainty according ot the Brighton Collaboration case classification, as Probable according to the CDC working definition, and as

		criterion hospitalization). On 14-May-2021, PRODUCT ADMINISTERED TO PATIENT OF INAPPROPRIATE AGE (inappropriate age at vaccination (17 years)) had resolved. On 28-May-2021, MYOCARDITIS (4.1(b) [redacted] and CHEST PAIN 4.1(b) [redacted] had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 15-May-2021, Blood creatine phosphokinase MB: increased (High) Increased. On 15-May-2021, Blood test: abnormal (abnormal) myopericarditis. On 15-May-2021, Electrocardiogram: abnormal (abnormal) abnormal. On 15-May-2021, Myoglobin blood: increased (High) Increased. On 15-May-2021, Troponin: increased (High) Increased. For mRNA-1273 (COVID 19 Vaccine Moderna) (Intramuscular), the reporter did not provide any causality assessments. Treatment information was not provided. Company Comment: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship for the events Myocarditis and Chest pain cannot be excluded. Causality for the event Product administered to patient of inappropriate age is assessed as not applicable. The action taken for m-RNA-1273 Covid-19 Moderna Vaccine was not applicable. Most recent FOLLOW-UP information incorporated above includes: On 24-Jun-2021: Follow-Up received on 24-June-2021 included update in action	possible according to the WHO causality assessment.

		taken and De-challenge for suspect product and updated narrative	
4.1(b)		This case was received via 4.1(b) (Reference number: 4.1(b) on 15-Jun-2021 and was forwarded to Moderna on 15-Jun-2021. This regulatory authority case was reported by a health care professional and describes the occurrence of CHEST PAIN (Chest pain), CHILLS (Chills), FATIGUE (Fatigue), TACHYCARDIA (Intermittent tachycardia), MYOCARDITIS (Myocarditis) and SARS-COV-2 TEST POSITIVE (COVID-19 IgG Ab positive) in a 15-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 002c21a) for COVID-19 vaccination. The patient's past medical history included Wolff-Parkinson-White syndrome. Concomitant products included HPV VACCINE VLP RL1 9V (YEAST) (GARDASIL 9) from 14-May-2021 to an unknown date for an unknown indication. On 14-May-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 2 dosage form. On 15-May-2021, the patient experienced CHEST PAIN (Chest pain) (seriousness criterion hospitalization), CHILLS (Chills) (seriousness criterion hospitalization), FATIGUE (Fatigue) (seriousness criterion hospitalization), TACHYCARDIA (Intermittent tachycardia) (seriousness criterion hospitalization), MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant) and SARS-COV-2 TEST POSITIVE (COVID-19 IgG Ab positive) (seriousness criterion hospitalization). At the time of the report, CHEST PAIN (Chest pain), CHILLS (Chills), FATIGUE (Fatigue), TACHYCARDIA (Intermittent tachycardia), MYOCARDITIS (Myocarditis) and SARS-COV-2 TEST POSITIVE (COVID-19 IgG Ab positive) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):	This is a 15 years old male with history if Wolff-Parkinson-White syndrome who the next day after the second dose of Spikevax developed chest pain and was diagnosed with myocarditis and COVID-19 infection. Patient had abnormal EKG, elevated troponin levels. Patient medical history including concurrent COVID-19 infection provides a more plausible explanation for the events reported by the patient. This case is classify as Level 1 of diagnostic certainty according ot the Brighton Collaboration case classification, as unassessable according to the CDC working definition, due to other identifiable cause of the symptoms, and as possible according to the WHO causality assessment.

		On 19-May-2021, C-reactive protein increased: 10.6 Increased. On 19-May-2021, COVID-19: positive (Positive) Positive. On 19-May-2021, Electrocardiogram: abnormal. On 19-May-2021, Electrocardiogram ST segment: abnormal. On 19-May-2021, Polymerase chain reaction: negative (Negative) Negative. On 19-May-2021, Troponin: 16.72 (High) 16.72. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medications were provided. Treatment medications was not provided. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Based on the mechanism of action of mRNA-1273, a causal association between the event of positive COVID-19 antibody test and mRNA-1273 is assessed as not applicable.	
4.1(b)	4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b) on 27-Jul-2021 and was forwarded to Moderna on 27-Jul-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCARDITIS (Myocarditis), CHEST PAIN (Chest pain), PALPITATIONS (Palpitations) and VACCINATION COMPLICATION (myocarditis related to COVID19 vaccine) in a 15-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. Concurrent medical conditions included Tic disorder, unspecified. Concomitant products included GUANFACINE for an unknown indication.	This is a 15 years old female with unknown medical history and Guanfacine as concomitant medication who the next day after an unknown dose of Spikevax experienced chest pain, palpitations and was diagnosed with myocarditis. Troponin levels were elevated in two different days. No other information was provided. This case is classify as Level 2 of diagnostic certainty according ot the Brighton Collaboration case classification, as probable according to the CDC working definition, and as probable according to the

		On 05-Jul-2021, the patient received dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 06-Jul-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant), CHEST PAIN (Chest pain) (seriousness criterion hospitalization), PALPITATIONS (Palpitations) (seriousness criterion hospitalization) and VACCINATION COMPLICATION (myocarditis related to COVID19 vaccine) (seriousness criterion hospitalization). On an unknown date, the patient experienced PRODUCT ADMINISTERED TO PATIENT OF INAPPROPRIATE AGE (Inappropriate age at vaccine administration). At the time of the report, MYOCARDITIS (Myocarditis), CHEST PAIN (Chest pain), PALPITATIONS (Palpitations) and VACCINATION COMPLICATION (myocarditis related to COVID19 vaccine) had resolved and PRODUCT ADMINISTERED TO PATIENT OF INAPPROPRIATE AGE (Inappropriate age at vaccine administration) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 08-Jul-2021, Troponin: 77 (High) increased, 36 (normal) normal and 47 (High) increased. On 09-Jul-2021, Troponin: 69 (High) High. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown) was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. No treatment information was provided. Company comment: This report refers to a case of Inappropriate age at vaccine administration for mRNA-1273, lot # unknown, with associated AEs (Chest pain, Myocarditis, Palpitations, and Vaccination complication) for this 15-	WHO causality assessment.

		year-old female. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.	
4.1(b)		This case was received via 4.1(b) (Reference number: 4.1(b) on 24-Aug-2021 and was forwarded to Moderna on 24-Aug-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of CHEST PAIN (Chest pain) and MYOCARDITIS (Myopericarditis) in a 17-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 016C21A and 016C21A) for COVID-19 vaccination. No Medical History information was reported. On 27-Jul-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 27-Jul-2021, received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 30-Jul-2021, the patient experienced CHEST PAIN (Chest pain) (seriousness criteria hospitalization and life threatening) and MYOCARDITIS (Myopericarditis) (seriousness criteria hospitalization, medically significant and life threatening). The patient was treated with IBUPROFEN (MOTRIN [IBUPROFEN]) for Chest pain, at an unspecified dose and frequency. At the time of the report, CHEST PAIN (Chest pain) and MYOCARDITIS (Myopericarditis) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 30-Jul-2021, Echocardiogram: normal normal. On 30-Jul-2021, Troponin: increased (High) ECG showed ST elevation and during follow up there is evidence of T wave inversion in lateral leads.	This is a 17 years old male with unknown medical history and unknown concomitant medication who according to the report received by the the regulatory authority received both doses of Spikevax the same day. Patient 3 days later experienced chest pain and was diagnosed with myocarditis. Troponin levels were elevated and an ECG showed ST elevation and during follow up there is evidence of T wave inversion in lateral leads. No other information was provided. This case is classify as Level 2 of diagnostic certainty according ot the Brighton Collaboration case classification, as unassessable according to the CDC working definition, and as possible according to the WHO causality assessment.

		For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. The patients Troponin was elevated ECG showed ST elevation and during follow up there is evidence of T wave inversion in lateral leads Echo has been always normal No concomitant drug details were reported. Company comment: Based on the current available information and temporal association between the use of the product and the start date of events, a causal relationship cannot be excluded. RA report states two doses given on same date (providing the same lot number for both). As per RA, dates were captured as such but it is a discrepancy also on some event dates regarding the narrative. No further information is expected.	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b) on 06-Sep-2021 and was forwarded to Moderna on 06-Sep-2021. This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (4.1(b)) in a 16-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 214008) for Prophylactic vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 19-Aug-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 21-Aug-2021, the patient experienced MYOCARDITIS 4.1(b)) (seriousness criteria hospitalization and medically significant). On an unknown date, the patient experienced PYREXIA (FEVER). On 26-Aug-2021, MYOCARDITIS (4.1(b)) was resolving. At the time of the report, PYREXIA (FEVER) outcome was unknown.	20 years old female with unknown medical history 16 days after the 2nd dose of the vaccine experienced pyrexia, chills, dypsnea, headache, and was diagnosed with pericarditis. Laboratory results showed mild thrombocytopenia, elevated CRP, normal troponin, elevated Firbin d-dimer. Electrocardiogram was abnormal with Slight changes T-wave changes in II,III and AVF. No other information was provided. Important information is missing in this report including patient's medical history, as well as clinical course of the events, laboratory tests conducted and any results, including SARS-CoV2 test.

		Concomitant product use was not provided by the reporter. Patient done the lab tests ECG: SR, 66/min, normal AV conduction, narrow QRS complexes, mild ST elevations from descending R in V3 to V6, T-wave morphology unremarkable, positive T-wave from V1, normal R progression. ECG monitoring after 4 hours: no relevant change in findings, sign of a singular VES. Echo: Good biventricular function, FS 34%, TAPSE 24, E/A ratio 2.1, E/E in septal, 7.2, minimal MI, no regional wall motion abnormalities. No pericardial effusion. Low TI, RV pressure normal (25 mmHg), laminar flow in aortal and pulmonary outflow tract, unremarkable left aortic arch. Coronary arteries as assessed in passing region: normal Assessment: Suspected myocarditis trop T initially 1.16 µg/l, after 4 hours, unchanged cardiac MRI: MRI: suspected myocarditis (left ventricular) without reduction in left ventricular EF. Patient took paracetamol 1g and ibuprofen 200 mg for fever and pain. Based on current available information and the temporal association between product use and the start date of the events a causal relationship cannot be excluded. Most recent FOLLOW-UP information incorporated above includes: On 06-Sep-2021: Translated document appended on 09-sep-2021, it contains significant information. Lab data were added in Inarrative.	
4.1(b)	4.1(b)	This case was initially received via European Medicines Agency (Reference number: 4.1(b)) on 17-Sep-2021. The most recent information was received on 17-Sep-2021 and was forwarded to Moderna on 21-Sep-2021. This regulatory authority case was reported by a physician and describes the occurrence of PERICARDITIS (Pericarditis), CHEST PAIN (Thoracic pain) and PYREXIA (Fever) in a 14-year-old male patient who received mRNA-	14-year-old, male patient with no reported medical history, who 2 days afte r the 2nd dose of the vacxcine experienced Chest pain and pyrexia and was diagnosed with Pericarditis. Laboratory results shiwed elevated troponin, chest x ray normal, no signs of pleural disease, echo showed fine line of pericardial effusion;

		1273 (Spikevax) (batch nos. 3005695 and 214013) for COVID-19 vaccination. No Medical History information was reported. On 29-Jul-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 26-Aug-2021, received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to 1 dosage form. On 27-Aug-2021, the patient experienced PERICARDITIS (Pericarditis) (seriousness criteria hospitalization prolonged and medically significant), CHEST PAIN (Thoracic pain) (seriousness criterion hospitalization prolonged) and PYREXIA (Fever) (seriousness criterion hospitalization prolonged). On 28-Aug-2021, PYREXIA (Fever) had resolved. At the time of the report, PERICARDITIS (Pericarditis) and CHEST PAIN (Thoracic pain) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 27-Aug-2021, Blood glucose: 102 mg/dl (normal) 102 mg/dL. On 27-Aug-2021, Blood urea: 36.7 mg/dl (High) 36.7 mg/dL. On 27-Aug-2021, Chest X-ray: No nodules or opacities are observed in the lung parenchyma. No signs of pleural disease are identified. Cardiothoracic ratio and mediastinum within the normal limit. No bone or soft tissue lesions are identified. No findings of pathological significance... On 27-Aug-2021, Coagulation test: abnormal (abnormal) Coagulation study: Patient (PT) 15.4 sec, Ratio (PT) 1.4 R, Activity (Quick Index) 61(70-130)%, INR 1.4 INR, Patient (aPTT) 29.3 sec, Ratio (aPTT) 0.95, Derived fibrinogen 5.65(2-4)g/L, D-dimer 561(0-500)ngr/mL. On 27-Aug-2021, Echocardiogram: normal (normal) Echocardiogram: Fine line of pericardial effusion visible in the long axis and subcostal planes.. On 27-Aug-2021, Electrocardiogram: normal (normal) Sinus rhythm. HR: 78 bpm. Generalized concave ST elevation. Slight decrease of PR segment in	EKG showed concave ST elevation, and slight decreased of PR segment. Pateint was tested for several microorganisms including COVID-19 and results were negative. No other informatin was provided. Important information is missing from this report.

		derivation [cohort.] No signs of repolarization [disturbances].. On 27-Aug-2021, Full blood count: [redacted] 14.1 g/dL; [redacted] 5.01 10^6/microL; [redacted] 40.8 %. [redacted] 9.60 10^3/microL ([redacted] 64.0 % (40-62); [redacted] 19.5 % (19-48); [redacted] 15.3 % (3-10)). [redacted] 161.0 10^3/microL. VSG 13 mm (3-12).. On 27-Aug-2021, Laboratory test: [redacted] [redacted] 102 mg/dL, [redacted] 36.7 mg/dL, [redacted] ([redacted] 0.82 mg/dL, [redacted] 136 mmol/L, [redacted] 3.7 mmol/L, [redacted] 103 mmol/L, [redacted] total 0.45 mg/dL, GPT (ALT) 24.8 U/L, GOT (AST) 27.0 U/L, Gamma GT 13.0 U/L, [redacted] 71.0(74-390)U/L, CPK - [redacted] 193 U/L, PCR 5.75(0.5) mg/dL, [redacted] 0.27 ng/mL. [redacted] 16.6(34)pg/mL, CK - MB Masa 0.60(<5.20)ng/mL. On 27-Aug-2021, Pharyngeal exudate: Bordetella pertussis y parapertussis, Chlamydia pneumoniae, Mycoplasma pneumoniae: [redacted]  mRNA-1273 (Spikevax) (Intramuscular) was withdrawn on 29-Jul-2021. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medications were provided. No treatment information was provided. This case concerns a 14-year-old, male patient with no relevant medical history, who experienced the unexpected event of Chest pain and the expected events of Pericarditis, Pyrexia. The events occurred around 2 days after the second dose of Spikevax. The rechallenge was	

		not applicable since no events were reported after the first dose. The events Pericarditis and Pyrexia 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. Most recent FOLLOW-UP information incorporated above includes: On 17-Sep-2021: Follow-Up received translation document, updating lab data result	
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. This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (4.1(b) COVID-19 IMMUNISATION (4.1(b) and CHEST PAIN 4.1(b)) in a 17-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 3002616) for COVID-19 vaccination. Previously administered products included for Vaccination: Comirnaty. 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) and CHEST PAIN (4.1(b)) (seriousness criterion hospitalization). In 2021, COVID-19 IMMUNISATION (4.1(b) was resolving. On 21-Sep-2021, MYOCARDITIS (4.1(b) and CHEST PAIN 4.1(b)) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):	17 years old female with unknown medical history and who received the other mRNA vaccine as the 1st dose, and that the same day afte rthe 2nd dose with the MOderna vaccine expereince chest pain and was diagniosed with myocarditis. Troponin levels were elevated and EKG results were abniornal suggestive of mycarditis. No other information was provided.

		In September 2021, Electrocardiogram: st-elevation (High) ST-elevation. In September 2021, Troponin: high (High) High. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medications reported No treatment medications provided	
4.1(b)		This spontaneous case was reported by a consumer and describes the occurrence of CARDIAC ARREST (Cardiac arrest) and MYOCARDITIS (Myocarditis (inflammation of heart tissue)) in a 55-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) (batch nos. 3002914 and 3001658) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Blood pressure high. On 18-Apr-2021, the patient received first dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (Intramuscular) 1 dosage form. On 17-Jun-2021, received second dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 17-Jun-2021, the patient experienced INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (Inappropriate schedule of vaccine administered). On 18-Jun-2021, after starting mRNA-1273 (Moderna CoviD-19 Vaccine), the patient experienced VACCINATION COMPLICATION (Common symptoms of vaccine) and PYREXIA (Fever). On 20-Jun-2021, the patient experienced CARDIAC ARREST (Cardiac arrest) (seriousness criteria hospitalization, medically significant and life threatening). On 21-Jun-2021, the patient experienced MYOCARDITIS (Myocarditis (inflammation of heart tissue)) (seriousness criteria hospitalization and medically significant). The patient was hospitalized from 20-Jun-2021 to 23-Jun-2021 due to CARDIAC ARREST and MYOCARDITIS. On 17-Jun-2021, INAPPROPRIATE	This is a 55 years old male with medical history of hypertension who 3 days after the 2nd dose of the vaccine developed cardiac arrest and the next day was diagnosed with myocarditis. According to the CDC definition this case is probable; according to the Brigton collaboration is a Level 1 case, and according to the WHO causality assessment, this case is considered possible. Important risks factors for this report included the pateint's age and the history of hypertension with no other deatil sprovided including concurrent medications. In the analysis of this case report, the main concern here is the lack of information on the patient’s full medical history and concomitant medications history. There is also important information missing regarding other laboratory tests conducted, treatment, medical course, etc.

	SCHEDULE OF PRODUCT ADMINISTRATION (Inappropriate schedule of vaccine administered) had resolved. At the time of the report, CARDIAC ARREST (Cardiac arrest), MYOCARDITIS (Myocarditis (inflammation of heart tissue)), VACCINATION COMPLICATION (Common symptoms of vaccine) and PYREXIA (Fever) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 20-Jun-2021, Blood pressure measurement: high (High) High. On 20-Jun-2021, Myocardial necrosis marker: elevated (High) Elevated levels. On 21-Jun-2021, Angiogram: myocarditis (abnormal) Myocarditis (inflammation of heart tissue). No concomitant information as provided. Treatment information was not provided. The caller reported that patient had all types of symptoms. It was reported that the patient said that since that day has been recovering every day and that it's strength was seriously depleted. The patient reported the cardiologist said that there was a correlation between the myocarditis and the vaccine. The causality for the event Inappropriate schedule of vaccine administered is not applicable.Regarding the other adverse events, based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Most recent FOLLOW-UP information incorporated above includes: On 09-Jul-2021: Event of inappropriate schedule of vaccine administered added from Follow-up 1. On 15-Jul-2021: NNI received On 15-Jul-2021: other email addre ss provided	

	On 15-Jul-2021: Follow up document received contains no significant information (NNI).	
4.1(b)	This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myopericarditis), PERICARDITIS (Myopericarditis), CHEST PAIN (Chest pain), NAUSEA (Nausea) and DYSPNOEA (Shortness of breath) in a 37-year-old male patient who received mRNA-1273 (COVID 19 Vaccine Moderna) (batch no. 3002544) for COVID-19 vaccination. No medical history was reported. Concurrent medical conditions included Penicillin allergy. Concomitant products included PARACETAMOL for Fever, IBUPROFEN for Knee pain, CARVEDILOL for an unknown indication. On 15-May-2021, the patient received first dose of mRNA-1273 (COVID 19 Vaccine Moderna) (Intramuscular) 1 dosage form. On 12-Jun-2021, received second dose of mRNA-1273 (COVID 19 Vaccine Moderna) (Intramuscular) dosage was changed to 1 dosage form. On 15-Jun-2021, the patient experienced MYOCARDITIS (Myopericarditis) (seriousness criteria hospitalization and medically significant), PERICARDITIS (Myopericarditis) (seriousness criteria hospitalization and medically significant), CHEST PAIN (Chest pain) (seriousness criterion hospitalization), NAUSEA (Nausea) (seriousness criterion hospitalization) and DYSPNOEA (Shortness of breath) (seriousness criterion hospitalization). The patient was hospitalized from 15-Jun-2021 to 17-Jun-2021 due to CHEST PAIN, DYSPNOEA, MYOCARDITIS, NAUSEA and PERICARDITIS. The patient was treated with COLCHICINE for Myocarditis, Pericarditis, Chest pain and Analgesia, at a dose of 500 microgram, UNK for 3 months; IBUPROFEN for Myocarditis, Pericarditis, Chest pain and Analgesia, at a dose of 400 mg, UNK for 7 days and ENALAPRIL for Cardiovascular event prophylaxis, at a dose of 2.5 mg at bedtime. On 17-Jun-2021,	This is a 37 years old male with medical history of hypertension who 3 days after the 2nd dose of the vaccine developed chest pain, nausea and dypsnea and was diagnosed with myopericarditis. According to the CDC definition this case is probable; according to the Brigton collaboration is a Level 1 case, and according to the WHO causality assessment, this case is considered conditional. Important risks factors for this report included the patient concurrent medical history of taking Carvedilol for left ventricular function with no other details provided (usually it is prescribe for patients with LV dysfunctioin due to myocardial ifacrtion). In the analysis of this case report, the main concern here is the lack of information on the patient's full medical history and concomitant medications history and the history of left ventricular function due to an unidentified condition. There is also important information missing regarding other laboratory tests conducted, treatment, medical course, etc.

	MYOCARDITIS (Myopericarditis) and PERICARDITIS (Myopericarditis) was resolving and CHEST PAIN (Chest pain), NAUSEA (Nausea) and DYSPNOEA (Shortness of breath) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In June 2021, Echocardiogram: normal left ventricular wall thickness (normal) normal global and region, normal valvular morphology and function, normal right ventricle. In June 2021, Ejection fraction: 60 % (Inconclusive) 60. In June 2021, Electrocardiogram: normal sinus rhythm is 70 beats per minute (normal) normal sinus rhythm is 70 beats per minute. In June 2021, Troponin: 42 to 49 (Inconclusive) no units provided. For mRNA-1273 (COVID 19 Vaccine Moderna) (Intramuscular), the reporter considered MYOCARDITIS (Myopericarditis), PERICARDITIS (Myopericarditis), CHEST PAIN (Chest pain), NAUSEA (Nausea) and DYSPNOEA (Shortness of breath) to be possibly related. The treatment information was not provided. Carvedilol 3.125mg BD to aid LV function Patient did not complain of any issues following his first dose. No symptoms were experienced other than those originally mentioned. No associated arrhythmias were noted. No other risk factors for developing the adverse drug reaction were noted. Patient is n ot enrolled in clinical trial. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded Most recent FOLLOW-UP information incorporated above includes:	

	On 09-Jul-2021: Medical history, lab data, suspect drug therapy details, treatment drugs, hospitalization dates and event causality were updated.	
4.1(b)	This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myopericarditis), PERICARDITIS (Myopericarditis), CHEST PAIN (Chest pain), NAUSEA (Nausea) and DYSPNOEA (Shortness of breath) in a 37-year-old male patient who received mRNA-1273 (COVID 19 Vaccine Moderna) (batch no. 3002544) for COVID-19 vaccination. No medical history was reported. Concurrent medical conditions included Penicillin allergy. Concomitant products included PARACETAMOL for Fever, IBUPROFEN for Knee pain, CARVEDILOL for an unknown indication. On 15-May-2021, the patient received first dose of mRNA-1273 (COVID 19 Vaccine Moderna) (Intramuscular) 1 dosage form. On 12-Jun-2021, received second dose of mRNA-1273 (COVID 19 Vaccine Moderna) (Intramuscular) dosage was changed to 1 dosage form. On 15-Jun-2021, the patient experienced MYOCARDITIS (Myopericarditis) (seriousness criteria hospitalization and medically significant), PERICARDITIS (Myopericarditis) (seriousness criteria hospitalization and medically significant), CHEST PAIN (Chest pain) (seriousness criterion hospitalization), NAUSEA (Nausea) (seriousness criterion hospitalization) and DYSPNOEA (Shortness of breath) (seriousness criterion hospitalization). The patient was hospitalized from 15-Jun-2021 to 17-Jun-2021 due to CHEST PAIN, DYSPNOEA, MYOCARDITIS, NAUSEA and PERICARDITIS. The patient was treated with COLCHICINE for Myocarditis, Pericarditis, Chest pain and Analgesia, at a dose of 500 microgram, UNK for 3 months; IBUPROFEN for Myocarditis, Pericarditis, Chest pain and Analgesia, at a dose of 400 mg, UNK for 7 days and ENALAPRIL for Cardiovascular event prophylaxis, at a dose of 2.5 mg at	This is a 37 years old male with medical history of hypertension who 3 days after the 2nd dose of the vaccine developed chest pain, nausea and dypsnea and was diagnosed with myopericarditis. According to the CDC definition this case is probable; according to the Brigton collaboration is a Level 1 case, and according to the WHO causality assessment, this case is considered conditional. Important risks factors for this report included the patient concurrent medical history of taking Carvedilol for left ventricular function with no other details provided (usually it is prescribe for patients with LV dysfunctioin due to myocardial ifacrtion). In the analysis of this case report, the main concern here is the lack of information on the patient's full medical history and concomitant medications history. There is also important information missing regarding other laboratory tests conducted, treatment, medical course, etc.

	bedtime. On 17-Jun-2021, MYOCARDITIS (Myopericarditis) and PERICARDITIS (Myopericarditis) was resolving and CHEST PAIN (Chest pain), NAUSEA (Nausea) and DYSPNOEA (Shortness of breath) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In June 2021, Echocardiogram: normal left ventricular wall thickness (normal) normal global and region, normal valvular morphology and function, normal right ventricle. In June 2021, Ejection fraction: 60 % (Inconclusive) 60. In June 2021, Electrocardiogram: normal sinus rhythm is 70 beats per minute (normal) normal sinus rhythm is 70 beats per minute. In June 2021, Troponin: 42 to 49 (Inconclusive) no units provided. For mRNA-1273 (COVID 19 Vaccine Moderna) (Intramuscular), the reporter considered MYOCARDITIS (Myopericarditis), PERICARDITIS (Myopericarditis), CHEST PAIN (Chest pain), NAUSEA (Nausea) and DYSPNOEA (Shortness of breath) to be possibly related. The treatment information was not provided. Carvedilol 3.125mg BD to aid LV function Patient did not complain of any issues following his first dose. No symptoms were experienced other than those originally mentioned. No associated arrhythmias were noted. No other risk factors for developing the adverse drug reaction were noted. Patient is n ot enrolled in clinical trial. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded Most recent FOLLOW-UP information incorporated above includes:	

	On 09-Jul-2021: Medical history, lab data, suspect drug therapy details, treatment drugs, hospitalization dates and event causality were updated.	
4.1(b)	This regulatory authority case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of MYOCARDITIS (Iatrogenic myopericarditis) and CHEST PAIN (Episodic chest pain, last episode duration 3-4 hours) in a 32-year-old male patient who received mRNA-1273 (COVID 19 Vaccine Moderna) (batch no. 3002332) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 28-May-2021, the patient received second dose of mRNA-1273 (COVID 19 Vaccine Moderna) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (COVID 19 Vaccine Moderna) (unknown route) 1 dosage form. On 29-May-2021 at 4:00 AM, after starting mRNA-1273 (COVID 19 Vaccine Moderna), the patient experienced PYREXIA (Body temperature 38 C). On 01-Jun-2021, the patient experienced MYOCARDITIS (Iatrogenic myopericarditis) (seriousness criteria hospitalization and medically significant) and CHEST PAIN (Episodic chest pain, last episode duration 3-4 hours) (seriousness criterion hospitalization). On 04-Jun-2021, CHEST PAIN (Episodic chest pain, last episode duration 3-4 hours) had resolved. At the time of the report, MYOCARDITIS (Iatrogenic myopericarditis) was resolving and PYREXIA (Body temperature 38 C) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 02-May-2021, Troponin I (Unknown-58 nanogram per litre): 5000 nanogram per litre (abnormal) abnormal, 5000 ng/L. In May 2021, Echocardiogram: normal (normal) Echo shows no deviations from norm.	This is a 32 years old male with unknown medical history who the next day after receiving the 2nd dose of the vaccine developed fever. Three days later the patient experience chest pain and was diagnosed with myopericarditis. According to the CDC definition this case is probable; according to the Brigton collaboration is a Level 2 case, and according to the WHO causality assessment, this case is considered unlikely. Laboratory tests performed 3 days later showed by PCR positive for rhinovirus and enterovirus. This laboratory findign provides a better explanation for the occurrence of the events.

	On 29-May-2021, Body temperature: 38 degree Celsius (High) 38 degree celsius. On 04-Jun-2021, Electrocardiogram: abnormal (abnormal) Non-specific T wave abnormalities. On 04-Jun-2021, Polymerase chain reaction: positive for rhinovirus and enterovirus (abnormal) Nasopharyngeal swab (PCR) contained rhinovirus and enterovirus. On 04-Jun-2021, Troponin T (Unknown-14 nanogram per litre): 127 nanogram per litre (abnormal) 127ng/L. Concomitant medications were not reported. Treatment medications were not reported. Company comment:Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.	
4.1(b)	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 (COVID 19 Vaccine Moderna) for COVID-19 vaccination. No Medical History information was reported. On 14-May-2021, the patient received first dose of mRNA-1273 (COVID 19 Vaccine Moderna) (Intramuscular) 1 dosage form. On 17-Jun-2021, received second dose of mRNA-1273 (COVID 19 Vaccine Moderna) (Intramuscular) dosage was changed to 1 dosage form. On 19-Jun-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. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):	This is a 20 years old male with very limited information provided who two days after receiving the 2nd dose of the vaccine patient was diagnosed with myocarditis. According to the CDC definition this case is considered probable; according to the Brigton collaboration is a Level 1 case, and according to the WHO causality assessment, this case is considered conditional. In the analysis of this case report, the main concern here is the lack of information on the patient's full medical history and concomitant medications history. There is also important information missing regarding other laboratory tests conducted, treatment, medical course, etc.

	On 20-Jun-2021, Electrocardiogram: abnormal (abnormal) Sinus rhythm tending to tachycardia, narrow QRS with around 1-mm generalized concave elevation without change. On 20-Jun-2021, Troponin I: 12.107 (High) Troponin: 12.107 (0-34.2). On 22-Jun-2021, Echocardiogram: 66 % (Inconclusive) LV borderline thickness, LVEF: 66%. No pericardial effusion. For mRNA-1273 (COVID 19 Vaccine Moderna) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medication was reported by the reporter No treatment medication was reported Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. Most recent FOLLOW-UP information incorporated above includes: On 06-Jul-2021: Translation received included translated laboratory investigation results and suspect vaccine details.	
4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b) on 06-Jul-2021 and was forwarded to Moderna on 06-Jul-2021. This regulatory authority case was reported by a health care professional 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. No Medical History information was reported. On 30-Apr-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 02-May-2021, the patient experienced MYOCARDITIS	This is a 27 years old male with very limited information provided who two days after receiving the 2nd dose of the vaccine patient was diagnosed with myocarditis. According to the CDC definition this case is considered probable; according to the Brigton collaboration is a Level 1 case, and according to the WHO causality assessment, this case is considered conditional. In the analysis of this case report, the main concern here is the lack of information on the patient's full medical history and concomitant medications history. There is also important

	(Myocarditis) (seriousness criterion medically significant). At the time of the report, MYOCARDITIS (Myocarditis) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Electrocardiogram: abnormal (abnormal) Abnormal. On an unknown date, Magnetic resonance imaging heart: abnormal (abnormal) Abnormal. On an unknown date, Troponin: elevated (High) Elevated. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medication was reported. No treatment medication was reported. Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.	information missing regarding other laboratory tests conducted, treatment, medical course, etc.
4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b) on 06-Jul-2021 and was forwarded to Moderna on 06-Jul-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of CHEST PAIN (Chest pain), MYOCARDITIS (Myocarditis) and PYREXIA (Pyrexia) in a 19-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. Concurrent medical conditions included Type 1 diabetes mellitus and Dyslipidemia. Concomitant products included INSULIN GLARGINE, INSULIN BOVINE (INSULIN REGULAR [INSULIN BOVINE]) and SIMVASTATIN (ZOCOR) for an unknown indication. On 19-Jun-2021, the patient received second dose of mRNA-1273 (Moderna	This is a 19 years old male with concurrent medical history of diabetes and dyslipidemia, and concurrent medication of simvastatin, who the next day afterreceiving the 2nd dose of the vaccine, experienced chest pain and pyrexia and was diagnosed with myocarditis. According to the CDC definition this case is considered a confirmed case; according to the Brigton collaboration is a Level 1 case, and according to the WHO causality assessment, this case is considered possible. Important risk factors included history of diabetes and dyslipidemia.

	COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 20-Jun-2021, the patient experienced CHEST PAIN (Chest pain) (seriousness criterion hospitalization), MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant) and PYREXIA (Pyrexia) (seriousness criterion hospitalization). At the time of the report, CHEST PAIN (Chest pain), MYOCARDITIS (Myocarditis) and PYREXIA (Pyrexia) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 20-Jun-2021, C-reactive protein: increased (High) increased. On 20-Jun-2021, Cardiac imaging procedure: abnormal (abnormal) abnormal. On 20-Jun-2021, Electrocardiogram: abnormal (abnormal) ST segment elevation. On 20-Jun-2021, Red blood cell sedimentation rate: increased (High) increased. On 20-Jun-2021, Troponin: increased (High) increased. On 24-Jun-2021, Magnetic resonance imaging heart: myocarditis (abnormal) consistent with Myocarditis. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. An echocardiogram was performed on 20June2021, results not provided. Additional laboratory tests included troponin levels (on 21JUN2021 and 24JUN2021), sedimentation rate (on 22JUN2021) and EKG (21JUN2021 and 22JUN2021) with results not provided for all. Treatment details were not provided. Company comment: Based on the current available information and temporal association between the use of	

	the product and the start date of the events, a causal relationship cannot be excluded. No further information is expected at this time.	
4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b) on 06-Jul-2021 and was forwarded to Moderna on 06-Jul-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCARDITIS (Myocarditis), CHEST DISCOMFORT (Chest discomfort) and PAIN (PAIN) in a 20-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No medical history was reported. Concomitant products included DEXMETHYLPHENIDATE HYDROCHLORIDE (4.1(b)), DEXMETHYLPHENIDATE HYDROCHLORIDE (4.1(b) [DEXMETHYLPHENIDATE HYDROCHLORIDE]) and MINOCYCLINE for an unknown indication. On 04-Jun-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 05-Jun-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant), CHEST DISCOMFORT (Chest discomfort) (seriousness criterion hospitalization) and PAIN (PAIN) (seriousness criterion hospitalization). At the time of the report, MYOCARDITIS (Myocarditis), CHEST DISCOMFORT (Chest discomfort) and PAIN (PAIN) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 05-Jun-2021, Electrocardiogram: abnormal (abnormal) Diffused ST segment elevations.. On 05-Jun-2021, Magnetic resonance imaging heart: abnormal (abnormal)	This is a 20 years old male with very limited information regarding medical history but who was taking concomitanly dexmethylphenidate hydrochloride (labelled for serious cardiovascular reactions) and minocycline (Minocycline hydrochloride, is a semisynthetic derivative of tetracycline) for an unknown indication, but that it is indicative of an infectious process. The next day after receiving the 2nd dose of the vaccine patient experience chest discomfort and was diagnosed with myocarditis. According to the CDC definition this case is not assessable due to the lack of information ; according to the Brigton collaboration is a Level 4 case, and according to the WHO causality assessment, this case is considered conditional. In the analysis of this case report, the main concern here is the lack of information on the patient's full medical history and concomitant medications history. There is also important information missing regarding other laboratory tests conducted, treatment, medical course, etc.

	inflammation of inferolateral wall consistent with myocarditis.. On 05-Jun-2021, Troponin T: 1449 (High) High. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. No treatment information was provided. Very limited information regarding these events has been provided at this time. Additional information required.	
4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b) on 06-Jul-2021 and was forwarded to Moderna on 06-Jul-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of CHEST PAIN (Chest pain), NAUSEA (Nausea), VOMITING (Vomiting), SINUS BRADYCARDIA (Sinus bradycardia) and MYOCARDITIS (Myocarditis) in an 18-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. On 14-Jun-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 14-Jun-2021, the patient experienced CHEST PAIN (Chest pain) (seriousness criterion hospitalization prolonged), NAUSEA (Nausea) (seriousness criterion hospitalization prolonged), VOMITING (Vomiting) (seriousness criterion hospitalization prolonged), SINUS BRADYCARDIA (Sinus bradycardia) (seriousness criterion hospitalization prolonged) and MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization prolonged and medically significant). The patient was hospitalized on 20-Jun-2021 due to CHEST PAIN, MYOCARDITIS, NAUSEA, SINUS	This is an 18 years old male with very limited information who the same day after receiving the 2nd dose of the vaccine patient experience chest pain, nausea, vomiting, sinus bradycardia and was diagnosed with myocarditis. According to the CDC definition this case is probable; according to the Brigton collaboration is a Level 2 case, and according to the WHO causality assessment, this case is considered conditional. In the analysis of this case report, the main concern here is the lack of information on the patient's full medical history and concomitant medications history. There is also important information missing regarding other laboratory tests conducted, treatment, medical course, etc.

	BRADYCARDIA and VOMITING. At the time of the report, CHEST PAIN (Chest pain), NAUSEA (Nausea), VOMITING (Vomiting), SINUS BRADYCARDIA (Sinus bradycardia) and MYOCARDITIS (Myocarditis) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 14-Jun-2021, Cardiac imaging procedure: normal (normal) did not show LGE. On 14-Jun-2021, Electrocardiogram: abnormal (abnormal) abnormal. On 14-Jun-2021, Electrocardiogram T wave inversion: inversion (abnormal) sinus bradycardia, Left axis deviation and T wave inversions in II, III and aVF.. On 14-Jun-2021, Heart rate: 39 (Low) HR was 39. On 14-Jun-2021, Influenza A virus test: negative (Negative) negative. On 14-Jun-2021, QRS axis: abnormal (abnormal) abnormal. On 14-Jun-2021, SARS-CoV-2 test: negative (Negative) negative. On 14-Jun-2021, Troponin: 168/283 (High) HS Troponin was elevated to 168 and peaked at 283.. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Concomitant product use was not provided by the reporter. No treatment information was provided. Company comment: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.	
4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b) on 06-Jul-2021 and was forwarded to Moderna on 06-Jul-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCARDITIS (Myocarditis), CHEST PAIN (Chest pain) and NAUSEA (Nausea) in a 32-year-old	This is a 32 years old male with very limited information who the next day after receiving the 2nd dose of the vaccine patient experience chest pain, and nausea, and was diagnosed with myocarditis. According to the CDC definition this

	male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 003C21A) for COVID-19 vaccination. The patient's medical history was not provided. Concomitant products included PROBIOTICS NOS for an unknown indication. On 26-Apr-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 27-Apr-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant), CHEST PAIN (Chest pain) (seriousness criterion hospitalization) and NAUSEA (Nausea) (seriousness criterion hospitalization). At the time of the report, MYOCARDITIS (Myocarditis), CHEST PAIN (Chest pain) and NAUSEA (Nausea) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 27-Apr-2021, Catheterisation cardiac: normal (normal) normal. On 27-Apr-2021, X-ray: normal (normal) normal. On 29-Apr-2021, Electrocardiogram: st elevation (abnormal) ST elevation inferiorly & anterolaterally. On 29-Apr-2021, Troponin: 6.3 (Inconclusive) 6.3. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. The patient was taken to Cath Lab where he was found to have angiographically normal coronary arteries & normal left ventricular function on LV gram. Treatment for the event included unspecified pain medication. Company Comment:	case is probable; according to the Brigton collaboration is a Level 2 case, and according to the WHO causality assessment, this case is considered conditional. In the analysis of this case report, the main concern here is the lack of information on the patient's full medical history and concomitant medications history. There is also important information missing regarding other laboratory tests conducted, treatment, medical course, etc.

	Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.	
4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b) on 06-Jul-2021 and was forwarded to Moderna on 06-Jul-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCARDITIS (Myocarditis), CHEST DISCOMFORT (Chest discomfort), CHEST PAIN (Chest pain), HEADACHE (Headache), LYMPHADENOPATHY (Lymphadenopathy) and TACHYCARDIA (Tachycardia) in a 24-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. On 15-Jun-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 15-Jun-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization, medically significant and life threatening), CHEST DISCOMFORT (Chest discomfort) (seriousness criteria hospitalization and life threatening), CHEST PAIN (Chest pain) (seriousness criteria hospitalization and life threatening), HEADACHE (Headache) (seriousness criteria hospitalization and life threatening), LYMPHADENOPATHY (Lymphadenopathy) (seriousness criteria hospitalization and life threatening) and TACHYCARDIA (Tachycardia) (seriousness criteria hospitalization and life threatening). The patient was treated with KETOROLAC TROMETHAMINE (TORADOL) at an unspecified dose and frequency; LORAZEPAM (ATIVAN) at an unspecified dose and frequency; DEXAMETHASONE for Myocarditis, at an unspecified dose and frequency and	This is a 24 years old male with very limited information who the same day after receiving the 2nd dose of the vaccine patient experience chest discomfort, chest pain, headache, lymphadenopathy and tachycardia, and was diagnosed with myocarditis. According to the CDC definition this case is probable; according to the Brigton collaboration is a Level 2 case, and according to the WHO causality assessment, this case is considered conditional. In the analysis of this case report, the main concern here is the lack of information on the patient's full medical history and concomitant medications history. There is also important information missing regarding other laboratory tests conducted, treatment, medical course, etc.

	METOPROLOL for Tachycardia, at an unspecified dose and frequency. At the time of the report, MYOCARDITIS (Myocarditis), CHEST DISCOMFORT (Chest discomfort), CHEST PAIN (Chest pain), HEADACHE (Headache), LYMPHADENOPATHY (Lymphadenopathy) and TACHYCARDIA (Tachycardia) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 15-Jun-2021, Anion gap: anion gap 13 (h) (High) Anion Gap 13 (H)-Increased.. On 15-Jun-2021, Aspartate aminotransferase: 44(h) (High) 44(H). On 15-Jun-2021, Blood glucose: 110 (h) (normal) 110 (H). On 15-Jun-2021, Brain natriuretic peptide: 160 (h) (High) 160 (H). On 15-Jun-2021, Cardiac telemetry: abnormal (abnormal) Abnormal. On 15-Jun-2021, Differential white blood cell count: abnormal (abnormal) Abnormal. On 15-Jun-2021, Fibrin D dimer: 069 (h) (High) 069 (H). On 15-Jun-2021, Full blood count: abnormal (abnormal) Abnormal. On 15-Jun-2021, Lymphocyte percentage: 5 22.9 (l) (Inconclusive) 5 22.9 (L). On 15-Jun-2021, Monocyte percentage: 9.3 % (High) 9.3 %. On 15-Jun-2021, SARS-CoV-2 test: negative (Negative) Negative.. On 15-Jun-2021, Troponin: increased (High) Increased. On 15-Jun-2021, Troponin T: increased (High) Increased. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments . No concomitant medications information was reported. Action taken with the mRNA-1273 in response to the event is not applicable.	

	Patient stated that he had headache and chest pain of 6/15 and 6/18 respectively and visited emergency room and gone through different lab tests. He stated that he consulted cardiologist and hospitalized. Limited information regarding the events has been provided at this time and is insufficient for causality assessment.	
4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b) on 06-Jul-2021 and was forwarded to Moderna on 06-Jul-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of ACUTE MYOCARDIAL INFARCTION (Acute myocardial infarction) and MYOCARDITIS (Myocarditis) in a 52-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 019B21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No medical history was reported. On 26-Mar-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 30-Mar-2021, the patient experienced ACUTE MYOCARDIAL INFARCTION (Acute myocardial infarction) (seriousness criterion medically significant) and CORONARY ARTERY DISEASE (Coronary artery disease). 30-Mar-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criterion medically significant). At the time of the report, ACUTE MYOCARDIAL INFARCTION (Acute myocardial infarction) and CORONARY ARTERY DISEASE (Coronary artery disease) had resolved and MYOCARDITIS (Myocarditis) outcome was unknown.	This is a 52 years old male with very limited information who 4 days after receiving the 2nd dose of the vaccine patient experience acute myocardial infarction and was diagnosed with coronary artery disease and myocarditis. According to the CDC definition this case is confirmed; according to the Brigton collaboration is a Level 1 case, and according to the WHO causality assessment, this case is considered conditional. In the analysis of this case report, the main concern here is the lack of information on the patient's full medical history and concomitant medications history. There is also important information missing regarding other laboratory tests conducted, treatment, medical course, etc.as well as the diagnosis of non-obstructive coronary artery disease which is an important risk factor for myocarditis and acute myocardial infarction.

	DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 30-Mar-2021, Angiogram: acute myocardial infarction (abnormal) Acute Myocardial Infarction in the setting of nonobstructive coronary artery disease. On 30-Mar-2021, Electrocardiogram: st segment elevation (abnormal) Results- ST segment elevation and abnormal (abnormal) Results- abnormal.. On 30-Mar-2021, Troponin: increased (High) increased.. On 31-Mar-2021, Magnetic resonance imaging heart: myocarditis (abnormal) Findings are consistent with myocarditis. Left ventricle is normal in size and global systolic function. Calculated LVEF is 57 %. No regional wall motion abnormalities. Right ventricle is normal in size and global systolic function. Calculated RVEF is 54 %.Delayed enhancement imaging is abnormal with patchy subepicardial myocardial enhancement involving the inferolateral wall and basal and mid inferior wall.. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No treatment medication provided by reporter. No concomitant medication provided by reporter. Patients laboratory data includes Magnetic resonance imaging heart on 30-MAR-2021,HS Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. The event coronary artery disease seems to be an erroneous capture from the narrative since the event was an acute myocardial infarction due to Myocarditis with normal coronary arteries.	
4.1(b)	This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Perimyocarditis) and PERICARDIAL EFFUSION (Some pericardial fluid) in a 23-year-old male patient who received	This is a 23 years old male with very limited information who 3 days after receiving the 2nd dose of the vaccine patient was diagnosed with myopericarditis.

	mRNA-1273 (COVID 19 Vaccine Moderna) for COVID-19 vaccination. No medical History was provided by the reporter. Concomitant products included Esomeprazole (NEXIUM) from 01-Dec-2020 to an unknown date for Gastroesophageal reflux, Fremanezumab (Ajovy) from 29-Dec-2020 to an unknown date for Migraine. On 23-Jun-2021, the patient received second dose of mRNA-1273 (COVID 19 Vaccine Moderna) (Intramuscular) 1 dosage form. On 26-Jun-2021, the patient experienced MYOCARDITIS (Perimyocarditis) (seriousness criteria hospitalization and medically significant). On an unknown date, the patient experienced PERICARDIAL EFFUSION (Some pericardial fluid) (seriousness criterion medically significant). At the time of the report, MYOCARDITIS (Perimyocarditis) was resolving and PERICARDIAL EFFUSION (Some pericardial fluid) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 26-Jun-2021, Blood creatine phosphokinase MB: 101-68-14 (Inconclusive) 101-68-14 microgram per litre of red blood cells. On 26-Jun-2021, C-reactive protein: 25-14 (High) 25-14 microgram per litre. On 26-Jun-2021, Echocardiogram: 51 (Inconclusive) Ejection fraction 51% Global longitudinal strain -20. On 26-Jun-2021, Electrocardiogram: st elevations (High) Concave ST elevations. On 26-Jun-2021, Magnetic resonance imaging: (Inconclusive) Cardiac MRI: Normal size left ventricle, some reduction in ejection fraction (51%). Quite extensive contrast reaction in the lateral wall, frontal, lower wall and apex of the left myocardium. Partly spotty pattern, mostly subepicardial. Some pericardial fluid. Findings corresponding to active inflammation/myocarditis.. On 26-Jun-2021, Serology test: negative (Negative) Negative.	According to the CDC definition this case is confirmed; according to the Brigton collaboration is a Level 1 case, and according to the WHO causality assessment, this case is considered conditional. In the analysis of this case report, the main concern here is the lack of information on the patient's full medical history and concomitant medications history. There is also important information missing regarding other laboratory tests conducted, treatment, medical course, etc.

	On 26-Jun-2021, Troponin T: 1182-3672-2344 (Inconclusive) 1182-3672-2344 nanogram per litre. On 26-Jun-2021, White blood cell count: 6.7 (normal) 10*9/L (billion per litre). For mRNA-1273 (COVID 19 Vaccine Moderna) (Intramuscular), the reporter did not provide any causality assessments. No treatment medication was reported by the reporter. Company Comment: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Most recent FOLLOW-UP information incorporated above includes: On 09-Jul-2021: Translation received on 14 JUL 2021 Contains no new information.	
4.1(b)	This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Perimyocarditis), CHEST DISCOMFORT (4.1(b)) and DYSPNOEA (4.1(b) in a 25-year-old male patient who received mRNA-1273 (COVID 19 Vaccine Moderna) (batch no. 3002917) for COVID-19 vaccination. No Medical History information was reported. On 26-May-2021, the patient received first dose of mRNA-1273 (COVID 19 Vaccine Moderna) (unknown route) 1 dosage form. On 30-Jun-2021, received second dose of mRNA-1273 (COVID 19 Vaccine Moderna) (unknown route) dosage was changed to 1 dosage form. On 02-Jul-2021, the patient experienced MYOCARDITIS (Perimyocarditis) (seriousness criteria hospitalization and medically significant), CHEST DISCOMFORT (4.1(b)) (seriousness criterion hospitalization) and DYSPNOEA (4.1(b) (seriousness criterion hospitalization). At the time of the report, MYOCARDITIS	This is a 25 years old male with very limited information provided for assessment who 2 days after receiving the 2nd dose of the vaccine patient experienced chest discomfort and dyspnea and was diagnosed with myocarditis. According to the CDC definition this case is probable; according to the Brigton collaboration is a Level 2 case, and according to the WHO causality assessment, this case is considered conditional. In the analysis of this case report, the main concern here is the lack of information on the patient's full medical history and concomitant medications history. There is also important information missing regarding other laboratory tests conducted,

	(Perimyocarditis), CHEST DISCOMFORT (4.1(b)) and DYSPNOEA (4.1(b) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Troponin: increased (High) 4.1(b) / increased. For mRNA-1273 (COVID 19 Vaccine Moderna) (Unknown), the reporter did not provide any causality assessments. The patient did not have any adverse reaction with first dose of mRNA-1273 (COVID 19 Vaccine Moderna). Concomitant product use was not provided by the reporter. No treatment information was provided. Limited information regarding the events has been provided at this time and a causal relationship cannot be excluded. Most recent FOLLOW-UP information incorporated above includes: On 15-Jul-2021: Significant follow-up received. Added batch number of second dose.	treatment, medical course, etc.
4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b) on 13-Jul-2021 and was forwarded to Moderna on 13-Jul-2021. 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. C44C21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Gouty pain. Concomitant products included COLCHICINE for Gouty pain, FAMOTIDINE for an unknown indication. On 21-Jun-2021, the patient received second dose of mRNA-1273 (Moderna	This is a 23 years old male with history of gout and very limited information provided who 2 days after receiving the 2nd dose of the vaccine patient was diagnosed with myocarditis. According to the CDC definition this case is probable; according to the Brigton collaboration is a Level 2 case, and according to the WHO causality assessment, this case is considered possible. In the analysis of this case report, the main concern here is the lack of information on the patient's full medical history and concomitant medications history. There is also important

	COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 23-Jun-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criterion medically significant) and CHEST PAIN (Chest pain). At the time of the report, MYOCARDITIS (Myocarditis) and CHEST PAIN (Chest pain) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 23-Jun-2021, Troponin: increased (Inconclusive) increased. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Patient was observed under telemetry unit. Treatment information was not provided. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.	information missing regarding other laboratory tests conducted, treatment, medical course, etc.
4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b) on 13-Jul-2021 and was forwarded to Moderna on 13-Jul-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of PERICARDITIS (Pericarditis), PERICARDIAL EFFUSION (Pericardial effusion), PLEURITIC PAIN (Pleuritic pain) and CHEST PAIN (Chest pain) in a 75-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No medical history was provided by the reporter. Concurrent medical conditions included Allergic rhinitis, Hypertension and Hyperlipidemia. Concomitant products included ATENOLOL, MONTELUKAST, ROSUVASTATIN, OLMESARTAN,	This is a 75 years old male with history of hypertension and hyperlipidemia who the same day after receiving the 2nd dose of the vaccine patient experience chest pain, pleuritic pain and was diagnosed with pericarditis and pericardial effusion. According to the CDC definition this case is classify as acute pericarditis; according to the Brigton collaboration is a Level 2 case, and according to the WHO causality assessment, this case is considered possible.Important risk factors for this report are the patient's advance age, an dhis history of

	TAMSULOSIN and ACETYLSALICYLIC ACID for an unknown indication. On 02-Mar-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 02-Mar-2021, the patient experienced PERICARDITIS (Pericarditis) (seriousness criteria hospitalization and medically significant), PERICARDIAL EFFUSION (Pericardial effusion) (seriousness criteria hospitalization and medically significant), PLEURITIC PAIN (Pleuritic pain) (seriousness criterion hospitalization) and CHEST PAIN (Chest pain) (seriousness criterion hospitalization). The patient was hospitalized on 23-Jun-2021 due to CHEST PAIN, PERICARDIAL EFFUSION, PERICARDITIS and PLEURITIC PAIN. At the time of the report, PERICARDITIS (Pericarditis), PERICARDIAL EFFUSION (Pericardial effusion), PLEURITIC PAIN (Pleuritic pain) and CHEST PAIN (Chest pain) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 02-Mar-2021, C-reactive protein: 135 (normal) normal. On 02-Mar-2021, Computerised tomogram thorax: abnormal (abnormal) 1 cm pericardial effusion - no PE.. On 02-Mar-2021, Echocardiogram: abnormal (abnormal) abnormal. On 02-Mar-2021, Electrocardiogram ST segment: elevated (High) elevated. On 02-Mar-2021, Troponin: negative (Negative) Negative. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. The patient experienced sudden onset of pleuritic left precordial pain that increased with supine position. Treatment information was not provided.	hypertension and hyperlipidemia. There is also important information missing regarding other laboratory tests conducted, treatment, medical course, etc.

	Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.	
4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b) on 13-Jul-2021 and was forwarded to Moderna on 13-Jul-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCARDITIS (Myocarditis), SINUS TACHYCARDIA (Sinus tachycardia) and CHEST PAIN (Chest pain) in a 20-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. No Medical History information was reported. On 24-Jun-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 24-Jun-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant), SINUS TACHYCARDIA (Sinus tachycardia) (seriousness criterion hospitalization), CHEST PAIN (Chest pain) (seriousness criterion hospitalization), FATIGUE (Fatigue), PAIN (Pain) and HEADACHE (Headache). The patient was treated with IBUPROFEN for Pain management, at a dose of 1 dosage form. In June 2021, FATIGUE (Fatigue), PAIN (Pain) and HEADACHE (Headache) had resolved. On 28-Jun-2021, CHEST PAIN (Chest pain) had resolved. At the time of the report, MYOCARDITIS (Myocarditis) and SINUS TACHYCARDIA (Sinus tachycardia) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):	This is a 20 years old male with very limited information provided who the same day after receiving the 2nd dose of the vaccine patient experienced chest pain, sinus tachycardia and was diagnosed with myocarditis. According to the CDC definition this case is probable; according to the Brigton collaboration is a Level 2 case, and according to the WHO causality assessment, this case is considered conditional. In the analysis of this case report, the main concern here is the lack of information on the patient's full medical history and concomitant medications history. There is also important information missing regarding other laboratory tests conducted, treatment, medical course, etc.

	On 24-Jun-2021, Cardiac telemetry: normal (normal) normal. On 24-Jun-2021, Echocardiogram: abnormal (abnormal) abnormal. On 24-Jun-2021, Ejection fraction: decreased (Low) decreased. On 24-Jun-2021, Electrocardiogram: abnormal (abnormal) abnormal. On 24-Jun-2021, Magnetic resonance imaging heart: unknown (Inconclusive) pending result. On 24-Jun-2021, Troponin I: increased (High) increased. On 27-Jun-2021, Electrocardiogram: sinus tachycardia (abnormal) showed sinus tachycardia at 112 BPM and was otherwise normal (no evidence for pericarditis noted). On 27-Jun-2021, Troponin I: 4.2 (High) Troponin I was 4.20 at 8:38 AM and was 6.3 at 2:00 PM and had trended down. On 28-Jun-2021, Echocardiogram: normal (normal) normal. On 28-Jun-2021, Ejection fraction: 55% (normal) normal estimated left ventricular ejection fraction of 55%. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. On 27 Jun 2021, the patient presented to the emergency department. No concomitant medications were reported. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded, limited information regarding this event has been provided at this time	
4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b) on 13-Jul-2021 and was forwarded to Moderna on 13-Jul-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCARDITIS (Myocarditis), CHEST DISCOMFORT (Chest discomfort), CHEST PAIN (Chest pain) and PAINFUL RESPIRATION (Painful respiration) in a 21-year-old male patient who received mRNA-1273	This is a 21 years old male with very limited information provided who 4 days after receiving the 2nd dose of the vaccine patient experience chest discomfort, chest pain, painful respiration and was diagnosed with myocarditis. According to the CDC definition this case is probable; according to the Brigton

	(Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concomitant products included FLUTICASONE PROPIONATE (FLONASE [FLUTICASONE PROPIONATE]) for an unknown indication. On 14-Jun-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 18-Jun-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant), CHEST DISCOMFORT (Chest discomfort) (seriousness criterion hospitalization), CHEST PAIN (Chest pain) (seriousness criterion hospitalization), PAINFUL RESPIRATION (Painful respiration) (seriousness criterion hospitalization prolonged), MALAISE (Malaise), NAUSEA (Nausea), PYREXIA (Pyrexia) and HEADACHE (Headache). The patient was treated with COLCHICINE at an unspecified dose and frequency and IBUPROFEN SODIUM (IBUPROFEN [IBUPROFEN SODIUM]) at an unspecified dose and frequency. At the time of the report, MYOCARDITIS (Myocarditis), CHEST DISCOMFORT (Chest discomfort), CHEST PAIN (Chest pain), PAINFUL RESPIRATION (Painful respiration), MALAISE (Malaise), NAUSEA (Nausea), PYREXIA (Pyrexia) and HEADACHE (Headache) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 18-Jun-2021, Cardiac imaging procedure: abnormal (abnormal) abnormal. On 18-Jun-2021, Troponin I: 13 (High) Troponin elevated. On 21-Jun-2021, Magnetic resonance imaging heart: abnormal (abnormal) acute myocarditis was noted.	collaboration is a Level 2 case, and according to the WHO causality assessment, this case is considered conditional. In the analysis of this case report, the main concern here is the lack of information on the patient's full medical history and concomitant medications history.

	For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. On 18 Jun 2021, in the morning, the patient had a 15-minute chest discomfort. It was moderate, midsternal chest pain radiating to left arm at rest but was worse with deep breath. This became worse by evening and the patient had to visit an ER.	
4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b) on 13-Jul-2021 and was forwarded to Moderna on 13-Jul-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCARDITIS (Myocarditis) and CHEST PAIN (Chest pain) in a 20-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 049C21A) for COVID-19 vaccination. Concurrent medical conditions included Drug allergy and Autism. On 18-Jun-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 20-Jun-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant) and CHEST PAIN (Chest pain) (seriousness criterion hospitalization). The patient was treated with KETOROLAC TROMETHAMINE (TORADOL) for Adverse event, at an unspecified dose and frequency and NAPROXEN SODIUM (NAPROSYN [NAPROXEN SODIUM]) for Adverse event, at an unspecified dose and frequency. At the time of the report, MYOCARDITIS (Myocarditis) and CHEST PAIN (Chest pain) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 21-Jun-2021, Chest X-ray: normal (normal) no acute changes.	This is a 20 years old male with very limited information provided who 2 days after receiving the 2nd dose of the vaccine patient experience chest pain and was diagnosed with myocarditis. According to the CDC definition this case is probable; according to the Brigton collaboration is a Level 2 case, and according to the WHO causality assessment, this case is considered conditional. In the analysis of this case report, the main concern here is the lack of information on the patient's full medical history and concomitant medications history. There is also important information missing regarding other laboratory tests conducted, treatment, medical course, etc.

	On 21-Jun-2021, Electrocardiogram: inconclusive inconclusive. On 21-Jun-2021, Troponin: increased (High) 840, 2470, 2400, 2033. On 22-Jun-2021, Echocardiogram: inconclusive inconclusive. On 22-Jun-2021, Electrocardiogram: inconclusive inconclusive. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Concomitant medications were not provided by reporter. Atypical chest pain, elevated troponin, suspected myocarditis. Inpatient observation for 24 hours. Very limited information regarding these events have been provided at this time. No further information is expected.	
4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b) on 13-Jul-2021 and was forwarded to Moderna on 13-Jul-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of SYNCOPE (Syncope), SINUS BRADYCARDIA (Sinus bradycardia), CHEST PAIN (Chest pain), HYPERHIDROSIS (Hyperhidrosis), VENTRICULAR EXTRASYSTOLES (Ventricular extrasystoles), VIRAL MYOCARDITIS (Viral myocarditis), CHILLS (Chills) and PAIN (Pain) in a 23-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 047B21A) for COVID-19 vaccination. Concurrent medical conditions included Penicillin allergy (PCN) and Asthma. Concomitant products included VITAMIN D [VITAMIN D NOS] for an unknown indication. On 22-Apr-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273	This is a 23 years old male with very limited information provided who 3 days after receiving the 2nd dose of the vaccine patient experience syncope, chest pain, hyperhidrosis, chills, pain, sinus bradycardia, ventricular extrasystoles and was diagnosed with positive Coxsackie virus test positive. Coxsackie virus B3and B4, and viral myocarditis. According to the CDC definition this case is probable; according to the Brigton collaboration is a Level 2 case, and according to the WHO causality assessment, this case is considered unlikely. The diagnosis of Coxsackie virus test positive, Coxsackie virus B3and B4 provides a better explanation for the ocurrence of the event of myocarditis.

	(Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 25-Apr-2021, the patient experienced SYNCOPE (Syncope) (seriousness criteria hospitalization and medically significant), SINUS BRADYCARDIA (Sinus bradycardia) (seriousness criterion hospitalization), CHEST PAIN (Chest pain) (seriousness criterion hospitalization), HYPERHIDROSIS (Hyperhidrosis) (seriousness criterion hospitalization), VENTRICULAR EXTRASYSTOLES (Ventricular extrasystoles) (seriousness criterion hospitalization), VIRAL MYOCARDITIS (Viral myocarditis) (seriousness criteria hospitalization and medically significant), CHILLS (Chills) (seriousness criterion hospitalization) and PAIN (Pain) (seriousness criterion hospitalization). The patient was hospitalized on 25-Apr-2021 due to CHILLS, HYPERHIDROSIS, SINUS BRADYCARDIA, SYNCOPE, VENTRICULAR EXTRASYSTOLES and VIRAL MYOCARDITIS, and then on 25-May-2021 due to PAIN. The patient was treated with HEPARIN at an unspecified dose and frequency. At the time of the report, SYNCOPE (Syncope), SINUS BRADYCARDIA (Sinus bradycardia), CHEST PAIN (Chest pain), HYPERHIDROSIS (Hyperhidrosis), VENTRICULAR EXTRASYSTOLES (Ventricular extrasystoles), VIRAL MYOCARDITIS (Viral myocarditis), CHILLS (Chills) and PAIN (Pain) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 25-Apr-2021, Blood test: abnormal (abnormal) Blood test abnormal. On 25-Apr-2021, Chest X-ray: normal (normal) Chest X-ray normal.. On 25-Apr-2021, Computerised tomogram coronary artery: inconclusive (Inconclusive) Inconclusive. On 25-Apr-2021, Computerised tomogram thorax: normal (normal) Computerised tomogram thorax normal. On 25-Apr-2021, Coxsackie viral infection: abnormal (abnormal) Coxsackie viral infection. On 25-Apr-2021, Coxsackie virus test: positive (Positive) Coxsackie virus test positive. Coxsackie virus B3and B4.	

	On 25-Apr-2021, Echocardiogram: abnormal (abnormal) Echocardiogram abnormal and abnormal (abnormal) EKG sinus bradycardia. On 25-Apr-202 1, Inflammatory marker test: high (High) Inflammatory marker increased. On 25-Apr-2021, Laboratory test: abnormal (abnormal) abnormal. On 25-Apr-2021, Oxygen saturation: 98-99 % (normal) SpO2 98-99. On 25-Apr-2021, Scan with contrast: normal (normal) CT with contrast, no wall abnormalities, no valve abnormalities, no clots, no arrhythmia (does have occasional PVCs. On 25-Apr-2021, Troponin: 0.4 (High) Troponin 0.4 and 0.9 ng/mL. On 26-Apr-2021, Troponin: 4.9 (High) Troponin 4.9 ng/mL. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.	
4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b) on 13-Jul-2021 and was forwarded to Moderna on 13-Jul-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCARDITIS (Myocarditis) and CHEST PAIN (Chest pain) in a 21-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No medical history provide by the reporter. On 09-Jun-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 11-Jun-2021, the patient experienced MYOCARDITIS	This is a 21 years old male with very limited information provided who 2 days after receiving the 2nd dose of the vaccine patient experienced chest pain and was diagnosed with myocarditis. According to the CDC definition this case is confirmed; according to the Brigton collaboration is a Level 1 case, and according to the WHO causality assessment, this case is considered conditional. In the analysis of this case report, the main concern here is the lack of information on the patient's full medical history and concomitant medications history. There is also important information missing

	(Myocarditis) (seriousness criteria hospitalization and medically significant) and CHEST PAIN (Chest pain) (seriousness criterion hospitalization). The patient was hospitalized from 11-Jun-2021 to 14-Jun-2021 due to CHEST PAIN and MYOCARDITIS. The patient was treated with COLCHICINE at an unspecified dose and frequency. At the time of the report, MYOCARDITIS (Myocarditis) and CHEST PAIN (Chest pain) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 11-Jun-2021, Cardiac imaging procedure: abnormal (abnormal) Abnormal. On 11-Jun-2021, Troponin: 2.340 ng/mL (High) Troponin increased. On 12-Jun-2021, Troponin: 7.640 ng/mL (High) Troponin increased. On 13-Jun-2021, Troponin: 5.830 ng/mL (High) Troponin increased. On 14-Jun-2021, Magnetic resonance imaging heart: myocarditis (abnormal) Myocarditis. On 14-Jun-2021, Troponin: 3.980 ng/mL (High) Troponin increased. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. On 14 Jun 2021, the patient was presented to the emergency department with chief complaint of left anterior chest pain. The patient's troponin was elevated upon admission to the hospital. The patient was provided with NSAIDs during hospital course. The patient was discharged to home. Concomitant product use was not provided by the reporter. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. No further information is expected at this time.	regarding treatment, medical course, etc.
4.1(b) [redacted]	This case was received via 4.1(b) [redacted] (Reference number:	This is a 23 years old male with very limited information provided who

	4.1(b) on 13-Jul-2021 and was forwarded to Moderna on 13-Jul-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCARDITIS (Myocarditis), THROMBOSIS (Thrombosis) and CHEST PAIN (Chest pain) in a 23-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. On 17-Jun-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 20-Jun-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization, medically significant and life threatening), THROMBOSIS (Thrombosis) (seriousness criteria hospitalization, medically significant and life threatening) and CHEST PAIN (Chest pain) (seriousness criteria hospitalization and life threatening). The patient was hospitalized on 20-Jun-2021 due to CHEST PAIN, MYOCARDITIS and THROMBOSIS. At the time of the report, MYOCARDITIS (Myocarditis), THROMBOSIS (Thrombosis) and CHEST PAIN (Chest pain) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 20-Jun-2021, Catheterisation cardiac: normal (normal) normal. On 20-Jun-2021, Echocardiogram: normal (normal) Echocardiogram showed normal but with definite lateral wall and apex mildly hypokinetic. On 20-Jun-2021, Troponin: abnormal (abnormal) Abnormal peaked at 57.12. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Treatment information not provided. Concomitant medication not provided. LHC revealed normal coronaries.	3 days after receiving the 2nd dose of the vaccine patient experienced chest pain and thrombosis and was diagnosed with myocarditis. According to the CDC definition this case is probable; according to the Brigton collaboration is a Level 1 case, and according to the WHO causality assessment, this case is considered conditional. In the analysis of this case report, the main concern here is the lack of information on the patient's full medical history and concomitant medications history. There is also important information missing regarding other laboratory tests conducted, treatment, medical course, etc.

	Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.	
4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b) on 13-Jul-2021 and was forwarded to Moderna on 13-Jul-2021. 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 COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 25-Jun-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 26-Jun-2021, the patient experienced PERICARDITIS (Pericarditis) (seriousness criterion medically significant), CHEST DISCOMFORT (Chest discomfort), GENERAL SYMPTOM (General symptom) and PLEURITIC PAIN (Pleuritic pain). At the time of the report, PERICARDITIS (Pericarditis), CHEST DISCOMFORT (Chest discomfort), GENERAL SYMPTOM (General symptom) and PLEURITIC PAIN (Pleuritic pain) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 26-Jun-2021, C-reactive protein: high (High) elevated CRP consistent with the diagnosis of acute pericarditis. On 26-Jun-2021, Electrocardiogram: abnormal (abnormal) ECG with diffuse ST elevations. On an unknown date, Auscultation: abnormal (abnormal) friction rub on auscultation.	This is a 20 years old male with very limited information provided who the next day after receiving the 2nd dose of the vaccine patient experienced chest discomforth, geenral symptoms and was diagnosed with pericarditis. According to the CDC definition this case is classify as acute pericarditis; according to the Brigton collaboration is a Level 2 case, and according to the WHO causality assessment, this case is considered conditional. In the analysis of this case report, the main concern here is the lack of information on the patient's full medical history and concomitant medications history. There is also important information missing regarding other laboratory tests conducted, treatment, medical course, etc.

	For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. No concomitant medications or treatment medications were reported. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was not applicable. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.	
4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b) on 20-Jul-2021 and was forwarded to Moderna on 20-Jul-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCARDITIS (Myocarditis), DYSPNOEA (Dyspnoea), MALAISE (Malaise) and PYREXIA (Fever) in a 37-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. Concurrent medical conditions included Factor V Leiden carrier and Penicillin allergy. Concomitant products included PARACETAMOL (TYLENOL) for an unknown indication. On 03-Jul-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 03-Jul-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant) and DYSPNOEA (Dyspnoea) (seriousness criterion hospitalization). 03-Jul-2021, the patient experienced MALAISE (Malaise) (seriousness criterion hospitalization) and PYREXIA (Fever) (seriousness criterion hospitalization). The patient was treated	This is a 37 years old male with history of Factor V Leiden and very limited information provided who the same day after receiving the 2nd dose of the vaccine patient experienced dyspnea, malaise, pyrexia, and was diagnosed with myocarditis. According to the CDC definition this case is confirmed; according to the Brigton collaboration is a Level 1 case, and according to the WHO causality assessment, this case is considered conditional. This report is confounded by the patient's medical history of Factor V Leiden. There is also important information missing regarding other laboratory tests conducted, treatment, medical course, etc.

	with ASPIRIN [ACETYLSALICYLIC ACID] ongoing from 03-Jul-2021 for Myocarditis, at an unspecified dose and frequency and COLCHICINE ongoing from 03-Jul-2021 for Myocarditis, at an unspecified dose and frequency. At the time of the report, MYOCARDITIS (Myocarditis), DYSPNOEA (Dyspnoea), MALAISE (Malaise) and PYREXIA (Fever) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 03-Jul-2021, C-reactive protein: 3.29 (High) Increased. On 03-Jul-2021, Computerised tomogram: equivocal (Inconclusive) equivocal. On 03-Jul-2021, Ejection fraction: 60% (normal) 60%. On 03-Jul-2021, Fibrin D dimer: 821 (High) 821. On 03-Jul-2021, Magnetic resonance imaging heart: abnormal (abnormal) EF 60%, no ischemia. Small amount of late gadolinium enhancement in the epicardium at the base of the inferior well and in the distal segment. Also epicardial gadolinium enhancement in the basal lateral wall and along the distal lateral wall. Findings consistent with myocarditis. On 03-Jul-2021, Troponin: 2.15 (Inconclusive) 2.15. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. The patient developed fevers and malaise within 10 hours of the vaccine and then subsequently developed progressive shortness of breath and presented to the emergency department (ED) locally. Was thought to have a pulmonary embolism (PE) and underwent CT images which was equivocal. The patient was transferred to hospital where an MRI cardiac stress indicated myocarditis. The patient started on aspirin and colchicine and will require cardiology outpatient follow up. Patient was feeling better at the time of the report.	

	Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.	
4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b) on 20-Jul-2021 and was forwarded to Moderna on 20-Jul-2021. This regulatory authority case was reported by a 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) (batch nos. 016C21A and 016C21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Rat-bite fever, Reactive airways disease and Low back pain. On 15-Jun-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 18-Jun-2021, the patient experienced MYOCARDITIS (myocarditis) (seriousness criteria hospitalization and medically significant) and CHEST PAIN (chest pain). The patient was hospitalized on sometime in 2021 due to MYOCARDITIS. The patient was treated with METOPROLOL for Myocarditis, at an unspecified dose and frequency. At the time of the report, MYOCARDITIS (myocarditis) and CHEST PAIN (chest pain) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 18-Jun-2021, Magnetic resonance imaging: unknown (abnormal) evidence of myocarditis. On 18-Jun-2021, Troponin: 112,337,276 (abnormal) units not provided. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter	This is a 24 years old male with concurrent medical history of rat-bite fever who 3 days after receiving the 2nd dose of the vaccine patient experienced chest pain and was diagnosed with myocarditis. According to the CDC definition this case is confirmed; according to the Brigton collaboration is a Level 1 case, and according to the WHO causality assessment, this case is considered unlikely. The diagnosis of concurrent rat-bite fever provides a better explanation for the ocurrence of the event.

	considered MYOCARDITIS (myocarditis) to be possibly related. No further causality assessment was provided for CHEST PAIN (chest pain). Concomitant product use was not provided by the reporter. The start date of first dose of vaccine was discrepant. On 18-Jun-2021, echocardiogram was carried out. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.	
4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b) on 20-Jul-2021 and was forwarded to Moderna on 20-Jul-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCARDITIS (Myocarditis), CHEST PAIN (Chest pain), PAIN (Pain), PAINFUL RESPIRATION (Painful respiration) and SLEEP DISORDER (Sleep disorder) in an 18-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. The patient's past medical history included Exercise induced asthma. On 19-Jun-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Subcutaneous) 1 dosage form. On 21-Jun-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant), CHEST PAIN (Chest pain) (seriousness criterion hospitalization), PAIN (Pain) (seriousness criterion hospitalization), PAINFUL RESPIRATION (Painful respiration) (seriousness criterion hospitalization) and SLEEP DISORDER (Sleep disorder) (seriousness criterion hospitalization). On an unknown date, the patient experienced INCORRECT ROUTE OF PRODUCT ADMINISTRATION (Inappropriate route	This is an 18 years old male with very limited information provided who 2 days after receiving the 2nd dose of the vaccine patient experienced chest pain, painful respirations, and sleep disorder and was diagnosed with myocarditis. According to the CDC definition this case is confirmed; according to the Brigton collaboration is a Level 1 case, and according to the WHO causality assessment, this case is considered conditional. In the analysis of this case report, the main concern here is the lack of information on the patient's full medical history and concomitant medications history. There is also important information missing regarding other laboratory tests conducted, treatment, medical course, etc.

	of vaccination). The patient was treated with IBUPROFEN at an unspecified dose and frequency and COLCHICINE at an unspecified dose and frequency. At the time of the report, MYOCARDITIS (Myocarditis), PAIN (Pain), PAINFUL RESPIRATION (Painful respiration) and SLEEP DISORDER (Sleep disorder) outcome was unknown and CHEST PAIN (Chest pain) and INCORRECT ROUTE OF PRODUCT ADMINISTRATION (Inappropriate route of vaccination) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 21-Jun-2021, C-reactive protein: increased (High) increased. On 21-Jun-2021, Cardiac imaging procedure: abnormal (abnormal) Abnormal. On 21-Jun-2021, Troponin: increased (High) Increased. For mRNA-1273 (Moderna COVID-19 Vaccine) (Subcutaneous), the reporter did not provide any causality assessments. No concomitant medications were provided. It was reported that patient experienced Endorsed acute chest pain around 1200 on 6/21 initially that seemed to get better. On the early morning of 6/22 at 0400, the pain woke him up from sleep with a 7-8/10 in severity. At this point it was extremely painful for the patient to breathe but he denies shortness of breath. He denies radiation of pain, felt better when he was lying down, worse when sitting up, and was extremely bothersome while ambulating. He was presented to hospital and was found to have elevated troponin (7.25-13.00-2.52). He was transferred to another Hospital Cardiac MRI supported the diagnosis of myopericarditis. By the time of transfer to Hospital, hos chest pain had resolved. He was treated with a 6 week course of ibuprofen and colchicine. It was also reported there was faint epicardial hyperenhancement involving the inferolateral and anterolateral LV	

	walls from base to near apex. This was a non-ischemic pattern of hyperenhancement that was most consistent with myocarditis. This region also demonstrates longer T1 and T2 times on T1/T2 mapping images. This finding may be consistent with myocardial edema in this region, which suggests an acute/subacute process. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.	
4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b) on 20-Jul-2021 and was forwarded to Moderna on 20-Jul-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCARDITIS (Myocarditis), CHEST PAIN (Chest pain), DYSPNOEA (Shortness of breath) and FATIGUE (Fatigue) in a 46-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 016B21A) for COVID-19 vaccination. Concurrent medical conditions included Post-traumatic stress disorder and Anxiety. Concomitant products included ESCITALOPRAM, LISDEXAMFETAMINE MESILATE (VYVANSE), BUPROPION, FISH OIL (OMEGA-3 FISH OIL), ALPRAZOLAM, ROSUVASTATIN, PRAZOSIN, CETIRIZINE and FAMOTIDINE for an unknown indication. On 28-May-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 29-May-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant), CHEST PAIN (Chest pain) (seriousness criterion hospitalization), DYSPNOEA (Shortness	This is a 46 years old male with very limited information provided who the next day after receiving the 2nd dose of the vaccine patient experienced chest pain, dyspnea, and fatigue and was diagnosed with myocarditis. According to the CDC definition this case is confirmed; according to the Brigton collaboration is a Level 1 case, and according to the WHO causality assessment, this case is considered conditional. In the analysis of this case report, the main concern here is the lack of information on the patient's full medical history and concomitant medications history. There is also important information missing regarding other laboratory tests conducted, treatment, medical course, etc.

	of breath) (seriousness criterion hospitalization) and FATIGUE (Fatigue) (seriousness criterion hospitalization). The patient was treated with NITROGLYCERIN for Adverse event, at a dose of 1 dosage form. At the time of the report, MYOCARDITIS (Myocarditis), CHEST PAIN (Chest pain), DYSPNOEA (Shortness of breath) and FATIGUE (Fatigue) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 29-May-2021, Angiogram: normal (normal) normal. On 29-May-2021, Magnetic resonance imaging: abnormal (abnormal) abnormal. On 29-May-2021, Troponin I: 10.4 (Inconclusive) 10.4. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Treatment included Heart Failure Clinic. Test results indicated ejection fraction of left ventricle to be 30%. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.	
4.1(b)	This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myocarditis), DYSPNOEA (Dyspnea), CHEST PAIN (oppressive chest pain that does not respond to analgesics) and PYREXIA (Fever) in a 28-year-old male patient who received mRNA-1273 (COVID 19 Vaccine Moderna) (batch nos. 3003655 and 3002545) for COVID-19 vaccination. Concurrent medical conditions included Hypertension arterial. Concomitant products included RAMIPRIL for Hypertension. On 30-May-2021, the patient received first dose of mRNA-1273 (COVID 19 Vaccine Moderna) (unknown route) .5 milliliter.	This is a 28 years old male with history of hypertension and no other information provided who the same day after receiving the 2nd dose of the vaccine patient experienced chest pain, dypsnea, and pyrexia and was diagnosed with myocarditis. According to the CDC definition this case is probable; according to the Brigton collaboration is a Level 2 case, and according to the WHO causality assessment, this case is considered possible. In the analysis of this case report, the main concern here is the lack of

	On 05-Jul-2021, received second dose of mRNA-1273 (COVID 19 Vaccine Moderna) (Intramuscular) dosage was changed to 1 dosage form. On 05-Jul-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant), DYSPNOEA (Dyspnea) (seriousness criterion hospitalization), CHEST PAIN (oppressive chest pain that does not respond to analgesics) (seriousness criterion hospitalization) and PYREXIA (Fever) (seriousness criterion hospitalization). At the time of the report, MYOCARDITIS (Myocarditis), DYSPNOEA (Dyspnea), CHEST PAIN (oppressive chest pain that does not respond to analgesics) and PYREXIA (Fever) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Electrocardiogram: high (High) ECG elevated. For mRNA-1273 (COVID 19 Vaccine Moderna) (Intramuscular), the reporter did not provide any causality assessments. Laboratory investigation reported, on 08-JUL-2021 patient done Troponin I, White blood cells, C-reactive protein result were not provided. on an unknown date TnI , result reported 2629->3750. There was no treatment medication reported. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Most recent FOLLOW-UP information incorporated above includes: On 27-Jul-2021: Translated document received on 27-JUL-2021 contains significant information, Laboratory investigation and Anatomical Location, batch number for dose one updated.	information on the patient's full medical history and concomitant medications history. There is also important information missing regarding other laboratory tests conducted, treatment, medical course, etc.

	On 27-Jul-2021: Follow-up received on 27-JUL-2021 Contain No new information.	
4.1(b)	This regulatory authority case was reported by a pharmacist and describes the occurrence of MYOCARDITIS (Myocarditis), CHEST PAIN (Stethalgia), COUGH (Cough) and DYSPNOEA (Shortness of breath) in an 18-year-old male patient who received mRNA-1273 (COVID 19 Vaccine Moderna) (batch no. 3003610) for COVID-19 vaccination. No Medical History information was reported. On 04-Jul-2021, the patient received second dose of mRNA-1273 (COVID 19 Vaccine Moderna) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (COVID 19 Vaccine Moderna) (unknown route) 1 dosage form. On 05-Jul-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant), CHEST PAIN (Stethalgia) (seriousness criterion hospitalization), COUGH (Cough) (seriousness criterion hospitalization) and DYSPNOEA (Shortness of breath) (seriousness criterion hospitalization). At the time of the report, MYOCARDITIS (Myocarditis) was resolving and CHEST PAIN (Stethalgia), COUGH (Cough) and DYSPNOEA (Shortness of breath) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 07-Jul-2021, C-reactive protein increased (0-5): 42.3 (High) High 42.3 milligram per litre. On 07-Jul-2021, Fibrin D dimer: 0.4 (normal) Normal 0.4 microgram per litre. On 07-Jul-2021, N-terminal prohormone brain natriuretic peptide: 495 (High) High 495 picogram per millilitre. On 07-Jul-2021, Troponin increased (0-14): 685 (High) High 685 nanogram per litre. On 07-Jul-2021, White blood cell count (3.91-10.9): 11.1 (High) Increased 11.1 billion per litre.	This is an 18 years old male with very limited information provided who the next day after receiving the 2nd dose of the vaccine patient experienced chest pain, cough, dyposnea and was diagnosed with myocarditis. According to the CDC definition this case is probable; according to the Brigton collaboration is a Level 2 case, and according to the WHO causality assessment, this case is considered conditional. In the analysis of this case report, the main concern here is the lack of information on the patient's full medical history and concomitant medications history. There is also important information missing regarding other laboratory tests conducted, treatment, medical course, etc.

	On 09-Jul-2021, Ejection fraction: 49 (Low) Low 49 percent. For mRNA-1273 (COVID 19 Vaccine Moderna) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medications were reported. No treatment medications were reported. Lab data included IRM[redacted] Sender's (Case) Safety Report Unique Identifier-[redacted] Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Most recent FOLLOW-UP information incorporated above includes: On 28-Jul-2021: Follow up document added; Lab data updated, outcome of event myocarditis changed to recovering.	
[redacted]	This case was received via [redacted] (Reference number: [redacted] on 27-Jul-2021 and was forwarded to Moderna on 27-Jul-2021. 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 23-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 046A21A) for COVID-19 vaccination. No Medical History information was reported. On 26-Mar-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown	This is a 23 years old male with very limited information provided who 3 days after receiving the 2nd dose of the vaccine patient experienced sharp, constant left sided chest pain which was relieved with sitting and was diagnosed with myocarditis. According to the CDC definition this case is probable; according to the Brigton collaboration is a Level 2 case, and according to the WHO causality assessment, this case is considered conditional. In the analysis of this case report, the main concern here is the lack of information on the patient's full medical

	route) 1 dosage form. On 29-Mar-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) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 29-Mar-2021, Angiocardiogram: normal (normal) Normal. On 29-Mar-2021, Blood creatine phosphokinase: 404 (High) 404. On 29-Mar-2021, Blood creatine phosphokinase MB: 27 (High) 27. On 29-Mar-2021, Blood thyroid stimulating hormone: 1.8 (Low) 1.8. On 29-Mar-2021, Brain natriuretic peptide: 13.8 (normal) 13.8. On 29-Mar-2021, Cardiac imaging procedure: normal (normal) Normal. On 29-Mar-2021, Chest X-ray: normal (normal) normal. On 29-Mar-2021, Echocardiogram: normal (normal) Normal. On 29-Mar-2021, Ejection fraction: normal (normal) Normal. On 29-Mar-2021, Electrocardiogram ST segment: abnormal (abnormal) Electrocardiogram NSR (normal sinus rhythm)with non-specific ST abnormalities. On 29-Mar-2021, Fibrin D dimer: 0.4 (High) 0.4. On 29-Mar-2021, Troponin I: 2.620 (High) Increased 2.620 ng/ml (0-.034). For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. No concomitant medications were given by the reporter. No Treatment information were provided by the reporter. Patient Developed sharp, constant left sided chest pain which was relieved with sitting forward 3 days after his second dose of Moderna Covid-19 vaccine.	history and concomitant medications history. There is also important information missing regarding other laboratory tests conducted, treatment, medical course, etc.

	Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.	
4.1(b)	This regulatory authority case was reported by a physician and describes the occurrence of CHEST DISCOMFORT (4.1(b) CHEST PAIN (4.1(b)), MYOCARDITIS (V.a. (Peri-)Myocarditis), INFLAMMATORY MARKER INCREASED (4.1(b)), MYOCARDIAL NECROSIS MARKER INCREASED (4.1(b) and EJECTION FRACTION DECREASED 4.1(b)) in a 21-year-old male patient who received mRNA-1273 (COVID 19 Vaccine Moderna) (batch no. 3003602) for COVID-19 vaccination. 4.1(b) On 08-Jul-2021, the patient received second dose of mRNA-1273 (COVID 19 Vaccine Moderna) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient received second dose of mRNA-1273 (COVID 19 Vaccine Moderna) (unknown route) 1 dosage form. On 09-Jul-2021, the patient experienced CHEST DISCOMFORT (4.1(b) (seriousness criterion hospitalization), CHEST PAIN (4.1(b)), MYOCARDITIS (V.a. (Peri-)Myocarditis) (seriousness criteria hospitalization and medically significant), INFLAMMATORY MARKER INCREASED (4.1(b)) (seriousness criterion hospitalization), MYOCARDIAL NECROSIS MARKER INCREASED (4.1(b)) (seriousness criteria hospitalization and	This is a 21 years old male with very limited information provided who the next day after receiving the 2nd dose of the vaccine patient experienced chest discomfort, chest pain and was diagnosed with myocarditis. According to the CDC definition this case is probable; according to the Brigton collaboration is a Level 2 case, and according to the WHO causality assessment, this case is considered conditional. In the analysis of this case report, the main concern here is the lack of information on the patient's full medical history and concomitant medications history. There is also important information missing regarding other laboratory tests conducted, treatment, medical course, etc.

	medically significant) and EJECTION FRACTION DECREASED [redacted]) (seriousness criterion hospitalization). At the time of the report, CHEST DISCOMFORT ([redacted]), CHEST PAIN [redacted], MYOCARDITIS (V.a. (Peri-)Myocarditis), INFLAMMATORY MARKER INCREASED ([redacted]), MYOCARDIAL NECROSIS MARKER INCREASED ([redacted] and EJECTION FRACTION DECREASED [redacted]) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 09-Jul-2021, Ejection fraction: decreased (Low) Decreased. On 09-Jul-2021, Inflammatory marker test: increased (High) Increased. On 09-Jul-2021, Myocardial necrosis marker: increased (High) Increased. For mRNA-1273 (COVID 19 Vaccine Moderna) (Unknown), the reporter considered CHEST DISCOMFORT ([redacted]), CHEST PAIN [redacted], MYOCARDITIS (V.a. (Peri-)Myocarditis), INFLAMMATORY MARKER INCREASED ([redacted]), MYOCARDIAL NECROSIS MARKER INCREASED ([redacted]) and EJECTION FRACTION DECREASED ([redacted]) to be probably related. No concomitant medications were provided. No treatment information was provided.	
[redacted]	This case was received via [redacted] (Reference number: [redacted]) on 27-Jul-2021 and was forwarded to Moderna on 27-Jul-2021.	This is a 19 years old male with very limited information provided who the next day after

	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 19-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. On 06-Jul-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 07-Jul-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. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 07-Jul-2021, Troponin: increased (High) Increased. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. It was reported that patient was transferred to tertiary care facility after experiencing the events. No concomitant medication information was reported. No treatment information was reported. Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded	receiving the 2nd dose of the vaccine patient experienced chest pain and was diagnosed with myocarditis. According to the CDC definition this case is probable; according to the Brigton collaboration is a Level 2 case, and according to the WHO causality assessment, this case is considered conditional. In the analysis of this case report, the main concern here is the lack of information on the patient's full medical history and concomitant medications history. There is also important information missing regarding other laboratory tests conducted, treatment, medical course, etc.
4.1(b) [redacted]	This case was initially received via 4.1(b) [redacted] (Reference number: 4.1(b) [redacted]) on 01-Nov-2021. The most recent information was received on 02-Nov-2021 and was forwarded to Moderna on 02-Nov-2021. 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.	29 years old male with unknown medical history who 4 days after the 2nd dose experienced chest pain and dyspnoea and was found to have elevated troponin, abnormal EGC, abnormal Echo and was diagnosed with myocarditis. Pending cMRI results. No other information was provided. Important information is missing in the report including patient's medical history as well as any

	No Medical History information was reported. 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. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 09-Oct-2021, Electrocardiogram: abnormal (abnormal) ST elevation inferior leads.. On 09-Oct-2021, Troponin: 686 ng/l (High) Troponin- 686 ng/l. On an unknown date, SARS-CoV-2 test: negative (Negative) Negative. On an unknown date, Troponin: 689 (High) 689 and 383 (High) 383. For mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. 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. Company comment:	other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and ECG results; a causal relationship cannot be excluded due to the lack of other information.

	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. Most recent FOLLOW-UP information incorporated above includes: On 02-Nov-2021: Lab data added. Action taken updated as not applicable.	
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. 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. The patient's past medical history included Aspergillosis. Concurrent medical conditions included Allergy to antibiotic (Red cell antibody allergy), Hypertension and Lupus nephritis. Concomitant products included LISINOPRIL for Product used for unknown indication, MYCOPHENOLATE MOFETIL (CELLCEPT [MYCOPHENOLATE MOFETIL]), HYDROXYCHLOROQUINE PHOSPHATE (PLAQUENIL [HYDROXYCHLOROQUINE PHOSPHATE]), AMLODIPINE, CARVEDILOL, HYDRALAZINE and	20 years old female with medical history of aspergillosis (unknown TTO) hypertension, and SLE, who next day after the 2nd dose experienced chest pain, pleuritic pain, and was found to have abnormal MRI of the heart, and was diagnosed with pericarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. This report is confounded by the associated risk factor of this patient including her medical history of SLE, given that pericarditis is the most common heart problem associated with active lupus an doccurs in about 25% of people with SLE. Hypertension in such a young person is also a very important risk factor,

	ISAVUCONAZONIUM SULFATE (CRESEMBA) for an unknown indication. 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. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 15-Oct-2021, Magnetic resonance imaging heart: abnormal (abnormal) There was circumferential late gadolinium enhancement of the pericardium consistent with active inflammation (pericarditis). For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. 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	as well as her history of aspergillosis for which there is no information related to when this comorbidity occurred. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the MRI results; a causal relationship cannot be excluded.
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.	18 years old male with unknown medical history who 3 days after the 2nd dose experienced chest pain, radiating to his left shoulder and back, and

	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. No Medical History information was reported. In 2021, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form. 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. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 24-Oct-2021, Blood creatine phosphokinase (47-222): 374 (High) 374. On 24-Oct-2021, C-reactive protein (0-10): 13 (High) mg/L. On 24-Oct-2021, Electrocardiogram: abnormal (abnormal) ST ascendant v3-v4-v5. On 24-Oct-2021, Troponin (Unknown-90 nanogram per litre): 494 nanogram per litre High. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered MYOCARDITIS (Myocarditis) to be possibly related. No concomitant medications were provided. 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,	was found to have elevated CRP, troponin, abnormal Echo, and EKG, and SARS-CoV-2 test negative. He was diagnosed with myopericarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including results B19, CMV, etc, that were nopt provided. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and EKG, and Echo results; a causal relationship cannot be excluded due to the missing information.

	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, EBV and HHV6 serological tests still need to be performed, and a cardiac MRI is pending. 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. Most recent FOLLOW-UP information incorporated above includes: On 03-Nov-2021: Translation received on 5-Nov-2021.Case narrative were translated treatment drugs were added. No new information	
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. The patient's past medical history included 4.1(b) abuse, episodic use on 21-Oct-2021.	29 years old male with unknown medical history and concomitant use of 4.1(b) alcohol abuse and smoker who 2 days after the 2nd dose experienced chest pain, fever, and myalgias, and was found to have elevated troponin, CK, abnormal EKG and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report

	Concurrent medical conditions included Alcohol abuse, unspecified drinking behavior and Smoker (15 UPA). In 2021, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form. On 23-Oct-2021, received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) dosage was changed to 1 dosage form.T60. 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. 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. 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. Concomitant medication and treatment medication were not reported. Patient was in usual good health, Habits of patient included High-risk alcohol consumption and Active smoking habit at 15 pack-years occasional 4.1(b) 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	including patient's medical history as well as any other laboratory test conducted including SARS-CoV. The use of 4.1(b) and alcohol abuse are important conmfounders in this report. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and ECG results; a causal relationship cannot be excluded due to the lack of some information.

	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. This case concerns a 29 year-old male patient with a history of alcohol and 4.1(b) 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 4.1(b) 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. Most recent FOLLOW-UP information incorporated above includes: 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)	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. 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	30 years old female with medical history of migraines and previously receving Cominarty who 4 days after the 3rd dose of Spikevax experienced chest pain, tachycardia, palpitations, dyspnoea, fatigue, and pain and was found to have elevated troponin, and abnormal EGC, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report

	female patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) (batch no. 3004674) for COVID-19 vaccination. Concurrent medical conditions included Migraine. Concomitant products included AMITRIPTYLINE for Migraine, TOZINAMERAN (COVID-19 MRNA VACCINE BNT162B2) for an unknown indication. 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. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 01-Nov-2021, Chest X-ray: normal (normal) Normal Clear. On 01-Nov-2021, Electrocardiogram: abnormal (abnormal) Abnormal. The action taken with mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown) was unknown.	including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and ECG results; a causal relationship cannot be excluded due to the lack of other information.

	For mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Lab test included Troponin on 1-Nov-2021 with value 3. 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. Treatment medications prescribed as anti inflammatories and pain relief. Company Comment: 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. Most recent FOLLOW-UP information incorporated above includes: On 04-Nov-2021: Follow up received as lab data results are added. 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) [redacted]	This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS	35 years old male with medical history of viral myocarditis a year before

	(Myopericarditis) in a 35-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination. The patient's past medical history included Viral myocarditis in 2020. Concurrent medical conditions included Smoker (10 pack-years) and Alcohol allergy (Alcohol occasional). On 20-Sep-2021, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form. 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. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 24-Oct-2021, Echocardiogram: reduced by 46% (abnormal) Abnormal. On 24-Oct-2021, Electrocardiogram: normal (normal) Normal Test was on 23-OCT-2021. On an unknown date, Electrocardiogram: abnormal (abnormal) Abnormal Test was on 25-OCT-2021. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered MYOCARDITIS (Myopericarditis) to be probably related. No concomitant medication reported. No Treatment Medication reported. Based on Medical Review, the event of inappropriate schedule of vaccine administered is applicable as dose 1 and dose 2 are 20 days apart. A little while after the vaccination, patient presented symptoms of myalgia, arthralgia and self-limiting chills. On 22 Oct 2021 he experienced respiration-	and a smoker who 3 days after the 2nd dose experienced myalgia, arthralgia and self-limiting chills, as well as respiration-dependent retrosternal pain, which worsened with movement. He was hospitalized and found to have elevated troponin, Ck, NT-proBNP, abnormal EGC, abnormal Echo and was diagnosed with myopericarditis. Patient was treated with ASA and lisinooril and was discharged 2 days later. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated laboratory results including troponin and ECG and Echo results; a causal relationship cannot be excluded due to the lack of other information.

	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. On 24 Oct 2021 Troponin T, Creatine kinase and NT-proBNP were performed with unknown results. 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. Most recent FOLLOW-UP information incorporated above includes: 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)	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. 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	19 years old male with medical history of PTSD and concomitant use of quetiapine (myocarditis is in the PI as an ADR in post-marketing) who 3 days after the 2nd dose experienced thoracic pressure, and was found to have elevated troponin, Ck, proBNP, D-dimer,

	(Spikevax) (batch no. 3004671) for Prophylactic vaccination. No Medical History information was reported. 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. Patient had medical history of posttraumatic stress disorder and drug allergy of quetiapine 25 mg. Gastrointestinal infection several weeks ago has been reported. 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.	abnormal Echo, and was diagnosed with myopericarditis. No other information was provided. Important information is missing in the report including patient's full medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and ECG and Echo results; a causal relationship cannot be excluded due to the missing information and the other confounders.

	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 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. Most recent FOLLOW-UP information incorporated above includes: 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)	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. This regulatory authority case was reported by a physician in a 27-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3004498) for Vaccination. The patient's past medical history included Overweight. 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	27 years old male with medical history of overweight who 3 days after the 2nd dose experienced general symptoms including malaise, asthenia, dizzines, palpitations, etc. Patient was evaluated but blood test (no other information provided) were all normal. 30 days later the patient experienced palpitations, cold sweat, and chest pain and after evaluation was found to have elevated troponin but all other tests were normal, including EKG and Echo. Patient was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's full medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO

	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 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	causality assessment this report is possible based on temporal association between the use of the product and the start of the events. A causal relationship cannot be excluded due to the lack of information.

	(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 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) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 13-Sep-2021, Blood test: normal (normal) Normal findings. On 13-Oct-2021, Chest X-ray: normal (normal) No focal densities, no signs of congestion or pleural effusion. Slim mediastinum and normal-sized heart. Normal skeletal parts. X-ray was compared to X-ray from 21-Sep-2014.. On 13-Oct-2021, Investigation: inconclusive (Inconclusive) Blood pressure 153/79 mmHg, pulse rate 84 bpm, respiratory frequence 14, oxygen saturation 100% Collum: No jugular vein congestion. No stenosis sounds over the carotids. Can place the chin on the chest. Thorax: Normal configuration and movement. Coronary: Regular action, no heart murmur, no heart rate deficit. Pulmonary: Vesicular respiratory sound, no foreign sounds. Upper extremities: A little tremor bilaterally, had since vaccination. Lower extremities: Equal	

	and warm, good pulse in ADP and ATP. No edema. Electrocardiography: sinus rythm, frequence 78 Lab: PS-Creatinine 105; Pt-GFR, estimated 83; PS-Sodium 140; P-Potassium 3.7; B-Hemoglobin 14.9; B-Platelets 291; B-Leukocytes 6.2; P-Troponin T 30- 27-26- 12; B-Glucose 4.9; PS-CRP 1- 0. On 15-Oct-2021, Computerised tomogram coronary artery: normal (normal) No findings of coronary stenosis.. In October 2021, Echocardiogram: normal (normal) Normal findings. In October 2021, Troponin: 30-27-26-12 (normal) 30-27-26-12 ng/L.. For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered 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,	
4.1(b) [redacted]	This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) [redacted]) on 05-Nov-2021 and was forwarded to Moderna on 09-Nov-2021. This case, initially reported to the 4.1(b) [redacted] by a physician, was received via the 4.1(b) (Ref, 4.1(b) [redacted] The patient had a pollinosis and took an over-the-counter fexofenadine hydrochloride depending on the season. On an unknown date, the patient received the 1st dose of this vaccine. On 01-Oct-2021, the patient received the 2nd dose of this vaccine. 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. On 04-Oct-2021, around 06:00, acute myocarditis developed. Chest pain was noted. The patient visited the previous	29 years old male with unknown medical history who 3 days after the 2nd dose experienced chest pain and was found to have elevated troponin, normal Ck and CK-MB, normal Echo, abnormal EKG and abnormal cMRI. Pending results for blood tests that were conducted to excluded viral myocarditis. Patient was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the

	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. On an unknown date, no abnormal findings were found at the time of hospitalization on echocardiography. Thereafter, no new findings were noted. Coronary artery CT was performed, but there was no significant stenosis. On 08-Oct-2021, the patient was doing well and was discharged from the hospital. On 26-Oct-2021, the resolution of the symptoms was confirmed. The outcome of pyrexia and acute myocarditis was reported as resolved. Follow-up investigation will be made. Reporter comments continuation: 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. Company Comment: The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	product and the start of the events, as well as the elevated troponin and the EKG and cMRI results. A causal relationship cannot be excluded due to the missing information.
4.1(b)	This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 05-Nov-2021 and	22 years old female with unknown medical history and concomitant medications including

	was forwarded to Moderna on 10-Nov-2021. This case, initially reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref 4.1(b) 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. On an unknown date, the patient received the 1st dose of the vaccine. On an unknown date, body temperature before the vaccination: 36.2 degrees Celsius. On 17-Oct-2021, the patient received the 2nd dose of the vaccine. 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. 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. 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. On an unknown date, after the hospitalization, the symptom showed a tendency of improvement.	levetiracetam (indicated for the treatment of partial seizures), perampanel hydrate (also indicated for the treatment of partialseizures) and valproate sodium (also indicated for the treatment of seizures and for migraines prophylaxis) who 16 days after the 2nd dose experienced pyrexia, malaise and chest pain. Patient was evaluated at that time and EKG and blood test were found to be within normal limits. Two days later as symptoms did not improved, patient went back tot he hospital were she was found to have elevated troponin, abnormal EKG, normal Echo. Additonal test results were not provided. Patient was diagnosed with acute myocarditis. Symptoms were resolving within 2 days. No other information was provided. Important information is missing in the report including patient's full medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events as well as the results of elevated troponin and the EKG results. A causal relationship cannot be excluded due to the missing information.

	On 04-Nov-2021, troponin I also decreased to around 300 in 2 days, and the symptom was confirmed to be resolving. 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)	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. This regulatory authority case was reported by an other health care professional and describes the occurrence of CARDIOMYOPATHY (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. The patient's past medical history included Hepatic steatosis and COVID-19 in August 2020. Concurrent medical conditions included Allergy to antibiotic (Amoxicillin), Depression, Anxiety and Vitamin D deficiency. Concomitant products included ESCITALOPRAM OXALATE, VITAMIN D [VITAMIN D NOS], MULTIVITAMIN [VITAMINS NOS] and LINUM USITATISSIMUM SEED OIL (FLAX OIL) for an unknown indication. 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)	22 years old male with medical history of hepatic steatosis and COVID-19 one year before who 6 days after the 2nd dose experienced chest pain and was found to have elevated CRP, troponin I, d-dimer, abnormal EKG, abnormal Echo with low ejection fraction, and abnormal cMRI suggestive of acute myocarditis and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's full medical history as well as any other laboratory test conducted. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and EKG, cMRI and Echo results; a causal relationship cannot be excluded.

	(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. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 25-Oct-2021, C-reactive protein: 1.710 (High) 1.710 mg/dL. On 25-Oct-2021, Chest X-ray: normal (normal) Normal. On 25-Oct-2021, Electrocardiogram: st-t segment abnormal (abnormal) ST-T segment abnormal and normal (normal) Normal. On 25-Oct-2021, Fibrin D dimer: 0.27 (normal) less than 0.27 ug/mL. On 25-Oct-2021, Red blood cell sedimentation rate: 7 (normal) 7 mm/hr. On 25-Oct-2021, Troponin I: 1.85 (High) 1.85 ng/mL and 3.22 (High) 3.22 ng/mL. On 26-Oct-2021, Echocardiogram: normal (normal) Normal. On 26-Oct-2021, Ejection fraction: 59 (Low) 59%. 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. On 27-Oct-2021, Troponin I: 2757 (High) 2757 ng/L. On 28-Oct-2021, Magnetic resonance imaging heart: acute myocarditis (abnormal) Non-ischemic pattern of edema/ hyperemia suggestive of acute myocarditis. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No treatment information provided. Company Comment: 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 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)	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. 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 the vaccine. On 22-Oct-2021, at 10:00, the patient received the 2nd dose of the vaccine. 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. 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. On 02-Nov-2021, the symptom was confirmed to be resolving, and the patient was discharged from the hospital. The outcome of myocarditis was reported as resolving. Follow-up investigation will be made. Company Comment:	37 years old male with unknown medical history who 3 days after the 2nd dose experienced chest pain and was found to have elevated troponin, and abnormal EKG and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including SARS-CoV-2 test. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and EKG results; a causal relationship cannot be excluded due to the lack of other information.

	The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	
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. 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 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 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. The outcome of pyrexia and myocarditis was reported as unknown. Follow-up investigation will be made. Company Comment: The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	15 years old male with unknown medical history who the same day after the 2nd dose experienced pyrexia, and two days later experienced chest discomfort and was found to have elevated troponin, and CK-MB, and abnormal EKG, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and EKG results; a causal relationship cannot be excluded.
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. 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) and MYOCARDITIS (Acute myocarditis) in a	28 years old male with unknown medical history who 3 days after the 2nd dose experienced chest pain and was found to have elevated myocardial necrosis marker increased (no additional information provided) and cMRI abnormal and was diagnosed with myocarditis. No other

	28-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 immunisation. No Medical History information was reported. 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. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 14-Oct-2021, Magnetic resonance imaging heart: abnormal (abnormal) ABNORMAL: ACUTE MYOCARDITIS. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. No concomitant medication was reported. No treatment medication use was reported. The action taken for Moderna COVID-19 vaccine was Not Applicable. 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	information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the test results and the cMRI results. A causal relationship cannot be excluded due to the incomplete of information.

	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)	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. 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. 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. 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. 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	18 years old male with unknown medical history who same day after the 2nd dose was found to have elevated troponin, and CK and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin. A causal relationship cannot be excluded due to the lack of information.

	(Cardiac troponin increased), BLOOD CREATINE PHOSPHOKINASE INCREASED (Creatine kinase increased) and MYOCARDITIS (Myocarditis) had not resolved. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. Concomitant medications were not reported. Treatment medications were not reported. 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)	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. No Medical History information was reported. On 14-Jul-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 01-Nov-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to .5 milliliter. 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	23 years old male with unknown medical history who the next day after the 2nd dose experienced chest pain an dwas found to have elevated troponin I, fibrin d-dimer, negative SARS-CoV-2 and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events as well as the elevated troponin. A causal relationship cannot be excluded due to the missing information.

	CHEST PAIN and MYOCARDITIS. At the time of the report, MYOCARDITIS (Vaccine myocarditis) and CHEST PAIN (Chest pain) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 02-Nov-2021, Fibrin D dimer: 277 (abnormal) 277. On 02-Nov-2021, Platelet aggregation test: 236 (abnormal) 236. On 02-Nov-2021, Polymerase chain reaction: negative (Negative) Negative. On 02-Nov-2021, SARS-CoV-2 test: negative (Negative) Negative. On 02-Nov-2021, Troponin I: 0.13 (abnormal) 0.13. On 02-Nov-2021, White blood cell count: 12600 (abnormal) 12600. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No concomitant and treatment medication was reported by patient. No chronic diseases were reported by patient. On 3 nov 2021 it was reported that Anti-PF4 test was submitted. Patient was diagnosed with vaccine myocarditis, and was admitted to the ICU for treatment. 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) [redacted]	This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 12-Nov-2021 and was forwarded to Moderna on 12-Nov-2021. This regulatory authority case was reported by a consumer and describes the occurrence of CHEST PAIN (Chest pain) and MYOCARDITIS	38 years old male with unknown medical history who 60 days after the 2nd dose experienced chest pain and was found to have elevated troponin and abnormal EKG that were described as corressponding to typical

	(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. No Medical History information was reported. 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. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 19-Oct-2021, Body temperature: 39.4 39.4 degree Celsius. On 21-Oct-2021, Angiocardiogram: no stenoses in coronary arteries No stenoses in coronary arteries. 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. On 23-Oct-2021, Troponin T: 983.8 983.8 ng/L (nanogram per litre). 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. On 25-Oct-2021, Electrocardiogram: sinus rhythm 61 bpm, ecg normal	myopericarditis, Echo was normal. Patient was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted. According to the WHO causality assessment this report is possible based on temporal association between the adminstratiomn of the vaccine and the ocurrence of the events, even though the TTO is somehow prolonged, as well as the findings of elevated troponin and abnormal EKG; a causal relationship cannot be excluded due to missing information.

	(normal) Sinus rhythm 61 BPM, ECG normal. On 26-Oct-2021, Echocardiogram: echocardiogram was normal (normal) Echocardiogram was normal. Concomitant product use was not provided by the reporter. Treatment information was not provided. Company comment: 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) [redacted]	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. No Medical History information was reported. On 13-Oct-2021, the patient received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) dosage was changed to 100 microgram. 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. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 17-Oct-2021, Blood creatine phosphokinase: 397 u/l (High) Elevated. On 17-Oct-2021, C-reactive protein increased: 27 mg/dl (High) Elevated. On 17-Oct-2021, Echocardiogram: normal (normal) Normal pumping function of the heart with unremarkable wall motion; no pericardial effusion was found.. On 17-Oct-2021, Electrocardiogram: abnormal (abnormal) revealed discrete ST elevations in leads V5, V6, and II.. On 17-Oct-2021, N-terminal prohormone brain natriuretic peptide: 1098 nanogram per litre (High) Increased. On 17-Oct-2021, Troponin: 439 microgram per litre (High) Elevated. On 17-Oct-2021, White blood cell count: 9 gram per litre (normal) normal.	19 years old male with unknown medical history who 2 days after the 2nd dose experienced chest pain and was found to have elevated troponin, Ck, NT-proBNP, abnormal EGC, normal Echo and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and ECG results; a causal relationship cannot be excluded due to the missing of other information.

	For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered MYOCARDITIS (Perimyocarditis) to be possibly related. No concomitant medications were reported. 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. Company Comment: 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. Most recent FOLLOW-UP information incorporated above includes: On 12-Nov-2021: Translated document received on 15-NOV-2021 contains updated event verbatim, lab data and narrative.	
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. 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-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. On 29-Jul-2021, the patient received first dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. 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-	24 years old male with unknown medical history who next day after the 2nd dose experienced chest pain, dyspnea, clod sweat, palpitations, tachycardia, and was found to have elevated troponin, abnormal EGC, SARS-CoV-2 negative, and was diagnosed with myopericarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and ECG results; a causal relationship cannot be excluded due to the missing information.

	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. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 04-Nov-2021, SARS-CoV-2 test: no - negative covid-19 test (Negative) No - Negative COVID-19 test. In November 2021, Blood test: 178 (High) Raised troponin 178, Troponin reference range 0-14. In November 2021, Electrocardiogram: presented as a heart attack presented as a heart attack.	

	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. The diagnosis was made by a Cardiologist. Treatment included paracetamol and unspecified medication. Discharged with medication Bisoprolol and Ramipril. Concomitant product use was not provided by the reporter. 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)	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.	39 years old male with medical history of neuroborreliosis in 2019, who 3 days after the 2nd dose experienced chest pain and was found to have elevated troponin, Ck, and abnormal EGC, and was diagnosed with

	The patient's past medical history included Neuroborreliosis in September 2019. On 26-May-2021, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form. 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. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 26-Jun-2021, Blood creatine phosphokinase (Unknown-<190): 266 (High) 266 U/l. On 26-Jun-2021, Troponin I (Unknown-<100): 3453 (High) 3453 ng/l. On 29-Jun-2021, Blood creatine phosphokinase (Unknown-<190): 80 (normal) 80 U/l. On 29-Jun-2021, Troponin I (Unknown-<100): 600 (High) 600 ng/l. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered MYOCARDITIS (Perimyocarditis) to be possibly related. On 26-Jun-2021, patient suffered thoracic pain and was hospitalized. 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. 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. On 29-Jun-2021, patient was discharged from hospital.	myocarditis. Patient was discharged 3 days later. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and ECG results; a causal relationship cannot be excluded due to the missing information.

	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. Most recent FOLLOW-UP information incorporated above includes: On 15-Nov-2021: Translated document received on 17-NOV-2021. Updated case narrative and event verbatim.	
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. 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.	25 years old male with unknown medical history who next day after the 2nd dose experienced chest discomfort and chest pain, dyspnoea, painful respiration, and was found to have elevated troponin, and was diagnosed with myocarditis. EKG and other diagnosic test results are pending. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin results; a causal relationship cannot be excluded.

	No Medical History information was reported. On 01-Oct-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. 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. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 02-Oct-2021, Chest X-ray: normal (normal) Normal. On 02-Oct-2021, Monocyte count (0.2-1.0): 2.6 (High) MONOCYTES ELEVATED AT 2.6 (RANGE .2-1.0). On 02-Oct-2021, Neutrophil count (0.00-0.04): 0.06 (High) IMMATURE NEUTROPHILS ELEVATED .06 (RANGE .00-.04). 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.). 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). For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medication was given. Patient had to take shallow breaths due to pain in chest when a normal breath is taken Laboratory data was mentioned as patient done respiratory panel and EKG in ED but results was not given.	

	As doctor suspect patient have myocarditis heart acho scheduled for tomorrow. No treatment medication was given. 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. Company Comment: 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 ….. continued in company comment section.	
4.1(b) [redacted]	This case was initially received via 4.1(b) [redacted] (Reference number: 4.1(b) [redacted]) on 16-Nov-2021. The most recent information was received on 18-Nov-	29 years old male with unknown medical history with conflicting information regarding the TTO for all the described events. According to the

	2021 and was forwarded to Moderna on 18-Nov-2021. 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 male patient who received mRNA-1273 (COVID 19 Vaccine Moderna) for COVID-19 vaccination. No Medical History information was reported. 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).	information provided the patient had ejection fraction decreased and myocarditis 2 days after the 2nd dose of Spikevax, but the events of chest pain and tachycardia, dypsnea and elevated troponin were not until 32 days after the 2nd dose of Spikevax. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and EKG results; a causal relationship cannot be excluded.

	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. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):	

	On an unknown date, Ejection fraction: 47 percent (Low) 47 percent. On an unknown date, SARS-CoV-2 test: negative (Negative) Negative. On an unknown date, Troponin: raised (High) raised. The action taken with mRNA-1273 (COVID 19 Vaccine Moderna) (Unknown) was unknown. 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. No concomitant drugs were provided. Patient underwent ECG, echocardiogram, 24 hour heart holter test, blood tests and the results were not provided. 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 Treatment medication reported included Ramparil and biosoprolol. More tests were pending Patient underwent troponin test ,which were raised. 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.	

	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)	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. This case, initially reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref, 4.1(b) 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) On an unknown date, the patient received the 1st dose of this vaccine. 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. 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.	16 years old male with unknown medical history who the same day after the 2nd dose experienced pyrexia, and two days later experienced chest pain and was found to have elevated troponin, CRP, CK-MB, abnormal EKG, and Echo, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and EKG and Echo results; a causal relationship cannot be excluded.

	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. The outcome of myocarditis was reported as ongoing and unchanged. Follow-up investigation will be made. Follow-up received on 10-NOV-2021 Updated: Reporter Information, Patient Information, Other Relevant History, Lab Data, Product Information, Narrative Company Comment: The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	
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. 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. On 21-Sep-2021, at 14:30, the patient received the 1st dose of this vaccine. On unknown date, Myalgia and pyrexia developed. On 19-Oct-2021, at 11:00, the patient received the 2nd dose of this vaccine. On 20-Oct-2021, myocarditis developed. Chest discomfort, chest pain, breathlessness, and the like developed. On 22-Oct-2021, as the symptoms were persisting, the patient visited a nearby hospital. The patient was referred to the	18 years old male with unknown medical history who the next day after the 2nd dose experienced chest pain, chest discomfort, dypsnea, and the next day was found to have elevated troponin, and CK-MB, CRP, abnormal EKG, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and EKG results; a causal

	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. 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. The outcome of myalgia and pyrexia was unknown. The outcome of myocarditis was reported as resolved. Follow-up investigation will be made. Company Comment: The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	relationship cannot be excluded.
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. 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. No Medical History information was reported. On 13-Jun-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form.	20 years old male with unknown medical history who 24 day after the 2nd dose experienced chills, headache, pyrexia, myalgia, and was found to have elevated troponin, and was diagnosed with myocarditis. It was reported that the patient had recently arrived from traveling. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2 which is very important due to the recent travel history. According to the WHO causality assessment this report is

	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. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. No concomitant medications were reported. 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. Company Comment: 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	possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin; a causal relationship cannot be excluded.

	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) [redacted]	This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 17-Nov-2021 and was forwarded to Moderna on 17-Nov-2021. 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. Previously administered products included for COVID-19 immunisation: COVID-19 VACCINE MODERNA in 2021. Past adverse reactions to the above products included No adverse reaction with COVID-19 VACCINE MODERNA. 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)	30 years old male with unknown medical history who 5 days after the 2nd dose experienced pyrexia, dyspnoea, chest pain, nausea, chills, and was found to have elevated troponin, abnormal EKG, abnormal CT scan and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and EKG results; a causal relationship cannot be excluded.

	(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. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 13-Oct-2021, Auscultation: normal (normal) Regular heart rhythm and no murmurs. On 13-Oct-2021, Blood pressure measurement: 121/72 (normal) 121/72 mmHg. On 13-Oct-2021, Electrocardiogram: normal (normal) No signs of ischemia. Regular sinus rhythm and frequency of 71 Beats per minute. On 13-Oct-2021, Fibrin D dimer: < 0.3 (normal) < 0.3 Unit not specified. On 13-Oct-2021, Heart rate: 75 (normal) 75 Beats per minute. On 13-Oct-2021, International normalised ratio: 1.0 (normal) 1.0 Unit not specified. On 13-Oct-2021, Oxygen saturation: 98 (normal) 98 percent. On 13-Oct-2021, Physical examination: normal (normal) Do not seem acutely or chronically affected. Do not seem pain affected. On 13-Oct-2021, Respiratory rate: 16 (normal) 16 Breaths per minute. On 13-Oct-2021, Troponin T: 281 (High) 281 Unit not specified. In October 2021, Computerised tomogram: abnormal (abnormal) with	

	heterogenous charge supporting myocarditis and normal (normal) Of heart, no cardiac sclerosis or stenosis. In October 2021, Electrocardiogram: normal (normal) No EKG changes during the hospitalisation. In October 2021, Troponin T: 529 (High) Maximum measured value of 529 Unit not specified. On 18-Oct-2021, Troponin T: low (Low) Immeasurable low. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medication reported. No Treatment Medication reported. On 13-OCT-2021, patient went for Blood test with unknown result 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)	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. This case, initially 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, at 17:00, acute myocarditis developed. On an unknown date, at the time of hospital visit, the patient had a high fever. Electrocardiogram showed ST	20 years old male with unknown medical history who 2 days after the 2nd dose experienced pyrexia, and was found to have elevated CPK and abnormal EKG, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association

	elevation in I, aVL, and V2-6 with circumferential wall hypokinesis by echocardiography and increased CPK of 424 IU/L, and thus the patient was diagnosed with acute myocarditis. On 01-Oct-2021, the patient was hospitalized. On 08-Oct-2021, the patient was discharged from the hospital. On 12-Nov-2021, the symptom was resolving. Subsequent blood test denied virus as the cause, and based on the course of the disease, the patient was diagnosed with acute myocarditis due to the vaccine. The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. 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.	between the use of the product and the start of the events, as well as the elevated CRP and EKG results; a causal relationship cannot be excluded.
4.1(b) [redacted]	This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) [redacted]) on 13-Nov-2021 and was forwarded to Moderna on 19-Nov-2021. This case, initially reported to the 4.1(b) [redacted] by a (pharmacist), was received via the 4.1(b) (Ref, 4.1(b) [redacted] On 21-Sep-2021, the patient received the 1st dose of the vaccine. On an unknown date, body temperature before the vaccination: 35.1 degrees Celsius. On 19-Oct-2021, at 16:15, the patient received the 2nd dose of the vaccine. On 20-Oct-2021, perimyocarditis developed. The patient experienced pyrexia of 39.0-39.9 degrees Celsius.	28 years old male with unknown medical history who 3 dayw after the 2nd dose experienced pyrexia, chest pain and was found to have elevated troponin, and CK-MB, and abnormal EKG, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and EKG results; a causal

	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. 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. 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. 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. 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. 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.	relationship cannot be excluded.

	The outcome of perimyocarditis was reported as resolved. 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)	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. This case, initially reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref. 4.1(b) On unknown date, the patient received the 1st dose of this vaccine. On 04-Nov-2021, around 16:30, the patient received the 2nd dose of this vaccine. A few hours after the vaccination, the patient experienced malaise and pyrexia. 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. On 06-Nov-2021, the patient was hospitalized with a diagnosis of acute pericarditis. 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. The outcome of malaise, pyrexia, acute pericarditis was reported as resolving. Follow-up investigation will be made.	17 years old male with unknown medical history who next day after the 2nd dose experienced chest pain and was found to have elevated cardiac enzymes and abnormal EKG and was diagnosed with pericarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted.According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated cardiac enzymes and EKG results; a causal relationship cannot be excluded due to the lack of other information.

	Company Comment: The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	
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. 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: 37.2 degrees Celsius. On 05-Nov-2021, at 18:45, the patient received the 2nd dose of this vaccine. On 06-Nov-2021, in the morning, pyrexia and chest discomfort developed. The patient was considered to experience myocarditis. On 07-Nov-2021, at night, the symptoms were exacerbated, and the patient was unable to sleep. Analgesics were ineffective. 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. On 15-Nov-2021, the symptoms were resolving, and the patient was discharged from the hospital. The outcome of myocarditis was reported as resolving. Follow-up investigation will be made.	14 years old male with unknown medical history who the next day after the 2nd dose experienced pyrexia, and chest discomfort and 2 dasy later was found to have elevated troponin, CRP and CPK, and abnormal EKG, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and EKG results; a causal relationship cannot be excluded.

	Company Comment: The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	
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. No Medical History information was reported. 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. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, C-reactive protein increased: 23 mg/l (abnormal) 23 mg/l. On an unknown date, Electrocardiogram: normal (normal) Rhythm normal, ST changes anterior wall (V1-V2).. On an unknown date, Troponin T: 872 ng/l (abnormal) 872 ng/l. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered MYOCARDITIS (Retrosternal pressure) to be possibly related. Concomitant medications was not reported. A small pericardial effusion was noted in the TTE. On Nov 08, 2021, Patinet felt slight pressure on his chest. He had then taken Dafalgan® (paracetamol,dose unknown.	17 years old male with unknown medical history who 3 days after the 2nd dose experienced chest pressure, and was found to have elevated troponin, and CRP, and abnormal EKG with pericardial effusion, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin, CRP and EKG results; a causal relationship cannot be excluded.

	On the day following the second vaccination, the patient developed a mild headache. 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 Most recent FOLLOW-UP information incorporated above includes: 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) [redacted]	This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) [redacted]) on 17-Nov-2021 and was forwarded to Moderna on 23-Nov-2021. This case, initially reported to the 4.1(b) [redacted] by a (physician), was received via the 4.1(b) (Ref, 4.1(b) [redacted] On an unknown date, the patient received the 1st dose of the vaccine. On 02-Aug-2021, the patient received the 2nd dose of the vaccine. 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. 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	38 years old male with unknown medical history who 29 days after the 2nd dose experienced epigastric pain, dypsnea, paresthesia, incomplete paralysis of the left llowere limb. Head MRI showed sporadic cerebral infarctions, and a cardioembolic stroke was suspected. EKG was abnormal, CK/CK-MB were normal, but troponin were elevated, as well as NT-proBNP. cMRI showed findings consistent with myocarditis, and myocarfial biopsy showed lymphocytes infiltration. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for

	the right cerebral hemisphere and left occipital lobe. On 28-Aug-2021, the patient was hospitalized. 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. No significant elevations were found in the pair serum of virus associated with myocarditis. Immunostaining for antibodies of the vaccine was performed using the myocardial biopsy specimens, and the result was positive. Based on the various findings, the symptoms were	SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the well documented information provided in this report; a causal relationship cannot be excluded.

	consistent with myocarditis associated with the vaccine. The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. On an unknown date, pericardial effusions decreased spontaneously. 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. The outcome of myocarditis, sporadic cerebral infarction, and suspected cardioembolic stroke was reported as resolving. Follow-up investigation will be made. Company Comment: The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	
4.1(b) [redacted]	This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) [redacted] on 13-Nov-2021 and was forwarded to Moderna on 23-Nov-2021. This case, initially reported to the 4.1(b) [redacted] by a physician, was received via the 4.1(b) [redacted] (Ref, 4.1(b) [redacted] On an unknown date, the patient received the 1st dose of this vaccine. On 07-Nov-2021, at 09:21, the patient received the 2nd dose of this vaccine. At 5 to 6 hours after the vaccination, headache and pyrexia of the highest 40.1 degrees Celsius. On 08-Nov-2021, the patient had a feeling of heaviness as if the chest was compressed, and antipyretics were taken	14 years old male with unknown medical history who the same day after the 2nd dose experienced pyrexia and headache, next day experienced chest pressure and chest pain, and next days was found to have elevated troponin, CRP, and CK-MB, and abnormal Echo, and was diagnosed with myopericarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association

	every 6 hours. The onset of myocarditis and pericarditis were suspected. 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. On 12-Nov-2021, the patient recovered from the symptoms and was discharged from the hospital. The outcome of headache, pyrexia, chest pressure sensation, chest pain, suspected myocarditis and pericarditis was reported as resolved. Follow-up investigation will be made. Company Comment: The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	between the use of the product and the start of the events, as well as the elevated troponin and Echo results; a causal relationship cannot be excluded.
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. 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 vaccination: 36.4 degrees Celsius. 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.	17 years old male with unknown medical history who the same day after the 2nd dose experienced pyrexia, and two days later experienced chest pain and dypsnea, and was found to have abnormal Echo, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the

	On 08-Nov-2021, breathlessness and chest pain developed. 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. On 16-Nov-2021, the patient recovered from the symptoms and was discharged from the hospital. The outcome of pyrexia and myocarditis was reported as recovered. Follow-up investigation will be made. Company Comment: The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	product and the start of the events, as well as the Echo results; a causal relationship cannot be excluded.
4.1(b) [redacted]	This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) [redacted]) on 20-Nov-2021 and was forwarded to Moderna on 23-Nov-2021. This case, initially reported to the 4.1(b) [redacted] by a pharmacist, was received via the 4.1(b) (Ref, 4.1(b) [redacted] On an unknown date, the patient received the 1st dose of this vaccine. On 23-Oct-2021, the patient received the 2nd dose of this vaccine. On 25-Oct-2021, around 17:30, precordial pain appeared. Deep breathing aggravated the pain. There was no comfortable position for the patient. At 19:30, the patient visited an emergency outpatient department at the reporting hospital and was hospitalized for suspected myocarditis associated	22 years old male with unknown medical history who 2 days after the 2nd dose experienced chest pain, and was found to have elevated CRO, and abnormal EKG, Echo was normal, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated CRP and EKG results; a causal

	with the vaccine. There were no wall motion abnormalities in echocardiography, and wide range of ST elevation and positive Tn-T were shown in electrocardiogram; therefore, the patient was diagnosed with myocarditis. The patient was hospitalized to be followed up. On an unknown date, the peak CPK was 25/39. The inflammatory response gradually decreased, and the patient's subjective symptoms almost disappeared. On 27-Oct-2021, echocardiography was performed, and there was no abnormality in a localized wall motion. On 29-Oct-2021, cardiac MRI was performed, and delayed imaging was not found. On 30-Oct-2021, the patient was discharged from the hospital as the symptoms improved. 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.	relationship cannot be excluded.
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. 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: 36.5 degrees Celsius. On 28-Oct-2021, at 10:30, the patient received the 2nd dose of this vaccine.	22 years old male with unknown medical history who 2 days after the 2nd dose experienced chest discomfort and was found to have elevated troponin, CRP and CK-MB, and abnormal EKG and Echo, and was diagnosed with myopericarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2.

	On 30-Oct-2021, at 04:00, chest pain was noted, and acute pericardial myocarditis developed. 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. 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. On 03-Nov-2021, the patient was discharged from the hospital as the symptoms resolved. The outcome of acute pericardial myocarditis was reported as resolving. Follow-up investigation will be made. Company Comment: The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin, CRP, and EKG results; a causal relationship cannot be excluded.
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. 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	39 years old female with unknown medical history who the same day after the 3rd dose of Spikevax experienced left chest pain, malaise, diaphoresis, that progressed in the 48 hours to fatigue, chills, fever, nausea, headache. 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. Three days after the 3rd dose the patient went to the ED and she was found to have elevated troponin, CRP, NT-proBNP, abnormal EKG, and cardiac MRI identified myopericarditis. Admitted for 1 night. No

	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. Concurrent medical conditions included Penicillin allergy (caused hives in patient) and Allergy to NSAIDs (avoiding due to history of idiopathic angioedema). 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 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	other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the well documented informarion provided in this report; a causal relationship cannot be excluded.

	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) and PYREXIA (Pyrexia) had not resolved and 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) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 08-Nov-2021, C-reactive protein: 29.9 (High) 29.9.	

	On 08-Nov-2021, Electrocardiogram: normal (normal) inverted T waves in V1-2, no ST segment abnormalities. 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. On 08-Nov-2021, N-terminal prohormone brain natriuretic peptide: 657 (High) 657. On 08-Nov-2021, Red blood cell sedimentation rate: 65 (High) 65. On 08-Nov-2021, Troponin: 344 (High) greater than 352, greater than 351, greater than 296. On 09-Nov-2021, Echocardiogram: normal (normal) LV systolic function normal, no segmental LV wall motion abnormalities, EF 60%, global longitudinal strain normal. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Concomitant medications included Calcium/Vitamin D. 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. Admitted for 1 night. Being treated with colch	
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. 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 female patient who received mRNA-1273 (COVID 19 Vaccine Moderna) (batch no. 3004222) for COVID-19 immunisation. No Medical History information was reported. 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. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):	Consumer report for a 19 years old female with unknown medical history who at an unknown TTO after the 2nd dose experienced fatigue, chest pain, dypsnea, tachycardia, and was found to have elevated troponin and was diagnosed with myocarditis. Other diagnostic test were conducted but results were not provided. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events. A causal relationship cannot be excluded due to the lack of information.

	On an unknown date, Troponin: 160 (High) 160 and raised (High) Raised. 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. No Concomitant medication information was reported. No treatment medications were provided.	
4.1(b) [redacted]	This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) [redacted]) on 18-Nov-2021 and was forwarded to Moderna on 24-Nov-2021. This case, initially reported to the 4.1(b) [redacted] by a (pharmacist), was received via the 4.1(b) (Ref, 4.1(b) [redacted] On an unknown date, the patient received the 1st dose of this vaccine. On 19-Oct-2021, the patient received the 2nd dose of this vaccine. The patient was hospitalized. On 20-Oct-2021, headache and pyrexia developed. On 21-Oct-2021, chest pain developed. 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 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	25 years old male with unknown medical history who the next day after the 2nd dose experienced headache and pyrexia, and two days later experienced chest pain and was found to have elevated troponin, and CK, and abnormal EKG, abnormal myocardial biopsy and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and EKG results; a causal relationship cannot be excluded.

	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. At 14:27 CK: 264 U/L, and highly sensitive TNT: 0.358 ng/mL. At 20:00 CK: 258 U/L, and highly sensitive TNT: 0.486 ng/mL. At 23:00 CK: 227 U/L, and highly sensitive TNT: 0.481 ng/mL. On 24-Oct-2021, the patient returned to sinus rhythm. Cardiac ultrasonography showed no significant findings. At 08:09, CK: 166 U/L, and highly sensitive TNT: 0.341 ng/mL. On 25-Oct-2021, at 06:48, CK: 84 U/L, and highly sensitive TNT: 0.140 ng/mL. 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. At 07:35, CK: 83 U/L, and highly sensitive TNT: 0.028 ng/mL. At 08:46, highly sensitive TNT: 0.007 ng/mL. On 01-Nov-2021, at 08:25, highly sensitive TNT: 0.003 ng/mL On 02-Nov-2021, the symptoms were resolving, and the patient was discharged from the hospital. The outcome of chest pain and acute myocarditis was reported as resolving. Follow-up investigation will be made. Company Comment: The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	

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. This case, initially reported to the 4.1(b) by a (physician), was received via the 4.1(b) (Ref, 4.1(b) The patient has a history of bundle branch block right. On 29-Sep-2021, the patient received the 1st dose of this vaccine. On an unknown date, body temperature before vaccination: 36.7 degrees Celsius. On 27-Oct-2021, at 15:30, the patient received the 2nd dose of this vaccine. On 30-Oct-2021, from the morning, the patient experienced left precordial pain and cold sweat. At 10:00, acute pericardial myocarditis developed. 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. On an unknown date, improvements were shown in electrocardiogram, cardiac enzymes, and echocardiography. On 04-Nov-2021, the patient was discharged with improvement of the symptoms. On 06-Nov-2021, cardiac MRI was performed, and the findings were consistent with myocarditis. The outcome of acute pericardial myocarditis was reported as resolving.	21 years old male with medical history of bundle branch block right who 3 days after the 2nd dose experienced chest pain and was found to have elevated troponin, CK and CK-MB, and abnormal EKG, and was diagnosed with myopericarditis. cMRI was performed 6 days later and confirmed the diagnosis of myopericarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and EKG results; a causal relationship cannot be excluded

	Follow-up investigation will be made. Company Comment: The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	
4.1(b) [redacted]	This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) [redacted]) on 17-Nov-2021 and was forwarded to Moderna on 25-Nov-2021. This case, initially reported to the 4.1(b) [redacted] by a physician, was received via the 4.1(b) (Ref 4.1(b) [redacted] On 21-Sep-2021, the patient received the 1st dose of the vaccine. On 22-Sep-2021, the patient merely had a low-grade fever of 37s degrees Celsius. From 28-Sep-2021 to 01-Oct-2021, the patient experienced pyrexia of 38s degrees Celsius, chest discomfort, malaise, and headache. 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. On an unknown date, body temperature before the vaccination: 36.5 degrees Celsius. On 20-Oct-2021, at 17:00, the patient received the 2nd dose of the vaccine. 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.	34 years old male with unknown medical history who the next day after the 2nd dose experienced pyrexia, chest tighnesss and dypsnea, and 4 days later was admitted to the hospital for suspected myopericarditis. This is a well documented case showing findings of Wenckebach type second degree atrioventricular block, but 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. But CRP and BNP were elevated. Patient also had thrombocytosis and increased D-dimer. 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. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the well documented information provided in this report; a causal

	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. [Actual symptoms on admission] 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). <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. <Chest> Cardiac sound: regular without cardiac murmur, respiratory sounds: clear on both lungs. <Abdomen> Flat and soft, and favorable bowel sounds on auscultation. No tenderness and no pain on percussion. No Murphy signs. <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. 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	relationship cannot be excluded.

	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. 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. 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 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.	

	On 31-Oct-2021, findings of Wenckebach type second degree atrioventricular block were intermittently found in the monitor electrocardiogram. There were no subjective symptoms. 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. 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. 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. 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. On 07-Nov-2021, the dose of heparin was gradually decreased to 5,000 units. 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. The outcome of pyrexia, malaise, and headache was reported as resolved. The outcome of chest discomfort was unknown. The outcome of myocarditis, pericarditis, thrombocytosis, Wenckebach type second degree atrioventricular block, and numbness in the right lower limb was reported as resolving. Follow-up investigation will be made. Laboratory test continuation: Leg vein echography: No visible thrombosis was found in the lower extremity venous within the observable range. 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. Plain chest CT: No evidence of respiratory infection.	

	Blood pressure: (right) 125/79 mmHg, (left) 141/82 mmHg. APTT: 3	
4.1(b)	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. No Medical History information was reported. In September 2021, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form. 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. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 12-Oct-2021, Echocardiogram: normal (normal) TTE of Oct 12, 2021 was reported as unremarkable. In October 2021, Blood test: high (High) Trop Peak 1500 ng/l, CRP 200mg/l, CK 147. In October 2021, Electrocardiogram: abnormal (abnormal) EKG result was	21 years old male with unknown medical history who next day after the 2nd dose experienced pyrexia, fatigue and arthalgia, and two days later experienced chest pain and was found to have elevated troponin, and CRP, and abnormal EKG, normal Echo, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and EKG results; a causal relationship cannot be excluded.

	reported as ST-elevation in II, III, aVF, V3-V6, ST reduction.. 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. No concomitant medications were reported. Treatment drug administered included aspirin, then ibuprofen and colchicine. 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. 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. 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. Most recent FOLLOW-UP information incorporated above includes: On 26-Nov-2021: Translated document received on 01 Dec 2021. Added senders comment. Event verbatim and narrative was updated.	
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. This regulatory authority case was reported by an other health care professional and describes the occurrence of CARDITIS (Carditis) and MYOCARDITIS (Myocarditis) 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. Concurrent medical conditions included Allergy to chemicals (Sulphur). 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) (seriousness criterion medically significant), MYOCARDITIS (Myocarditis) (seriousness criterion medically significant), CHEST DISCOMFORT (Chest discomfort), CHEST PAIN (Chest pain), DYSPNOEA (Dyspnoea), PAIN IN EXTREMITY (Pain in extremity), PARAESTHESIA (Paraesthesia), HYPOAESTHESIA (Hypoaesthesia), LYMPHADENOPATHY (Lymphadenopathy), TROPONIN INCREASED (Troponin increased), ELECTROCARDIOGRAM ABNORMAL (Electrocardiogram abnormal), C-REACTIVE PROTEIN INCREASED (C-reactive protein increased), CHEST X-	34 years old female with unknown medical history who next day after the 3rd dose experienced chest pain and chest discomfort and was found to have elevated troponin, CRP, and abnormal EKG, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin, CRP, and EKG results; a causal relationship cannot be excluded.

	RAY NORMAL (Chest X-ray normal), ECHOCARDIOGRAM (Echocardiogram) and LABORATORY TEST (Laboratory test). 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), LYMPHADENOPATHY (Lymphadenopathy), 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) and LABORATORY TEST (Laboratory test) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, C-reactive protein: high (High) High. On an unknown date, Electrocardiogram: abnormal (abnormal) abnormalities. On an unknown date, Troponin: high (High) High. On an unknown date, X-ray: normal (normal) Nothing in lungs. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Patient other Medications included Vyvanse and lexapro 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. 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. Laboratory data included Echocardiogram with unknown results.	
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. 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. The patient's past medical history included Glomerulonephritis. 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	19 years old male with medical history of glomerulonephritis who 2 days after the 2nd dose experienced chest pain, dyspnoea, pyrexia, myalgia, and was found to have elevated troponin, CRP, CKP, and normal Echo, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin, and CRP; a causal relationship cannot be excluded.

	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. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 18-Nov-2021, Blood creatine phosphokinase: 406 (High) 406 at 06:22 and 1038 (High) 1038 at 18:08. On 18-Nov-2021, C-reactive protein increased: 48.7 (High) 48.7. 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. On 18-Nov-2021, Troponin: (High) 0.42 at 05:58 and (High) 1.70 at 18:08. On 19-Nov-2021, Blood creatine phosphokinase: 1061 (High) 1061 at 05:22. On 19-Nov-2021, Troponin: (High) 2.65 at 05:22. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. 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. No concomitant medications provided. No treatment medications provided.	
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. 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), PYREXIA (Pyrexia), SARS-COV-2 TEST NEGATIVE (SARS-CoV-2 test negative), TROPONIN I INCREASED (Troponin I increased), VIRAL TEST NEGATIVE (Viral test negative), VOMITING (Vomiting), PERICARDITIS (Pericarditis) and MYOCARDITIS (Myocarditis) 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. The patient's past medical history included TB in 2009. On 05-Nov-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. 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),	15 years old male with medical history of latent TB s/p 9 mths INH tx with persistent GI symptoms who the next days after the 3rd dose of Spikevax experienced pyrexia, chills, fatigue, and two days later experienced chest discomfort and persisent fever and was found to have elevated troponin, and CK-MB, and abnormal EKG, with normal Echo, and negative SARA-CoV-2 test. Patient was diagnosed with myopericarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin, CRP and EKG results; a causal relationship cannot be excluded.

	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 criteria hospitalization prolonged and medically significant), ELECTROCARDIOGRAM ABNORMAL (Electrocardiogram abnormal) (seriousness criterion hospitalization prolonged), FATIGUE (Fatigue) (seriousness criterion hospitalization prolonged), HYPERHIDROSIS (Hyperhidrosis) (seriousness criterion hospitalization prolonged), 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), VOMITING (Vomiting) (seriousness criterion hospitalization prolonged), PERICARDITIS (Pericarditis) (seriousness criteria hospitalization prolonged and medically significant) and MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization prolonged and medically significant). 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),	

		PYREXIA (Pyrexia), SARS-COV-2 TEST NEGATIVE (SARS-CoV-2 test negative), TROPONIN I INCREASED (Troponin I increased), VIRAL TEST NEGATIVE (Viral test negative), VOMITING (Vomiting), PERICARDITIS (Pericarditis) and MYOCARDITIS (Myocarditis) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 08-Nov-2021, Blood creatine phosphokinase: increased (High) increased. On 08-Nov-2021, Echocardiogram: normal (normal) normal. On 08-Nov-2021, Troponin: increased (High) 0507, 6266. On 08-Nov-2021, Viral test: negative (Negative) Negative. On 09-Nov-2021, Troponin: increased (High) 0910, 2762. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Other Meds : Cetirizine QD prn, Fluticasone Nasal QD, Montelukast 10 mg QD, Loestrin 1.5/30 QD, Omeprazole 40 mg QD. 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	
4.1(b)	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 34-year-old female	34 years old female with medical history of mitral valve prolapse and contraceptive use who 2 days after the 2nd dose of

		patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for an unknown indication. No Medical History information was reported. 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. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Age of the patient was reported as 34.4. The patient had past history of mitral valve prolapse. The patient took contraceptives and denied other medications used. 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 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.	Spikevax experienced shortness of breath, palpitations, dyspnoea on exertion and orthopnea for about two weeks before going to the ER where and ECG showed diffuse Twave inversion and a suspected diagnosis of myocarditis was given. Cardiac enzymes were normal. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the EKG results; a causal relationship cannot be excluded.

		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. Three days later, the patient's symptom subside and electrolyte was corrected. CTA showed no evidence of CAD and Holter showed. 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. The patient was expected to come for a follow-up visit on 02-Dec-2021 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) [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. This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCARDITIS	30 years old male with unknown medical history who 3 days after the 2nd dose experienced pyrexia, chest tighness, palpitatioms, dyspnea, and was found to have elevated troponin, and NT-proBNP, and was

		(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. No Medical History information was reported. 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. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medication were reported No treatment medication were reported 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. This case concerns a 30-year-old male patient with no medical history, who experienced the unexpected serious	diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin results; a causal relationship cannot be excluded.

		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. 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. No Medical History information was reported. 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. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. 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. 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.	26 years old male with unknown medical history who 3 days after the 2nd dose of Spikevax experienced pyrexia, chest tightness and wheezing. Symptoms persisted for 7 days when the pateint went to the hosptal and was found to have elevated cardiac enzymes, and abnormal EKG, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated cardiac enzymes and EKG results; a causal relationship cannot be excluded.

		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. On November 20, 2021, the patient started to suffer from chest tightness in addition to wheezing. 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. 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. Relevant concomitant medications were not provided. Treatment information was not provided. 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.	24 year old male with unknown medical history and who received AstraZeneca Covid-19 vaccine as first dose and 1 day after the second dose of Spikevax experienced chest tightness, fever and chest pain. 2 days later

		No Medical History information was reported. 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. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medications reported. 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. 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 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. 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	the patient went to the cardiology outpatient clinic due to dyspnea and chest pain and was found to have abnormal EKG 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, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated cardiac enzymes and EKG results; a causal relationship cannot be excluded.

		attention as soon as possible in case of chest discomforts. Patient has no history of chronic illness. 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) [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 35-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. Concurrent medical conditions included Mitral valve prolapse. 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.	35 years old female with medical history of mitral valve prolapse and Astrazeneca vaccine as her first dose who 8 days after the 2nd dose experienced chest tighness, loss of conciousness and was taken to the ED where she was found to have pyrexia, elevated blood pressure, elevated troponin, abnormal ECG, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2.

		For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medication were reported. 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 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. 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	According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and EKG results; a causal relationship cannot be excluded.

		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 07-Dec-2021 and was forwarded to Moderna on 07-Dec-2021. This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Acute myocarditis) in a 15-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. Concurrent medical conditions included Overweight. On 13-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On an unknown date, the patient experienced MYOCARDITIS (Acute myocarditis) (seriousness criteria hospitalization prolonged and medically significant). At the time of the report, MYOCARDITIS (Acute myocarditis) had resolved with sequelae. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In September 2021, Magnetic resonance imaging: normal (normal) VI and VD with segmental and global contractility normal Signs of non-ischemic myocardial damage in relation to myocarditis. On 17-Sep-2021, Blood creatine phosphokinase: high (High) 496. On 17-Sep-2021, Electrocardiogram: abnormal (abnormal) RS at 110 bpm. On 17-Sep-2021, SARS-CoV-2 test negative: negative (Negative) Negative. On 17-Sep-2021, Troponin: abnormal (abnormal) 366. On 21-Sep-2021, Echocardiogram: abnormal (abnormal) Trivalva aortic valve, normal appearance and function. Transvalve flow with v of 1.15 m/s. Aorta ascending measures 27 mm in Valsalva sinuses and 21 mm at tubular level. Left auricula of normal size, measures 30 mm on long axis Normal-looking mitral valve Mitral flow E 77 cm/s, A 57 cm/s e ¿lateral 6.3 cm/s e ¿medial 7.1 cm/s E/e	15 years old male with medical history of overweight who 4 days after the 2nd dose was found to have elevated troponin, and CK-MB, and abnormal EKG, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and EKG results; a causal relationship cannot be excluded.

		11.6 Left ventricle with DTD 50 mm, septum 7.8 mm, pp 11.6 mm, VTD 125 ml (68 ml/m2) FE 51%, no contraction alterations would. Right ventricle of normal size and function with TAPSE 19 mm Normal tricuspid and pulmonary valves. Don't spill pericardial. Normal.Measures 15 mm Coronary sinus dilation is observed, suggesting the existence of a persistent left superior vena cava draining into the coronary sinus. We administer agitated physiological serum into vein of the left arm, observing its appearance in the coronary sinus Conclusions VI of normal size with 51% VCSI persistent FE drained to the coronary sinus. On 23-Sep-2021, Echocardiogram: normal (normal) Trivalva aortic valve, normal appearance and function. Transvalve flow with v 1.15 m/s ascending aorta measures 27 mm in sinuses of Valsalva and 21 mm at tubular level.Left auricula normal size, measures 30 mm on long axis Normal-looking mitral valve E 77 cm/s A 57 cm/s and lateral 6.3 cm/s e ¿medial 7.1 cm/s E/E ¿11,6Left ventricle with DTD 50 mm, septum 7.8 mm, pp 11.6 mm, VTD 125 ml (68 ml/m2) FE 51%, without segmental contraction alterations. Right ventricle of normal size and function with TAPSE 19 mmNormal tricuspid and pulmonary valves. No pericardial effusion. Normal IV.Measures 15 mmCoronary sinus dilation is observed, suggesting the existence of a persistent left superior vena cava draining into the coronary sinus. We administer agitated physiological serum into vein of the left arm, observing its appearance in the coronary sinus Conclusions VI of normal size with 51% VCSI persistent FE drained to the coronary sinus. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. Concomitant medications were not provided. Treatment medication was not provided. Company comment: This case concerns a 15-year-old male patient, with no relevant medical history, who experienced the serious expected event of MYOCARDITIS. The event occurred	

		after an unknown time interval after the second dose of the mRNA-1273 vaccine. The rechallenge is not applicable since no information about further dosing has been disclosed. An electrocardiogram, a echocardiogram and a blood test with creatine phosphokinase and troponin dosage were performed with abnormal results. Magnetic resonance imaging was also performed with no signs of myocarditis. The benefit-risk relationship of the mRNA-1273 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 09-Dec-2021 and was forwarded to Moderna on 09-Dec-2021. This regulatory authority case was reported by a physician and describes the occurrence of HYPOXIA (HYPOXIA), MYOCARDITIS (MYOPERICARDITIS), PALPITATIONS (PALPITATIONS), CHEST PAIN (CHEST PAIN) and CHEST DISCOMFORT (CHEST PRESSURE) in a 25-year-old male patient who received mRNA-1273 (Spikevax) (batch no. FE9174) for Vaccination. Previously administered products included for Vaccination: Comirnaty. Past adverse reactions to the above products included No adverse event with Comirnaty. Concurrent medical conditions included Asthma (Mild disease. The patient uses no medications for his asthma.). On 19-Nov-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On an unknown date, the patient experienced HYPOXIA (HYPOXIA) (seriousness criterion hospitalization), MYOCARDITIS (MYOPERICARDITIS) (seriousness criteria hospitalization and medically significant), PALPITATIONS (PALPITATIONS) (seriousness criterion hospitalization), CHEST PAIN (CHEST PAIN) (seriousness criterion hospitalization) and CHEST DISCOMFORT (CHEST PRESSURE) (seriousness criterion hospitalization). At the time of the report, HYPOXIA (HYPOXIA), MYOCARDITIS	35 years old female with medical history ofasthma and Cominarty vaccine as his first dose who 3 days after the 2nd dose with Spikevax experienced chest pain, palpitations, chest discomfort as chest pressure and was hospitalized where he was found to have elevated blood pressure, elevated troponin, abnormal ECG, and Echo and was diagnosed with myopericarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and EKG results; a causal relationship cannot be excluded.

		(MYOPERICARDITIS), PALPITATIONS (PALPITATIONS), CHEST PAIN (CHEST PAIN) and CHEST DISCOMFORT (CHEST PRESSURE) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In November 2021, Blood gases: 9.3 kpa 9.3 kPa (kilopascal). In November 2021, C-reactive protein: 13 mg/l 13 mg/L (milligram per litre) and 37 mg/l 37 mg/L (milligram per litre). In November 2021, Echocardiogram: decreased (Low) Diffuse decreased strain basal segments.. In November 2021, Electrocardiogram: increased (High) ECG shows global ST-elevation.. In November 2021, Fibrin D dimer: normal (normal) Normal. In November 2021, Liver function test: normal (normal) Normal. In November 2021, Physical examination: normal (normal) At examination the patient had nice vitalia and effortless respiration.. In November 2021, Renal function test: normal (normal) Normal. In November 2021, Troponin: 20 ng/l 20 ng/L (nanogram per litre) and 20 ng/l 20 ng/L (nanogram per litre). In November 2021, White blood cell count: normal (normal) Normal. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medication details was provided. No treatment medication details was provided. Company Comment: This is a case of Interchange of vaccine products for this 25-year-old, male subject with a medical history of prior vaccination with Comirnaty vaccine and mild asthma, who experienced the serious expected event of Myopericarditis (AESI) and the serious unexpected events of Hypoxia, Palpitations, Chest pain, and Chest discomfort. These events, which caused	

		hospitalization, occurred 3 days after the second dose of mRNA 1273 Vaccine. Diagnostic tests were done on unknown dates: Troponin was elevated (20 ng/L), C-reactive protein was elevated (13 mg/L, 37 mg/L), ABG's showed mild hypoxemia(9.3kPa), Echocardiography showed diffuse decreased strain in basal segments, ECG showed global ST-elevation). No treatment medication given was mentioned. Rechallenge was not applicable as no information regarding an additional dose was given. At the time of the report, outcome of the events was unknown. The events were considered related to the product per the reporter's assessment. The patient's age and gender, which are predisposing factors for Myopericarditis, and medical history of prior vaccination with Comirnaty vaccine and mild asthma remain as 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 Takeda Pharmaceuticals (Reference number: 4.1(b) on 06-Dec-2021 and was forwarded to Moderna on 13-Dec-2021. 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. On an unknown date, the patient received the 1st dose of this vaccine. On 26-Nov-2021, the patient received the 2nd dose of this vaccine. On 27-Nov-2021, around 20:00, the patient was aware of precordial pain and experienced myocarditis. On 28-Nov-2021, the precordial pain was relieved. Newly, the patient experienced a feeling of suffocation, as if the body had been submerged in water. On 29-Nov-2021, the patient visited a medical institution. The patient was referred to and visited the reporting hospital because of the suspected myocarditis. The blood test performed at the reporting hospital showed an abnormally high value of hsTnI 415.2. No abnormal finding was noted on the electrocardiogram and echocardiography. Family members were asked to follow up with the patient at	25 years old male with unknown medical history who the next day after the 2nd dose experienced chest pain, and two days later was found to have elevated troponin, and normal EKG and Echo, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin; a causal relationship cannot be excluded.

		home. The patient was prescribed a non-steroidal anti-inflammatory drug and returned home. On 03-Dec-2021, at an outpatient visit, the disappearance of symptoms was confirmed. The symptoms were observed to be resolved. The outcome of myocarditis was reported as resolved. 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. Company comment: This is a regulatory authority case concerning a 25-year-old, male patient with no reported medical history, who experienced the expected, serious, AESI event of myocarditis which resulted to hospital consultation. The event myocarditis occurred approximately 1 day after the second dose of mRNA-1273 vaccine administration. Laboratories and Diagnostics were performed as follows, blood test hsTnI 415.2 ng/mL showed abnormally high value while the electrocardiogram and echocardiography showed no abnormal findings. The patient was prescribed a non-steroidal anti-inflammatory drug and returned home. Patient's follow up revealed symptoms resolved and the outcome of myocarditis was reported as resolved. The rechallenge was not applicable. 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 14-Dec-2021 and was forwarded to Moderna on 14-Dec-2021. 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.	40 years old male with medical history of chronic kidney disease stage 5, hypertension,goutn and mesangioproliferative glomerulonephritis, who 31 days after the 2nd dose experienced chest pain, dyspnea, and was found to have pericardial effusion on the echocardiogram and was diagnosed with pericarditis. No other information was provided. Important information is missing in the report including patient's full medical history as well as

		Concurrent medical conditions included Chronic kidney disease stage 5 (CKD Stage -V), High cholesterol, Hypertension, Gout and Mesangioproliferative glomerulonephritis. On 09-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. 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. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Echocardiogram: abnormal (abnormal) small pericardial effusion. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medication was reported. No treatment information was reported. Other medications included furosemide 200 mg BID, verapamil 80, prednisone 10, lipitor 20, labetalol 300 BID and sodium and bicarb and flomax 4.	any other laboratory test conducted, including testing for SARS-CoV-2. Pericardial disease is common in patients with renal disease. Approximately 20% of uremic patients develop uremic pericarditis. In all forms of uremic pericarditis, cardiac tamponade is the main danger, and can be life-threatening, also is more common in dialyzed than in non-dialyzed patients with chronic renal failure . The medical history of the patient of CKD- stage V, hypertension and glomerulonephritis before the occurrence of the events are important risk factors that provide a more plausible explanation for the occurrence of the reported events. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events; a causal relationship cannot be excluded.

		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. 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) [redacted]	4.1(b) [redacted]	This case was received via 4.1(b) [redacted] (Reference number: 4.1(b) [redacted] on 14-Dec-2021 and was forwarded to Moderna on 14-Dec-2021. 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. The patient's past medical history included Obesity.	21-year-old female patient with medical history of obesity, who next day after the 2nd dose of Spikevax fatigue, nausea, headache, chest pain, shortness of breath, vomiting. Found to have sinus tachycardia in the 130s-140s. She was admitted to rule out myocarditis. Diagnostic test included Echocardiogram and Electrocardiogram and both showed myopericarditis; Troponin was normal and CRP was decreased 1 day after vaccine on admission. No other information was provided. Important

		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. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): 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.. On an unknown date, Echocardiogram: showed to clear evidence of myocarditis/pericardit (abnormal) showed to clear evidence of myocarditis/pericarditis.. On an unknown date, Electrocardiogram: showed to clear evidence of myocarditis/pericardit (abnormal) showed to clear evidence of myocarditis/pericarditis.. On an unknown date, Troponin: negative (Negative) Negative.	information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the Echo and EKG results; a causal relationship cannot be excluded.

		For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. No concomitant medications were reported. 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. Treatment medications were not reported. 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. 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),	30 years old male with unknown medical history who the next day after the 2nd dose experienced pyrexia, chest pain, dyspnea, and was found to have elevated troponin, and abnormal EKG, and was diagnosed with myopericarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any

		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. No Medical History information was reported. 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) (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. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Electrocardiogram: abnormal (abnormal) Electrocardiogram with diffuse STE. On an unknown date, Troponin: 440 (Inconclusive) 440, 447 (Inconclusive) 447 and 800 (Inconclusive) 800.	other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and EKG results; a causal relationship cannot be excluded.

		For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No concomitant product use was provided by the reporter. 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. Treatment medication included NSAIDs and colchicine and was improved with treatment. Company comment: 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 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. 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. Previously administered products included for COVID-19 vaccination:	18 years old male with unknown medical history who the 4 days after the 3rd dose experienced fatigue, chest pain, tachycardia, dypsnea, and was found to have elevated troponin, CRP, and abnormal EKG and Echo, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association

		SARS-COV-2 VIRUS and SARS-COV-2 VIRUS. Past adverse reactions to the above products included No adverse event with SARS-COV-2 VIRUS and SARS-COV-2 VIRUS. Concurrent medical conditions included Asthma (on inhalers.). Concomitant products included SALBUTAMOL for Asthma. 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. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 01-Dec-2021, Blood creatine: 73 (abnormal) abnormal. On 01-Dec-2021, Blood potassium: 4.6 (abnormal) abnormal. On 01-Dec-2021, Blood sodium: 136 (abnormal) abnormal. On 01-Dec-2021, Blood urea: 3.0 (abnormal) abnormal. On 01-Dec-2021, C-reactive protein: 17 (abnormal) abnormal. On 01-Dec-2021, Chest X-ray: normal (normal) Normal. On 01-Dec-2021, Echocardiogram: results not provided Results not provided.	between the use of the product and the start of the events, as well as the elevated troponin and EKG results; a causal relationship cannot be excluded.

		On 01-Dec-2021, Electrocardiogram: results not provided Results not provided. On 01-Dec-2021, Full blood count: hb 160, wc 10.3 (abnormal) Hb 160, WC 10.3. On 01-Dec-2021, SARS-CoV-2 test: negative (Negative) No - Negative COVID-19 test. On 01-Dec-2021, Troponin: 759 (abnormal) abnormal. On 03-Dec-2021, Troponin: 6023 (abnormal) abnormal. On 06-Dec-2021, C-reactive protein: 3 (abnormal) abnormal. On 07-Dec-2021, Magnetic resonance imaging heart: epicardial oedema (abnormal) Epicardial oedema. For mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. 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. Concomitant medication included INHALERS. 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. 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 Takeda Pharmaceuticals (Reference number: 4.1(b) on 08-Dec-2021 and was forwarded to Moderna on 14-Dec-2021. 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.	28 years old male with unknown medical history who the 3 days after the 2nd dose experienced chest pain and was found to have elevated troponin, and CK-MB, and abnormal EKG, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and EKG results; a causal relationship cannot be excluded.

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. 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. 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. Previously administered products included for Product used for unknown indication: 152686.04.003 on 15-May-2021. Past adverse reactions to the above products included Ramsay-Hunt syndrome with 152686.04.003. Concomitant products included ELASOMERAN (COVID-19 VACCINE MODERNA) for COVID-19 vaccination. 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)	38 years old male with medical history of Ramsay-Hunt syndrome who 71 days after the 2nd dose experienced fatigue, chest pain, dyspnea, palpitations, flank pan, peripheral swelling, and gastric ulcer and was found to have abnormal EKG, and was diagnosed with pericarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the EKG results; a causal relationship cannot be excluded.

		(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. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Electrocardiogram: result not reported No information. On an unknown date, X-ray: result not reported No information. Patient has not had symptoms associated with COVID-19 not had a COVID-19 test not tested positive for COVID-19 since vaccine. 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. 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 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 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. 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 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. The patient's past medical history included Substance user (Previous monthly user of 4.1(b) but nothing since summer 2021) in 2021. Previously administered products included for COVID-19 immunisation: SPIKEVAX in 2021.	28-year-old male with medical history of substance Abuse 4.1(b) who next day after the 2nd dose of Spikevax experienced Dyspnoea, Pyrexia, Malaise, Chest discomfort, Myalgia and was found to have elevated troponing, CRP, and normal Echo, with ECG abnormal and investigation (not especify) showing myopericarditis without pericardial effusion. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test

		Past adverse reactions to the above products included No adverse event with SPIKEVAX. Concurrent medical conditions included Cigarette smoker (Smokes 5 cigarettes per week). 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 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. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In November 2021, Cardiac telemetry: no arrhythmias No arrhythmias. In November 2021, Echocardiogram: nothing abnormal, no pericardial accumulation Nothing abnormal, no pericardial accumulation. 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.	conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and EKG results; a causal relationship cannot be excluded.

		On 20-Nov-2021, C-reactive protein: 68 (At hospitalisation) 68 Unit not specified. On 20-Nov-2021, Troponin T: 139 (At hospitalisation) 139 Unit not specified. On 21-Nov-2021, C-reactive protein: 31 (At discharge) 31 Unit not specified. On 21-Nov-2021, Investigation: perimyocarditis without pericardial effusion (abnormal) Perimyocarditis without pericardial effusion and slight enzyme emission Slight enzyme emission. On 21-Nov-2021, Physical examination: feeling well and without pain Feeling well and without pain. On 21-Nov-2021, Troponin T: 83 (At discharge) 83 Unit not specified. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medication were reported. No treatment medication were reported. This is a regulatory authority case concerning a 28-year-old, male patient with past medical history of substance Abuse (4.1(b) 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 (4.1(b) 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 Takeda Pharmaceuticals (Reference number: 4.1(b)) on 13-Dec-2021 and was forwarded to Moderna on 17-Dec-2021. This case, initially reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref,	35 years old female with unknown medical history who 3 days after the 2nd dose experienced not described events and was found to have abnormal Echo, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report

		4.1(b) Myocarditis was assessed as serious by the MAH. 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. 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. 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.	including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the Echo results; a causal relationship cannot be excluded.
4.1(b)	4.1(b)	This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b)) on 14-Dec-2021 and was forwarded to Moderna on 17-Dec-2021. This case, initially reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref, 4.1(b) On 17-Oct-2021, the patient received the 1st dose of the vaccine. On 14-Nov-2021, around noon, the patient received the 2nd dose of the vaccine. On 15-Nov-2021, at 08:00, the patient experienced chest pain with pyrexia, chest tightness, and dyspnea. Thereafter, the symptoms were relieved temporarily. Around 23:00, symptoms were aggravated. On 16-Nov-2021, at 03:00, the patient visited an emergency outpatient department. Electrocardiogram showed ST elevations in chest leads with increased CPK, and the patient was referred to and admitted to the reporting hospital with suspected acute myocarditis. The emergency coronary angiography revealed no significant stenosis, and myocardial biopsy showed no appreciable findings.	16 years old male with unknown medical history who the next day after the 2nd dose experienced pyrexia, chest pain, chest tighness, and dypsnea and was found to have elevated troponin, and CK-MB, and abnormal EKG, myocardial biopsy showed no important findgings and cMRIS showed acute myocarditis. Myocarditis was considered mild No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of

		Cardiac MRI showed a finding of oedema in the left ventricular lateral wall which was suggestive of acute myocarditis. On an unknown date, the symptoms improved spontaneously with a follow up. Left ventricular asynergy, which was found by echocardiography, was relieved spontaneously. As CPK increased only to 700 U/L, the myocarditis was considered to be mild. On 25-Nov-2021, the patient was doing well. The symptoms resolved, and the patient was discharged from the hospital. The outcome of chest pain and suspected acute myocarditis was reported as resolved. Follow-up investigation will be made. Company Comment: The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. LP company comment: The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship Company comment: This case concerns a 16-year-old male patient with no relevant medical history, who experienced the serious expected event of Myocarditis (AESI), as well as serious unexpected event of Chest pain. AS per case description, one day after the administration of the second dose, the patient developed chest pain with pyrexia, chest tightness and dyspnea. Thereafter, the symptoms were relieved temporarily. However, in the evening, symptoms were aggravated and the patient visited an emergency outpatient department. ECG showed ST elevations,CPK was increased, and the patient was admitted to the hospital with suspected acute myocarditis. The emergency coronary angiography revealed no significant stenosis, and myocardial biopsy showed no appreciable findings. Left ventricular asynergy was found by echocardiography. Cardiac MRI showed a finding of oedema in the left ventricular lateral wall which was suggestive of acute myocarditis. At the time of the report, the events had resolved and the patient was discharged from the hospital. The re-challenge is not applicable in line	the events, as well as the elevated troponin and other diagnostic results; a causal relationship cannot be excluded.

		with source document, as it was stated that no rechallenge was done and recurrence is 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 Takeda Pharmaceuticals (Reference number: 4.1(b)) on 16-Dec-2021 and was forwarded to Moderna on 20-Dec-2021. 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. No Medical History information was reported. 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. 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. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 31-Oct-2021, Blood test: normal (normal) No abnormalities. On 31-Oct-2021, Electrocardiogram: normal (normal) No abnormalities. On 01-Nov-2021, Blood test: abnormal (abnormal) Diagnosed with acute myocarditis. On 01-Nov-2021, Echocardiogram: abnormal (abnormal) Diagnosed with acute myocarditis. On 01-Nov-2021, Electrocardiogram: abnormal (abnormal) Diagnosed with acute myocarditis.	18 years old male with unknown medical history who the 2 days after the 2nd dose was found to have abnormal EKG and Echo suggestive of myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the EKG and echo results; a causal relationship cannot be excluded.

		On an unknown date, Body temperature: 36.6 (normal) 36.6 degree Celsius. For mRNA-1273 (COVID-19 Vaccine Moderna Intramuscular Injection) (Intramuscular), the reporter considered MYOCARDITIS (Acute myocarditis) to be possibly related. 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. This regulatory authority case was reported by a physician and describes the occurrence of the first episode of CHEST PAIN (Chest pain), DYSPNOEA (Breath shortness), the second episode of CHEST PAIN (Chest pain), FATIGUE (Fatigue), CHEST PAIN (Chest Pain), DYSPNOEA (Dyspnoea), TACHYCARDIA (Tachycardia), PAIN (Generalised aching), DYSPNOEA (Shortness of breath), PERICARDIAL EFFUSION (Pericardial effusion), MYOCARDITIS (Myocarditis) and PERICARDITIS (Pericarditis) in a 39-year-old female patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for COVID-19 vaccination.	39 years old female with unknown medical history and the Astrazeneca vaccine as the primary series for Covid-19 vaccination, who the next day after the 3rd dose experiencedchest pain, dyspnea, fatigue, tachycardia, generalized pain, and was found to have elevated troponin, CRP, and abnormal EKG, and echo with pericardial effusion and was diagnosed with myopericarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including

		Co-suspect product included non-company product COLCHICINE for an unknown indication. 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. On 08-Dec-2021, the patient received third dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On an unknown date, the patient started COLCHICINE (unknown route) at an unspecified dose. On 08-Dec-2021, the patient experienced the first 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 FATIGUE (Fatigue) (seriousness criteria hospitalization, disability, medically significant and life threatening), CHEST PAIN (Chest Pain) (seriousness criteria hospitalization, disability, medically significant and life threatening), DYSPNOEA (Dyspnoea) (seriousness criteria hospitalization, disability, medically significant and life threatening), TACHYCARDIA (Tachycardia) (seriousness criteria hospitalization, disability, medically significant and life threatening), PAIN (Generalised aching) (seriousness criteria hospitalization, disability, medically significant and life threatening), DYSPNOEA (Shortness of breath) (seriousness criteria hospitalization, disability, medically	testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and EKG and echo results; a causal relationship cannot be excluded.

		significant and life threatening) and PERICARDIAL EFFUSION (Pericardial effusion) (seriousness criteria hospitalization, disability, medically significant and life threatening). At the time of the report, DYSPNOEA (Breath shortness), the last episode of CHEST PAIN (Chest pain), MYOCARDITIS (Myocarditis) and PERICARDITIS (Pericarditis) had not resolved, FATIGUE (Fatigue), CHEST PAIN (Chest Pain), DYSPNOEA (Dyspnoea), TACHYCARDIA (Tachycardia) and PAIN (Generalised aching) outcome was unknown and DYSPNOEA (Shortness of breath) and PERICARDIAL EFFUSION (Pericardial effusion) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 13-Dec-2021, Chest X-ray: abnormal (abnormal) Slightly enlarged heart. On 13-Dec-2021, Computerised tomogram thorax: abnormal (abnormal) Small pericardial effusion. On 13-Dec-2021, SARS-CoV-2 test: negative (Negative) No - Negative COVID-19 test. On 13-Dec-2021, Troponin: elevated (High) Elevated. On 14-Dec-2021, Echocardiogram: abnormal (abnormal) Pericardial effusion. On an unknown date, Blood test: result not provided (Inconclusive) Result not provided. On an unknown date, C-reactive protein: 345 345. On an unknown date, Ejection fraction: 40 40%. For mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. No medical history was provided by the reporter. 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. 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. Patient not tested positive for COVID-19 since she had the vaccine and not had symptoms associated with COVID-19. It was reported that the event was relate to possible myocarditis or pericarditis Patient did few tests like ECHO, Troponin, Basic blood test. Patient had Myocarditis and pericarditis. 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. Most recent FOLLOW-UP information incorporated above includes: On 19-Dec-2021: Follow up document received contains, events and lab investigation were added, action taken was updated.	
4.1(b)	4.1(b) [redacted]	This literature-non-study case was reported in a literature article and describes the occurrence of MYOCARDITIS (Acute myocarditis) in a 20-year-old male patient who received mRNA-1273 (COVID-19 Vaccine	Literature report on a 20-yearold male who presented with on-going chest pain for the preceding 6 hours. The patient had no significant

		Moderna) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. LITERATURE REFERENCE: Abellan C, Vivekanantham H, Mahmoudi A, Cook S, Doll S, Arroyo D. A case series of acute myocarditis associated with SARS-CoV-2 mRNA vaccination. Cardiovasc Med. 2021;24:w10103 Concurrent medical conditions included Cannabis use (regular cannabis consumer). On an unknown date, the patient received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (unknown route) 1 dosage form. On an unknown date, the patient experienced MYOCARDITIS (Acute myocarditis) (seriousness criteria hospitalization and medically significant). an unknown date, the patient experienced CHILLS (Chills), NAUSEA (Nausea) and VOMITING (Vomiting). The patient was hospitalized for 3 days due to MYOCARDITIS. The patient was treated with LISINOPRIL ongoing since an unknown date for Adverse event, at a dose of 10 milligram. At the time of the report, MYOCARDITIS (Acute myocarditis), CHILLS (Chills), NAUSEA (Nausea) and VOMITING (Vomiting) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Angiogram: normal (normal) Coronary angiography revealed normal coronary arteries. On an unknown date, Blood creatine phosphokinase: 529 u/l 529 U/l and 786 u/l (High) 786 U/l (on day 2). On an unknown date, C-reactive protein: 28 mg/l 28 mg/l. On an unknown date, Ejection fraction: 55 percent 55 percent with apical hypokinesia. On an unknown date, Electrocardiogram: abnormal (abnormal) Initial 12-lead ECG showing sinus rhythm at 66 bpm with an incomplete right bundle branch block pattern and significant ST-segment elevation in leads II, III, aVF and from V4 to V6. ST segment depression and	medical history and was a regular cannabis consumer. Three days earlier, he received the second dose of the Moderna vaccine against SARS-CoV-2. The next day, he suffered from fever, chills, nausea and vomiting. The patient was afebrile, stable and in mild distress, with physical examination being unremarkable. Coronary angiography revealed normal coronary arteries Relevant laboratory findings were: high-sensitive cardiac troponin T elevated, CK elevated, NTproBNP elevated, CRP elevated, PCR was negative for SARS-CoV-2. Echo and ECG abnormal. On day 3, cardiac magnetic resonance imaging (CMR) showed two areas of marked subepicardial late gadolinium enhancement (LGE), in basal to mid, and apical lateral walls, with signs of inflammation/oedema on dedicated sequences (short-tau inversion recovery [STIR]), and minimal pericardial effusion. Patient was discharged on day 4 on lisinopril 10 mg once daily (OD). According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the well document information provided by the authors; a causal relationship cannot be excluded.

		inverted T wave in leads aVR, V1 and V2 can be seen.. On an unknown date, Magnetic resonance imaging: abnormal (abnormal) showed two areas of marked subepicardial late gadolinium enhancement (LGE), in basal to mid, and apical lateral walls, with signs of inflammation/oedema on dedicated sequences(short-tau inversion recovery [STIR]), and minimal pericardial effusion (on day 3).. On an unknown date, N-terminal prohormone brain natriuretic peptide: 328 ng/l 328 ng/l normal value: <300 pg/ml. On an unknown date, SARS-CoV-2 test: negative (Negative) Negative. On an unknown date, Troponin T (<14 ng/l-Unknown): 607 ng/l (High) 607 ng/l and 1139 ng/l (High) 1139 ng/l (on day 2). For mRNA-1273 (COVID-19 Vaccine Moderna) (Unknown), the reporter considered MYOCARDITIS (Acute myocarditis), CHILLS (Chills), NAUSEA (Nausea) and VOMITING (Vomiting) to be related. No concomitant medication were reported. The patient was afebrile, stable and in mild distress, with physical examination being unremarkable. The patient had chest pain and pyrexia. Company comment: This literature report from 4.1(b) reported by other HCP concerns a 20 year-old, male patient with no relevant medical history, who experienced the serious (due to hospitalization) expected, – according to 4.1(b) SmPC AESI of myocarditis and the non serious expected, – according to 4.1(b) SmPC events of chills, nausea and vomiting. The events occurred after the second dose of mRNA-1273 vaccine, exact dates not provided. The patient presented with chest pain 3 days after vaccination and developed fever, chills, nausea and vomiting. The patient was hospitalized for 4 days, received treatment with Angiotensin-converting-enzyme inhibitors and was discharged on	

		lisinopril. The outcome of the events was recovered. The rechallenge was not applicable, as the events were 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. This case was linked to 4.1(b) [redacted] (Patient Link).	
4.1(b) [redacted]	4.1(b) [redacted]	This literature-non-study case was reported in a literature article 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. The occurrence of additional non-serious events is detailed below. LITERATURE REFERENCE: Abellan C, Vivekanantham H, Mahmoudi A, Cook S, Doll S, Arroyo D. A case series of acute myocarditis associated with SARS-CoV-2 mRNA vaccination. Cardiovasc Med. 2021;24:w10103 No Medical History information was reported. On an unknown date, the patient received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (unknown route) 1 dosage form. On an unknown date, after starting mRNA-1273 (COVID-19 Vaccine Moderna), the patient experienced MYOCARDITIS (Acute myocarditis) (seriousness criteria hospitalization and medically significant) and INFLUENZA LIKE ILLNESS (flu-like symptoms). The patient was hospitalized for 2 days due to MYOCARDITIS. The patient was treated with LISINOPRIL ongoing since an unknown date for Adverse event, at a dose of 5 milligram once a day. At the time of the report, MYOCARDITIS (Acute myocarditis) and INFLUENZA LIKE ILLNESS (flu-like symptoms) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):	Literature report for a 21-year-old healthy male presented with acute onset chest pain. Two days earlier, he had received the second of Spikevax and he developed flu-like symptoms and fever. The patient was afebrile and in no distress. Physical examination. was unremarkable. He was found to have elevated troponin, CK, NT-proBNP, negative RT-PCR for SARSCoV-2. CMR performed on the same day showed lateral wall subepicardial LGE. The patient was discharged on day 3 on lisinopril 5 mg OD. Patient was asymptomatic and doing well at 1-month clinical assessment. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the well document information provided by the authors; a causal relationship cannot be excluded.

		On an unknown date, Blood creatine phosphokinase: 516 u/l 516 U/l and 652 u/l 652 U/l. On an unknown date, C-reactive protein: 94 mg/l 94 mg/l. On an unknown date, Culture throat: negative RT-PCR was negative for SARS-CoV-2. On an unknown date, Echocardiogram: normal normal LVEF. On an unknown date, Electrocardiogram: 91 bpm Initial 12-lead ECG showing a sinus rhythm at 91 bpm with diffuse concave ST-segment elevation, and PR segment depression.. On an unknown date, Magnetic resonance imaging: abnormal (abnormal) showed lateral wall subepicardial LGE. On an unknown date, N-terminal prohormone brain natriuretic peptide: 178 ng/l 178 ng/l. On an unknown date, SARS-CoV-2 test: negative (Negative) Negative. On an unknown date, Troponin T: 523 ng/l High-Sensitivity Cardiac Troponin T - 523 ng/l and 552 ng/l 552 ng/l. For mRNA-1273 (COVID-19 Vaccine Moderna) (Unknown), the reporter considered MYOCARDITIS (Acute myocarditis) and INFLUENZA LIKE ILLNESS (flu-like symptoms) to be related. The patient was afebrile and in no distress. Physical examination was unremarkable. The patient had chest pain and pyrexia. The patient was admitted and started on an ACEi. CMR performed on the same day showed lateral wall subepicardial LGE No concomitant medications were not reported. Company comment: This literature report from 4.1(b) reported by other HCP concerns a 21 year-old, male patient with no reported medical history, who experienced the serious (due to hospitalization) expected, – according to 4.1(b) SmPC AESI of myocarditis and the non serious unexpected, – according	

		to 4.1(b) SmPC event of Influenza like illness. The events occurred after the second dose of mRNA-1273 vaccine, exact dates not provided. The patient presented with chest pain two days after vaccination and developed Influenza like illness and pyrexia. The patient was hospitalized for 3 days, received treatment with Angiotensin-converting-enzyme inhibitors and was discharged on lisinopril. The outcome of the events was recovered. The rechallenge was not applicable, as the events were 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. This case was linked to 4.1(b) [redacted] (Patient Link).	
4.1(b) [redacted]	4.1(b) [redacted]	This case was received via 4.1(b) [redacted] (Reference number: 4.1(b) [redacted] on 21-Dec-2021 and was forwarded to Moderna on 21-Dec-2021. 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. No Medical History information was reported. 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	25 years old male with unknown medical history who the next day after the third dose experienced chest pain and was found to have elevated troponin, and CRP, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and EKG results; a causal relationship cannot be excluded.

		(C-reactive protein increased), CHEST PAIN (Chest pain), MYOCARDITIS (Myocarditis) and TROPONIN (Troponin) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, C-reactive protein: elevated (High) Elevated C-reactive protein. On an unknown date, Troponin: 12 (High) 12. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Symptom Text: Myocarditis Troponin = 12 Required hospital admission Sxs = severe, worsening chest pain beginning approximately 24hrs following booster dose. 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. 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	23 years old male with unknown medical history who 4 days after the 3rd dose experienced chest oain, nausea, tachycardia, and was found to have elevated troponin, fibrn d-dimer, CRP, abnormal ECG, cMRI, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO

		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. Concurrent medical conditions included Schizophrenia. 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 COMPUTERISED TOMOGRAM THORAX NORMAL (Computerised tomogram thorax normal) (seriousness criterion hospitalization). At the time of the report, C-REACTIVE	causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the well documented diagnostic test results; a causal relationship cannot be excluded.

		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. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 01-Dec-2021, C-reactive protein: high (High) high. On 01-Dec-2021, Chest X-ray: normal (normal) normal. On 01-Dec-2021, Computerised tomogram: normal (normal) no pulmonary embolism. On 01-Dec-2021, Echocardiogram: abnormal (abnormal) myocarditis. On 01-Dec-2021, Electrocardiogram: abnormal (abnormal) abnormal. On 01-Dec-2021, Fibrin D dimer: elevated (High) elevated. On 01-Dec-2021, Magnetic resonance imaging: abnormal (abnormal) myocarditis. On 01-Dec-2021, Tachycardia: 120 (High) 120bp. On 01-Dec-2021, Troponin: 7.9 (High) Blood drawn troponin 7.9. On 01-Dec-2021, Ultrasound scan: abnormal (abnormal) mild effusion. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No treatment medications were provided Other Medication provided 300 mg, clozapine 20 mg, Lexapro 200 mg, Minocycline 750 mg, metformin 1000 mg, omega 3	

		Patient experienced myocarditis 4 days after vaccination Patient was experienced Exhaustion patient went to ER and admitted in hospital on 01 Dec 2021 to 02 Dec 2021 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. 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. Concurrent medical conditions included Chiari malformation, Scoliosis, Anxiety and Depression. 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	24-year-old male patient with no relevant medical history who 3 days after the 3rd dose of Spikevax was found to have CRP elevated, Troponin elevated, EKG - with mild ST segment elevation, Echo showed normal LV size and systolic function, no pericardial effusion. The event was managed as outpatient with colchicine and ibuprofen.No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and EKG results; a causal relationship cannot be excluded.

		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 (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. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 22-Nov-2021, C-reactive protein: 5.0 (High) C Reactive protein - 5.0mg/dL (elevated). On 22-Nov-2021, Electrocardiogram ST segment: elevation (High) EKG - with mild ST segment elevation. 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. On 29-Nov-2021, Echocardiogram: normal (normal) normal LV size and systolic function, no pericardial effusion. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Other medications include Duloxetine, Trazadone, hydroxyzine. 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. 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) [redacted]	4.1(b) [redacted]	This literature-non-study case was reported in a literature article and describes the occurrence of MYOCARDITIS (recurrent myopericarditis) in a 20-year-old male patient who received mRNA-1273 (COVID 19 Vaccine Moderna) for COVID-19 vaccination. LITERATURE REFERENCE: Umei TC, Kishino. Recurrence of myopericarditis following mRNA COVID-19 vaccination in a male adolescent. CJC Open. 2021 The patient's past medical history included Myopericarditis (intial episode of influenza virus-induced myopericarditis.) in 2016. On an unknown date, the patient received second dose of mRNA-1273 (COVID 19 Vaccine Moderna) (unknown route) 1 dosage form. On an unknown date, the patient experienced MYOCARDITIS (recurrent myopericarditis) (seriousness criterion medically significant). At the time of the report, MYOCARDITIS (recurrent myopericarditis) outcome was unknown. For mRNA-1273 (COVID 19 Vaccine Moderna) (Unknown), the reporter considered MYOCARDITIS (recurrent myopericarditis) to be related. No relevant concomitant medications were reported. No treatment information was provided.	Literature report for a 20-year-old male adolescent with history of seasonal influenza virus-induced myopericarditis in 2016 who 2 days after the 2nd dose of Spikevax had fever and severe sharp chest pain in deep breathing improved by sitting up. The patient had been well and free from any flu-like illnesses a couple of months before admission. ECG showed global ST–T wave elevation. Echo showed regional hypokinesis of the anteroseptal wall, an ejection fraction 1 of 53.8%, and no pericardial effusion. cMRI showed suggestive findings for acute myocarditis. CK and troponin were elevated. SARS-CoV and Influenza test were negative as well as any other virus test conducted. His symptoms gradually resolved, and he was discharged on day 5. He remained stable and his left ventricular function improved one month after discharge. According to the WHO causality assessment this report is probable based on temporal association between the use of the product and the start of the events, as well as the well document information presented in this article; a

		Comapny comment: This is a literature case concerning a 20 year-old, male patient with a history of myocarditis (induced by influenza virus), who experienced the serious (due to medically important condition) expected, according CCDS, AESI of myocarditis. The event occurred on an unknown date after the second dose of the mRNA-1273 vaccine, date not provided. The rechallenge was not applicable, as the event was reported exclusively after the second dose and no information on additional dosing is available. The medical history, of myocarditis (induced by influenza virus) remains a confounder. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.	causal relationship cannot be excluded. His previous medical history of myocarditis remains a confounder.
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. 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. Previously administered products included for COVID-19 immunisation: SPIKEVAX on 04-Sep-2021. Past adverse reactions to the above products included No adverse event with SPIKEVAX. 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	33-year-old male patient with unknown medical history, who the next day after his 2nd dose of Spikevac experienced chest pain, malaise and feeling cold and was found to have elevated troponin and normal ECG and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events. A causal relationship cannot be excluded due to the lack of information.

		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. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In October 2021, Electrocardiogram: normal (normal) Normal sinus rhythm. In October 2021, Troponin I: low (Low) Decreased from 210 to 40 in one day. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medications reported. Treatment details were not provided. 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 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) [redacted]	4.1(b) [redacted]	This case was received via 4.1(b) [redacted] (Reference number: 4.1(b) [redacted]) on 21-Dec-2021 and was forwarded to Moderna on 21-Dec-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of ADENOVIRUS TEST	25 years old male with unknown medical history who the next day after his 3rd dose of Spikevax presented with chest pain, he was found to have elevated troponin (EKG non-ischemic, no

		(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. No Medical History information was reported. 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	arrhythmia; BP and HR normal) and was diagnosed with myocarditis. Full viral test panel were conducted and all were negative. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events. A causal relationship cannot be excluded due to the lack of information.

		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 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. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 06-Dec-2021, Adenovirus test: negative (Negative) Negative. On 06-Dec-2021, Influenza B virus test: negative (Negative) Negative. On 06-Dec-2021, Metapneumovirus infection: negative (Negative) Negative. On 06-Dec-2021, Parainfluenzae virus infection: negative (Negative) Negative.	

		On 06-Dec-2021, Pneumonia influenzal: negative (Negative) Negative. On 06-Dec-2021, Polymerase chain reaction: negative (Negative) Negative. On 06-Dec-2021, Rhinovirus infection: negative (Negative) Negative. On 06-Dec-2021, Troponin: elevated troponin (High) elevated troponin. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. 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. No concomitant medications provided. No treatment medications provided. 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.	
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. 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. This case, initially reported to the 4.1(b)	21 years old male with unknown medical history who 3 days after the 2nd dose experienced chest pain and was found to have elevated troponin, and normal EKG and echo, and was diagnosed with myocarditis. Patient was discharged 2 days later. No other information was provided. Important information is missing in the report including

		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. Company Comment: The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin; a causal relationship cannot be excluded.
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. This case, reported to the 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	22 years old male with unknown medical history who 3 days after the 2nd dose experienced pyrexia, and chest pain and was found to have elevated CPK, and abnormal Echo, myocardial biopsy showed inflitratioin of inflamatory cells was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the

		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.	product and the start of the events, as well as document results including the myocardial biopsy; a causal relationship cannot be excluded.
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. 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 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,	14 years old male with unknown medical history who 3 day after the 2nd dose experienced chest pain and was found to have elevated troponin, and CK-MB, and abnormal EKG, abnormal cMRI and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and EKG results; a causal relationship cannot be excluded.

		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.	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 23-Dec-2021 and was forwarded to Moderna on 23-Dec-2021. 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. 3004730) for COVID-19 vaccination. Previously administered products included for COVID-19 immunisation: SPIKEVAX on 31-Aug-2021. Past adverse reactions to the above products included No adverse event with SPIKEVAX. On 28-Nov-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On an unknown date, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criterion medically significant). At the time of the report, MYOCARDITIS (Myocarditis) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In 2021, C-reactive protein: high (High) Elevated. In 2021, Cardiac telemetry: normal (normal) normal. In 2021, Echocardiogram: normal (normal) normal. In 2021, Troponin T: high (High) Elevated. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No concomitant product use was provided by the reporter.	20 years old male with unknown medical history who at an unknown TTO after the 2nd dose was found to have elevated troponin, and CRP, normal EKG, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and CRP results; a causal relationship cannot be excluded.

		No treatment medications were reported.	
4.1(b)	4.1(b)	This case was received via Medison Pharma Ltd. (Reference number: 4.1(b) on 23-Dec-2021 and was forwarded to Moderna on 26-Dec-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of CHEST PAIN (stabbing pain in her chest) and MYOCARDITIS (Perimyocarditis) in a 33-year-old female patient who received mRNA-1273 (COVID 19 Vaccine Moderna) (batch no. 3001659) for COVID-19 vaccination. The patient's past medical history included COVID-19 in February 2021. Family history included IHD since an unknown date. On an unknown date, the patient received first dose of mRNA-1273 (COVID 19 Vaccine Moderna) (unknown route) 1 dosage form. On an unknown date, received second dose of mRNA-1273 (COVID 19 Vaccine Moderna) (unknown route) dosage was changed to 1 dosage form. On an unknown date, the patient experienced CHEST PAIN (stabbing pain in her chest) (seriousness criterion hospitalization) and MYOCARDITIS (Perimyocarditis) (seriousness criteria hospitalization and medically significant). The patient was hospitalized for 2 days due to CHEST PAIN and MYOCARDITIS. At the time of the report, CHEST PAIN (stabbing pain in her chest) and MYOCARDITIS (Perimyocarditis) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Angiogram: normal (normal) normal. On an unknown date, C-reactive protein: 11 (High) 11. On an unknown date, Echocardiogram: abnormal (abnormal) a mild contractile disorder in the lower lateral wall. On an unknown date, Electrocardiogram: abnormal (abnormal) sinus tachycardia with no S-T-segment elevation. On an unknown date, Troponin: 3000 (High) 3000.	Consumer report for a 33 years old female with medical history of COVID-19 who at an unknown day after the 2nd dose experienced chest pain and was found to have elevated troponin, CRP, elevated WBC, abnormal EKG and echo, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin, CRP, and EKG and echo results; a causal relationship cannot be excluded.

		On an unknown date, White blood cell count: 19000 (High) 19000. For mRNA-1273 (COVID 19 Vaccine Moderna) (Unknown Route), the reporter did not provide any causality assessments. patient was referred to an MRI No Concomitant medication were provided No Treatment medication were provided	
4.1(b)		This spontaneous prospective pregnancy case was reported by an other health care professional and describes the occurrence of MYOCARDITIS (Perimyocarditis) and DYSPNOEA (Pain when taking deep breaths) in a 30-year-old female patient (gravida 1) who received mRNA-1273 (COVID 19 Vaccine Moderna) (batch no. 3005889) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Hypothyroidism. Concomitant products included LEVOTHYROXINE for Hypothyroidism. On an unknown date, the patient received second dose of mRNA-1273 (COVID 19 Vaccine Moderna) (unknown route) 1 dosage form. On an unknown date, received first dose of mRNA-1273 (COVID 19 Vaccine Moderna) (unknown route) dosage was changed to 1 dosage form. Last menstrual period and estimated date of delivery were not provided. On an unknown date, the patient experienced MYOCARDITIS (Perimyocarditis) (seriousness criteria hospitalization and medically significant), DYSPNOEA (Pain when taking deep breaths) (seriousness criterion medically significant), BACK PAIN (Back pain), CHEST DISCOMFORT (Pressure in the chest), PALPITATIONS (Palpitation), COUGH (Dry cough), NIGHT SWEATS (night sweats) and MATERNAL EXPOSURE DURING PREGNANCY (Maternal exposure during pregnancy). The patient was treated with PARACETAMOL (4.1(b) [PARACETAMOL]) (oral) for	30 years old pregnant female with medical history of hypothyroidism who at an unknown TTO after the 2nd dose experienced dypsnea, chest discomfort, palpitations, cough, night sweats, and back pain, and was found to have elevated troponin, CRP, and abnormal EKG but normal echo, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's full medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and EKG results; a causal relationship cannot be excluded.

		Back pain, at an unspecified dose and frequency and PREDNISONE for Dyspnoea, at an unspecified dose and frequency. At the time of the report, MYOCARDITIS (Perimyocarditis), DYSPNOEA (Pain when taking deep breaths), BACK PAIN (Back pain), CHEST DISCOMFORT (Pressure in the chest), PALPITATIONS (Palpitation), COUGH (Dry cough) and NIGHT SWEATS (night sweats) outcome was unknown and MATERNAL EXPOSURE DURING PREGNANCY (Maternal exposure during pregnancy) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, C-reactive protein: 90 90. On an unknown date, Chest X-ray: normal (normal) normal. On an unknown date, Echocardiogram: normal (normal) normal. On an unknown date, Electrocardiogram: abnormal (abnormal) abnormal. On an unknown date, Heart rate: 140 (High) 140. On an unknown date, Troponin: 122 122. For mRNA-1273 (COVID 19 Vaccine Moderna) (Unknown), the reporter did not provide any causality assessments.	
4.1(b) [redacted]	4.1(b) [redacted]	This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) [redacted] on 17-Dec-2021 and was forwarded to Moderna on 23-Dec-2021. This regulatory authority case was reported by a pharmacist and describes the occurrence of PERICARDITIS (Pericarditis) in a 17-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna Intramuscular Injection) for COVID-19 vaccination. No Medical History information was reported. On 16-Oct-2021, the patient received second dose of mRNA-1273 (COVID-19 Vaccine Moderna Intramuscular Injection) (Intramuscular) dosage was changed to 1 dosage form.	17 years old male with unknown medical history who 2 days after the 2nd dose experienced chest pain, palpitations, and was found to have elevated inflamatory markers, but normal EKG, and was diagnosed with pericarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association

		On an unknown date, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna Intramuscular Injection) (Intramuscular) 1 dosage form. On an unknown date, the patient experienced PERICARDITIS (Pericarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, PERICARDITIS (Pericarditis) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 17-Oct-2021, Body temperature: 38 Test Result:Above 38 Cel. On 18-Oct-2021, Blood test: abnormal Elevated levels of inflammatory reaction. On 18-Oct-2021, Chest X-ray: no abnormal Test Result:No abnormal. On 20-Oct-2021, Electrocardiogram: no abnormal Test Result:No abnormal. For mRNA-1273 (COVID-19 Vaccine Moderna Intramuscular Injection) (Intramuscular), the reporter considered PERICARDITIS (Pericarditis) to be possibly related. This case, initially reported to the 4.1(b) by a pharmacist, was received via the 4.1(b) (Ref, 4.1(b) On an unknown date, the patient received the 1st dose of the vaccine. On 16-Oct-2021, at 17:00, the patient received the 2nd dose of the vaccine. On 17-Oct-2021, the patient experienced generalized malaise, pyrexia above 38 degrees Celsius, and arthralgia from the neck to low back and from the arm to shoulder. On 18-Oct-2021,at 00:00, the patient noticed a pain in the middle of the chest. Palpitation also developed. The pain was intensified thereafter, and thus the patient visited the reporting hospital. Chest X-ray showed no abnormal findings. As the blood test confirmed elevated levels of inflammatory reaction, the patient was hospitalized for suspected pericarditis. On 20-Oct-2021, electrocardiogram was performed. No abnormalities were confirmed, and the patient was diagnosed with pericarditis after vaccination with the vaccine because	between the use of the product and the start of the events, as well as the elevated inflammatory markers; a causal relationship cannot be excluded.

		there were no other underlying pathological conditions. On 21-Oct-2021, the patient recovered from the disease, with the chest pain resolving, and was discharged from the hospital. The outcome of pericarditis was reported as recovered. 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. Company comment: This case concerns a 17-year-old male patient with no relevant medical history who experienced serious due to hospitalization and medical significance, expected event of pericarditis. The event occurred after the second dose of the mRNA-1273 with first symptom of chest pain and palpitations occurring 2 days after. Chest X ray and ECG were unremarkable whereas blood tests showed elevated inflammatory marker and the patient was subsequently diagnosed with pericarditis , 4 days after mRNA-1273.The rechallenge was not applicable since due to occurrence after the seco There have been several reports of pericarditis associated with the vaccine, and the patient background is known to be predominantly male in their teens and 20s. In this case, the patient complained of chest pain after the 2nd vaccination with the vaccine, which was consistent with the previous reports. Also, chest X-ray and electrocardiogram showed no abnormal findings, and the blood test confirmed elevated levels of inflammatory reaction, leading to the diagnosis of pericarditis.	
4.1(b) [redacted]	4.1(b) [redacted]	This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 27-Dec-2021 and was forwarded to Moderna on 27-Dec-2021. This regulatory authority case was reported by a physician and describes the occurrence of SINUS ARRHYTHMIA (Pericarditis (diagnosed by MRI) with sinus arrhythmia on ECG), DYSPNOEA (dyspnea for 10 days), CARDIOVASCULAR DISORDER (Cardiovascular problem), CHEST PAIN	24 years old female with unknown medical history who after first vaccination had vague thoracic pain with angina for 2 to 3 days and then after an unknown TTO after second dose had severe thoracic pain with pronounced exercise intolerance, dyspnea for 10 days and was found to abnormal EKG, and abnormal cMRI suggestive

		(vague thoracic pain with angina for 2 to 3 days), ANGINA PECTORIS (vague thoracic pain with angina for 2 to 3 days), EXERCISE TOLERANCE DECREASED (pronounced exercise intolerance) and PERICARDITIS (Pericarditis (diagnosed by MRI) with sinus arrhythmia on ECG) in a 24-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 4301081) for COVID-19 vaccination. Previously administered products included for Product used for unknown indication: Spikevax on 15-Jun-2021. Past adverse reactions to the above products included No adverse event with Spikevax. On 13-Jul-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On an unknown date, the patient experienced SINUS ARRHYTHMIA (Pericarditis (diagnosed by MRI) with sinus arrhythmia on ECG) (seriousness criterion medically significant), DYSPNOEA (dyspnea for 10 days) (seriousness criterion medically significant), CARDIOVASCULAR DISORDER (Cardiovascular problem) (seriousness criterion medically significant), CHEST PAIN (vague thoracic pain with angina for 2 to 3 days) (seriousness criterion medically significant), ANGINA PECTORIS (vague thoracic pain with angina for 2 to 3 days) (seriousness criterion medically significant), EXERCISE TOLERANCE DECREASED (pronounced exercise intolerance) (seriousness criterion medically significant) and PERICARDITIS (Pericarditis (diagnosed by MRI) with sinus arrhythmia on ECG) (seriousness criterion medically significant). At the time of the report, SINUS ARRHYTHMIA (Pericarditis (diagnosed by MRI) with sinus arrhythmia on ECG), DYSPNOEA (dyspnea for 10 days), CARDIOVASCULAR DISORDER (Cardiovascular problem), CHEST PAIN (vague thoracic pain with angina for 2 to 3 days), ANGINA PECTORIS (vague thoracic pain with angina for 2 to 3 days), EXERCISE TOLERANCE DECREASED	of pericarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the EKG and cMRI results; a causal relationship cannot be excluded.

		(pronounced exercise intolerance) and PERICARDITIS (Pericarditis (diagnosed by MRI) with sinus arrhythmia on ECG) was resolving. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. No concomitant medication provided. No treatment information mentioned. The Medical imaging included MRI Cardiological review with ECG, bicycle test and lab ADR description - Pericarditis (diagnosed with MRI) with sinus arrhythmia on ECG More time relationship information (ADR) - After first vaccination, vague thoracic pain with angina for 2 to 3 days After second vaccination severe thoracic pain with pronounced exercise intolerance, dyspnea for 10 days Current during exercise thoracic pain/angina. Has stopped exercising to date. COVID-19 VACCINE MODERNA on 13 July 2021 on (2) (3003602) COVID-19 VACCINE MODERNA [15 June 2021] (1) (3002916) Dosage text reported as- Second dose administered After first vaccination vague thoracic pain with angina for 2 to 3 days After second vaccination severe thoracic pain with pronounced exercise intolerance, dyspnea for 10 days Current during exercise thoracic pain/angina. Has stopped exercising to date.	
4.1(b) [redacted]	4.1(b) [redacted]	This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 27-Dec-2021 and was forwarded to Moderna on 27-Dec-2021. 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. Concurrent medical conditions included Smoker. On 08-Sep-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 04-Oct-2021, received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to	34 years old female (conflicting information) with unknwon medical history who 14 days after the 2nd dose of Spikevax experienced chest pain. Seven days later was admitted due to myopericarditis and was found to have suggestive ECG, characteristic MRI, elevated troponin. No concomitant drugs and no identification to date of another causative agent according to the reporter. No other information was provided. Important information is missing in the report including patient's medical history as well as any other

		1 dosage form. On 18-Nov-2021, the patient experienced MYOCARDITIS (Myopericarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Myopericarditis) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): 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). On 25-Nov-2021, Troponin T: 461 ng/l iu international unit(s) (High) 461 ng/L Iu international unit(s). For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Concomitant Elements: Healthy Concomitant product use was not provided by the reporter. No treatment information was provided.	laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and EKG results; a causal relationship cannot be excluded.
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. This regulatory authority case was reported by a nurse 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 an unknown indication. Concomitant products included COLCHICINE, DOXYCYCLINE from 28-Oct-2021 to 04-Nov-2021, MEBEVERINE and SUMATRIPTAN for an unknown indication. On 15-Dec-2021, the patient received second dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 18-Dec-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant) and CHEST PAIN (Chest Pain) (seriousness criteria hospitalization and medically significant). On an unknown date, the patient experienced PYREXIA	19 years old female with unknown medical history who 3 day after the 2nd dose experienced pyrexia, and chest pain and was found to have elevated troponin, was diagnosed with myocarditis. Results for the ECG and Echo were not provided. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin; a causal relationship cannot be excluded.

		(Fever) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Myocarditis) had not resolved and CHEST PAIN (Chest Pain) and PYREXIA (Fever) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 19-Dec-2021, Troponin: 15,197 (High) 15,197. On an unknown date, Echocardiogram: result was not reported (Inconclusive) Result was not reported. On an unknown date, Electrocardiogram: result was not reported (Inconclusive) Result was not reported. For mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Myocarditis and pericarditis were reported. The patient was still hospitalized. Patient visited cardiologist. Treatment was provided to the patient which includes NSAIDS and colchicine. Company Comment: This case concerns a 19 year-old female patient with no reported medical history who experienced the unexpected serious adverse events of special interest of myocarditis and the unexpected serious events of chest pain which occurred 4 days after the second dose of mRNA-1273 vaccine and the unexpected serious event of pyrexia which occurred on an unknown date relative to vaccination with mRNA-1273. The benefit-risk relationship of mRNA-1273 is not affected by this report. Events' seriousness assessed as per Regulatory Authority reporting. Most recent FOLLOW-UP information incorporated above includes: On 23-Dec-2021: Follow-up document received on 23-Dec-2021 contains significant information lab data updated and event coding updated.	
4.1(b)	4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b)) on 23-Dec-	22 years old female with unknown medical history who next day after the 3rd

	4.1(b) [redacted]	2021 and was forwarded to Moderna on 23-Dec-2021. 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. Concomitant products included ELASOMERAN (COVID-19 VACCINE MODERNA) and ELASOMERAN (COVID-19 VACCINE MODERNA) for an unknown indication. 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. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Blood test: crp 11 CRP 11. On an unknown date, Electrocardiogram: indicated pericarditis indicated pericarditis. On an unknown date, Troponin: raised 11 raised 11. other treatment medications- Ibuprofen and omeprazole Patient has not had symptoms associated with COVID-19 Not had a COVID-19 test Patient has not tested positive for COVID-19 since having the vaccine Patient is not enrolled in clinical trial	dose experienced chest pain, and fatigue, and was found to have elevated troponin, and abnormal ECG, and was diagnosed with pericarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and ECG; a causal relationship cannot be excluded.

		Most recent FOLLOW-UP information incorporated above includes: 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 received via 4.1(b) (Reference number: 4.1(b)) on 27-Dec-2021 and was forwarded to Moderna on 27-Dec-2021. This regulatory authority case was reported by a consumer and describes the occurrence of CHEST PAIN (Chest pain), DYSPNOEA (Shortness of breath), PALPITATIONS (Heart palpitations), FATIGUE (Fatigue/unusual tiredness) and MYOCARDITIS (Myocarditis) in a 34-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) (batch no. 00014A) for an unknown indication. The patient's past medical history included ECG. 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, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). On an unknown date, the patient experienced CHEST PAIN (Chest 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) and FATIGUE (Fatigue/unusual tiredness) (seriousness criteria hospitalization and medically significant). At the time of the report, CHEST PAIN (Chest pain), DYSPNOEA (Shortness of breath), PALPITATIONS (Heart palpitations) and FATIGUE (Fatigue/unusual tiredness) outcome was unknown and MYOCARDITIS (Myocarditis) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):	Consumer report for a 34 years old male with unknown medical history who 2 days after the 3rd dose experienced chest pain, dypsnea, palpitations, and fatigue and was found to have elevated troponin, was diagnosed with myocarditis. Results for the ECG and Echo were not provided. SARS-CoV-2 test negative. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin; a causal relationship cannot be excluded.

		On 25-Dec-2021, SARS-CoV-2 test: no - negative covid-19 test (Negative) No - Negative COVID-19 test. The action taken with mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown) was unknown. Concomitant product use was not provided by the reporter. Patient did not had symptoms associated with COVID-19. Post vaccine, patient had heart palpitation, sore chest, high blood pressure, raised troponin levels. The laboratory exam was done that included ECG and the result was found to be not provided, blood Pressure was 178/110. There was no history of high blood pressure. The x-ray was also done but the result were not provided, all bloods tests were completed and lab confirmed troponin levels. The blood tests which had certain proteins (called troponin) that signal heart muscle damage taken and it was found that his blood troponin levels were raised. Since the patient had received the vaccine, she had not tested positive for COVID-19. Patient was prescribed amlodipine as a treatment medication.	
4.1(b)	4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b)) on 28-Dec-2021 and was forwarded to Moderna on 28-Dec-2021. This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myocarditis) in a 35-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) (batch no. 000040A) for an unknown indication. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Kidney polycystic (adult polycystic kidney disease). Concomitant products included COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (COVID-19 VACCINE ASTRAZENECA) from 01-Apr-2021 to an unknown date for Immunisation.	35 years old male with medical history of kidney polycystic and receiving the Astrazeneca vaccine who 4 days after the 3rd dose experienced chest pain and was found to have elevated troponin, and abnormal ECG. Echo showed not pericardial effusion and chest x-ray was normal. SARS-CoV-2 test was negative. Patient was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted. According to the WHO causality assessment this report is

		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, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criterion medically significant). On an unknown date, the patient experienced CHEST PAIN (Chest Pain). At the time of the report, MYOCARDITIS (Myocarditis) had not resolved and CHEST PAIN (Chest Pain) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 24-Dec-2021, SARS-CoV-2 test: no - negative covid-19 test (Negative) No - Negative COVID-19 test. On an unknown date, Angiocardiogram: results not reported Results not reported. On an unknown date, Chest X-ray: results not reported Results not reported. On an unknown date, Electrocardiogram: results not reported Results not reported. On an unknown date, Magnetic resonance imaging heart: results not reported Results not reported. The action taken with mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown) was unknown. For mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Patient admitted on 24-DEC-2021 with chest tightness ECH changes indicative of pericarditis, cardiac troponin raised on admission shows 3000, on 24-12-2021 at 07:30 shows 2944, peak troponin value shows 4915. Lab data investigations shows ECG-ST elevation in all leads, worse inferiorly, Chest X-ray is clear and nil acute, Echocardiogram shows no effusion. Patient took Treatment for myo-pericarditis with analgesia at present. Patient well otherwise.	possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and ECG results; a causal relationship cannot be excluded.
4.1(b)	4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b)) on 23-Dec-	29 years old male with unknown medical history who next day after the 3rd

	4.1(b) [redacted]	2021 and was forwarded to Moderna on 23-Dec-2021. This regulatory authority case was reported by a physician and describes the occurrence of CHILLS (rigors), MYALGIA (generalised muscle ache), FATIGUE (Fatigue), CHEST PAIN (Chest Pain), PYREXIA (Fever), DYSPNOEA (Dyspnoea), PALPITATIONS (Palpitations), SYNCOPE (Syncope) and MYOCARDITIS (Myocarditis) in a 29-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for COVID-19 vaccination. No past medical history Patient has not had symptoms associated with COVID-19. 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.	dose experienced chest pain, chills, myalgia, fatigue, pyrexia, and was found to have elevated troponin, and CRP. ECG results not provided. SARS-CoV-2 test was negative. Patient was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin; a causal relationship cannot be excluded.

		DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 20-Dec-2021, SARS-CoV-2 test: negative (Negative) No - Negative COVID-19 test. On 22-Dec-2021, Troponin I (0-50): 3379 (Inconclusive) 3379. On an unknown date, C-reactive protein: 31 (Inconclusive) 31. On an unknown date, Chest X-ray: normal (normal) normal. On an unknown date, Electrocardiogram: results not reported Results not reported. The action taken with mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown) was unknown. For mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. No concomitant medication was provided by reporter. 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 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" 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 Takeda Pharmaceuticals (Reference number: 4.1(b) on 27-Dec-2021 and was forwarded to Moderna on 29-Dec-2021. 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 22-Oct-2021, the patient received the 2nd dose of this vaccine. On 23-Oct-2021, the patient was observed with pyrexia of 39 degrees Celsius, but it was decided to wait and see. On 24-Oct-2021, at 18:30, acute myocarditis developed. The patient was aware of chest pressure sensation at night. On 25-Oct-2021, chest pressure sensation was aggravated and the patient visited a previous physician. On 26-Oct-2021, although the patient was scheduled to be referred to the initial visit outpatient of the reporting hospital in the morning, the patient visited the emergency department due to a flare-up of chest pain. The patient was diagnosed with findings that are no different myocarditis based on electrocardiogram changes and elevated cardiac enzymes and was hospitalized. On 27-Oct-2021, coronary angiography, right heart catheterization, and myocardial biopsy were performed to confirm the absence of coronary artery disease. Then resolving was done by symptomatic therapy with antipyretic analgesics. On 01-Nov-2021. the patient was discharged from the hospital because of resolving symptoms. The results of the myocardial biopsy showed obvious diagnostic criteria for inflammatory cells, but edematous changes were observed. Considering his age, it was diagnosed as possible inflammation. Virus tests were	16 years old male with unknown medical history who next day after the 2nd dose experienced chest pressure and was found to have elevated cardiac enzymes, abnormal ECG and mycardial biopsy showing inflammatory changes suggestive of myocarditis. Patient was diagnosed with myocarditis. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated cardiac enzymes and ECG and biopsy results; a causal relationship cannot be excluded.

		also performed, but there was no obvious suspicion. 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 received via 4.1(b) (Reference number: 4.1(b) on 28-Dec-2021 and was forwarded to Moderna on 28-Dec-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of ELECTROCARDIOGRAM T WAVE INVERSION (Electrocardiogram T wave inversion), PERICARDIAL EFFUSION (Pericardial effusion) and MYOCARDITIS (Myocarditis) in a 35-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. The patient's past medical history included Renal cell carcinoma (Resected Renal Cell Carcinoma in remission without active treatment.). Concurrent medical conditions included Drug allergy (Vancomycin - Itching) and Drug allergy (Morphine - Itching). On 11-Dec-2021, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 13-Dec-2021, the patient experienced ELECTROCARDIOGRAM T WAVE INVERSION (Electrocardiogram T wave inversion) (seriousness criterion medically significant), PERICARDIAL EFFUSION (Pericardial effusion) (seriousness criterion medically significant), MYOCARDITIS (Myocarditis) (seriousness criterion medically significant), CHEST PAIN (Chest pain), ECHOCARDIOGRAM (Echocardiogram), ELECTROCARDIOGRAM (Electrocardiogram), FLANK PAIN (Flank pain), HYPERHIDROSIS (Hyperhidrosis), PAIN (Pain), TROPONIN (Troponin) and VOMITING (Vomiting). At the time of the report,	35 years old male with medical history of renal cell carcinoma in remission who 2 days after the 3rd dose experienced chest pain, hyperhidrosis, and vomiting and was found to have abnormal ECG, Echo showed pericardial effusion, but troponin negative twice. Patient was diagnosed with presumptive myopericarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated ECG and echo results; a causal relationship cannot be excluded.

		ELECTROCARDIOGRAM T WAVE INVERSION (Electrocardiogram T wave inversion), PERICARDIAL EFFUSION (Pericardial effusion), MYOCARDITIS (Myocarditis), CHEST PAIN (Chest pain), ECHOCARDIOGRAM (Echocardiogram), ELECTROCARDIOGRAM (Electrocardiogram), FLANK PAIN (Flank pain), HYPERHIDROSIS (Hyperhidrosis), PAIN (Pain), TROPONIN (Troponin) and VOMITING (Vomiting) outcome was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Other medications included Testosterone and Adderall. At 48 hours on 13-Dec-2021, the patient developed left sided flank pain. Progressed to severe sub-sternal chest pain on 15-Dec-2021 prompting emergency department visit. Chest pain radiated to neck, worse with deep inspiration, relieved with sitting forward. Chest pain associated with diaphoresis and vomiting secondary to pain. Electrocardiogram changes new T wave inversions V4-V6, and I and II Bedside echo without clinically significant effusion. Troponin negative twice 2 and discharged home with presumptive diagnosis of pericarditis or myocarditis. No treatment medication was provided.	
4.1(b) [redacted]		This case was received via Zuellig Pharma (Reference number: 4.1(b) [redacted] on 28-Dec-2021 and was forwarded to Moderna on 29-Dec-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCARDITIS (myopercarditis) in a 39-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) (batch no. 3005841) for an unknown indication. No Medical History information was reported. On 09-Nov-2021, the patient received third dose of mRNA-1273 (COVID-19 Vaccine Moderna) (unknown route) 1	39 years old male with unknown medical history who at an unknown TTO after the 3rd dose was found to have elevated troponin, elevated CRP and abnormal ECG. Patient was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted. According to the WHO causality assessment this report is possible based on temporal association

		dosage form. On an unknown date, the patient experienced MYOCARDITIS (myopercarditis) (seriousness criterion medically significant). At the time of the report, MYOCARDITIS (myopercarditis) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Troponin: 482-79 482-79. The action taken with mRNA-1273 (COVID-19 Vaccine Moderna) (Unknown) was unknown. For mRNA-1273 (COVID-19 Vaccine Moderna) (Unknown), the reporter did not provide any causality assessments. EKG :SR,ER was the same as previous baseline CRP 15.9 -> 4 CMR : increase T2 and T1 at apical segment of LV small area of pachy myocardial involvement in LGE No concomitant medications were reported. Treatment information was not provided.	between the use of the product and the start of the events, as well as the elevated troponin and ECG results; a causal relationship cannot be excluded.
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. This regulatory authority case was reported by a physician and describes the occurrence of PERICARDITIS (Pericarditis), SYNCOPE (Syncope), INFLUENZA LIKE ILLNESS (flu like symptoms), CHEST PAIN (Chest Pain), DYSPNOEA (Dyspnoea), HYPOAESTHESIA (Numbness of limbs) and PYREXIA (Fever) in a 29-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for COVID-19 vaccination. The patient's past medical history included TMJ syndrome (TMJ dysfunction) and TB (TB when younger). Concomitant products included TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) and TOZINAMERAN (PFIZER BIONTECH	29 years old male with unknown medical history and having the Pfizer vaccine as the primary series who 2 days after the 3rd dose of Spikevax experienced chest pain, left arm numbness, flu like symptoms, dypsnea, pyrexia, and was found to have elevated troponin, normal EKG, negative SARS-CoV-2 test and was diagnosed with myopericarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted. According to the WHO causality assessment this report is possible based on temporal association

		COVID-19 VACCINE) for COVID-19 vaccination. 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, after starting mRNA-1273 (Moderna CoviD-19 Vaccine), the patient experienced PERICARDITIS (Pericarditis) (seriousness criteria hospitalization, disability and medically significant). On an unknown date, the patient experienced SYNCOPE (Syncope) (seriousness criteria hospitalization, disability and medically significant), INFLUENZA LIKE ILLNESS (flu like symptoms) (seriousness criteria hospitalization and disability), CHEST PAIN (Chest Pain) (seriousness criteria hospitalization and disability), DYSPNOEA (Dyspnoea) (seriousness criteria hospitalization and disability), HYPOAESTHESIA (Numbness of limbs) (seriousness criteria hospitalization and disability) and PYREXIA (Fever) (seriousness criteria hospitalization and disability). At the time of the report, PERICARDITIS (Pericarditis) was resolving, SYNCOPE (Syncope), CHEST PAIN (Chest Pain), DYSPNOEA (Dyspnoea), HYPOAESTHESIA (Numbness of limbs) and PYREXIA (Fever) outcome was unknown and INFLUENZA LIKE ILLNESS (flu like symptoms) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 22-Dec-2021, Electrocardiogram: normal (normal) Normal. On 22-Dec-2021, SARS-CoV-2 test: negative (Negative) No - Negative COVID-19 test. On 22-Dec-2021, Troponin: 3000 3000. For mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Patient has not had symptoms associated with COVID-19. The patient experienced Chest pain/left arm numbness, Flu like symptoms. Some	between the use of the product and the start of the events, as well as the elevated troponin; a causal relationship cannot be excluded.

		subjective shortness of breath (SOB). Rise in troponin to 3000. Settling with NSAIDs. Patient has not tested positive for COVID-19 since having the vaccine.Unsure if patient was enrolled in clinical trial. The patient's report was related to possible myocarditis or pericarditis. The patient was hospitalized for 2 days. The patient seen by a cardiologist and diagnosed with Myopericarditis. The patient received treatment Aspirin/Colchicine/PPI.	
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. This regulatory authority case was reported by a physician and describes the occurrence of CHEST PAIN (Chest Pain), PALPITATIONS (Palpitations), TACHYCARDIA (Tachycardia), LEFT VENTRICULAR DYSFUNCTION (Left ventricular dysfunction) and MYOCARDITIS (Myocarditis) in a 21-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for COVID-19 immunisation. Concomitant products included TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) from 25-Jun-2021 to an unknown date and TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) from 25-Jun-2021 to 03-Sep-2021 for COVID-19 immunisation. On 20-Dec-2021, the patient received third dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 22-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), PALPITATIONS (Palpitations) (seriousness criterion medically significant), TACHYCARDIA (Tachycardia) (seriousness criterion medically significant) and LEFT VENTRICULAR DYSFUNCTION (Left ventricular dysfunction) (seriousness	21 years old male with unknown medical history and who had the Pfizer vaccine as the primary series who 2 days after the 3rd dose experienced chest pain, palpitations, tachycardia, and was found to have elevated troponin, and abnormal EKG, cMRI, and negative SARS-CoV-2 test, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and EKG and cMRI results; a causal relationship cannot be excluded.

		criterion medically significant). At the time of the report, CHEST PAIN (Chest Pain), PALPITATIONS (Palpitations), TACHYCARDIA (Tachycardia) and LEFT VENTRICULAR DYSFUNCTION (Left ventricular dysfunction) outcome was unknown and MYOCARDITIS (Myocarditis) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 22-Dec-2021, SARS-CoV-2 test: negative (Negative) No - Negative COVID-19 test. On 22-Dec-2021, Troponin: 490 (normal) Troponin 490. On 23-Dec-2021, Troponin: 833 level raised (High) 833 level raised. On 24-Dec-2021, Magnetic resonance imaging heart: myocarditis with oedema and subepicardial enhancem (abnormal) Myocarditis with oedema and subepicardial enhancem. On an unknown date, Chest X-ray: result not reported Result not reported. On an unknown date, Echocardiogram: nomal (normal) Echocardiogram normal. On an unknown date, Electrocardiogram: sinus tachycardia on telemetry " (abnormal) Sinus tachycardia on telemetry ". For mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Patient reported that he experienced Chest pain, Myocarditis, Palpitations and Tachycardia. Patient had vaccine on Sunday. On Wednesday had chest pains waking him up at nigh. Presented with raised troponins 400 more than 800. This report was related to possible myocarditis or pericarditis. MRI confirmed myocarditis with mild LV impairment. Patient was admitted to hospital for 2 days and still ongoing. Ibuprofen was used as treatment for the patient. Troponin was measured on 22-Dec-2021 was 490 and on 23-Dec-2021 was 833. Cardiac troponin was raised. 851 was the peak troponin value. ECG	

		was carried out and result was sinus tachycardia on telemetry. Patient had not tested positive for COVID-19 since having the vaccine. Patient had not had symptoms associated with COVID-19. Patient was not enrolled in clinical trial. No treatment medication were reported. Most recent FOLLOW-UP information incorporated above includes: On 30-Dec-2021: Follow up received Suspect product, Indication, Event updated.	
4.1(b)		This case was received via 4.1(b) (Reference number: 4.1(b) on 28-Dec-2021 and was forwarded to Moderna on 28-Dec-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of BLOOD POTASSIUM DECREASED (Blood potassium decreased), CARDIAC TELEMETRY (Cardiac telemetry), CHEST DISCOMFORT (Chest discomfort), CHEST PAIN (Chest pain), DIFFERENTIAL WHITE BLOOD CELL COUNT (Differential white blood cell count), ECHOCARDIOGRAM (Echocardiogram), ELECTROCARDIOGRAM NORMAL (Electrocardiogram normal), FIBRIN D DIMER NORMAL (Fibrin D dimer normal), FULL BLOOD COUNT (Full blood count), HYPOKALAEMIA (Hypokalaemia), LABORATORY TEST ABNORMAL (Laboratory test abnormal), NAUSEA (Nausea), SLEEP DISORDER (Sleep disorder), TROPONIN INCREASED (Troponin increased) and MYOCARDITIS (Myocarditis) in a 21-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for an unknown indication. Concurrent medical conditions included Penicillin allergy. On 10-Dec-2021, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 12-Dec-2021, the patient experienced BLOOD	21 years old male with unknown medical history and who 2 days after the 3rd dose experienced chest pain, nausea, and chest discomfort, and was found to have elevated troponin, elevated fibrin d-dimer, and abnormal EKG, Echo, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and EKG results; a causal relationship cannot be excluded.

		POTASSIUM DECREASED (Blood potassium decreased) (seriousness criterion hospitalization), CARDIAC TELEMETRY (Cardiac telemetry) (seriousness criterion hospitalization), CHEST DISCOMFORT (Chest discomfort) (seriousness criterion hospitalization), CHEST PAIN (Chest pain) (seriousness criterion hospitalization), DIFFERENTIAL WHITE BLOOD CELL COUNT (Differential white blood cell count) (seriousness criterion hospitalization), ECHOCARDIOGRAM (Echocardiogram) (seriousness criterion hospitalization), ELECTROCARDIOGRAM NORMAL (Electrocardiogram normal) (seriousness criterion hospitalization), FIBRIN D DIMER NORMAL (Fibrin D dimer normal) (seriousness criterion hospitalization), FULL BLOOD COUNT (Full blood count) (seriousness criterion hospitalization), HYPOKALAEMIA (Hypokalaemia) (seriousness criterion hospitalization), LABORATORY TEST ABNORMAL (Laboratory test abnormal) (seriousness criterion hospitalization), NAUSEA (Nausea) (seriousness criterion hospitalization), SLEEP DISORDER (Sleep disorder) (seriousness criterion hospitalization), TROPONIN INCREASED (Troponin increased) (seriousness criterion hospitalization) and MYOCARDITIS (Myocarditis) (seriousness criterion hospitalization). At the time of the report, BLOOD POTASSIUM DECREASED (Blood potassium decreased), CARDIAC TELEMETRY (Cardiac telemetry), CHEST DISCOMFORT (Chest discomfort), CHEST PAIN (Chest pain), DIFFERENTIAL WHITE BLOOD CELL COUNT (Differential white blood cell count), ECHOCARDIOGRAM (Echocardiogram), ELECTROCARDIOGRAM NORMAL (Electrocardiogram normal), FIBRIN D DIMER NORMAL (Fibrin D dimer normal), FULL BLOOD COUNT (Full blood count), HYPOKALAEMIA (Hypokalaemia), LABORATORY TEST ABNORMAL (Laboratory test abnormal), NAUSEA (Nausea), SLEEP DISORDER (Sleep disorder), TROPONIN INCREASED (Troponin increased) and	

		MYOCARDITIS (Myocarditis) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 13-Dec-2021, Blood potassium: 3.4 (Low) Chem panel - K = 3.4 (low). On 13-Dec-2021, Cardiac telemetry: 60-65% (Low) 60-65%. On 13-Dec-2021, Ejection fraction: 60-65 ECHO -LVEF 60-65%. On 13-Dec-2021, Electrocardiogram: normal (normal) normal. On 13-Dec-2021, Fibrin D dimer: 0.33 0.33. On 13-Dec-2021, Full blood count: results not reported CBC w/ diff. On 13-Dec-2021, Troponin: 4396 (High) 4396 pg/mL and 3377.4 1 3377.4 1. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Patient had hives. Other medications included creatine powder, occasional ibuprofen use. No treatment drug reported. 4.1(b) received Moderna booster on 12/10/21. He had got his 2 dose series with Pfizer initially. He flew on the 12/11 or 12/12. He began experiencing mild diffuse anterior chest discomfort on 12/12 3PM. At 3:30AM on 12/13, he was awakened from sleep with severe diffuse anterior chest pain, non-radiating. He had associated nausea without vomiting. He sought care in the ER where he was given morphine and ondansetron that improved his symptoms. He was admitted for myocarditis and mild hypokalemia. This is a regulatory case concerning a 21-year-old male patient with relevant medical history of drug hypersensitivity, who experienced the serious expected AESI event of myocarditis and serious unexpected events of blood potassium decreased, cardiac telemetry, chest discomfort, chest pain, differential white blood cell count, echocardiogram, electrocardiogram normal, fibrin D dimer normal, full blood count, hypokalaemia, laboratory test abnormal, nausea, sleep	

		disorder, troponin increased. The events occurred 3 days after the third dose of mRNA-1273 vaccine administration. The events were assessed as related to the product administration. The rechallenge was not applicable since the events occurred after the third dose and no further dosing is expected. The medical history of drug hypersensitivity considered 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 28-Dec-2021 and was forwarded to Moderna on 28-Dec-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of CARDIOMYOPATHY (Cardiomyopathy), CATHETERISATION CARDIAC ABNORMAL (Catheterisation cardiac abnormal), CHEST PAIN (Chest pain), ECHOCARDIOGRAM (Echocardiogram), EJECTION FRACTION (Ejection fraction), ELECTROCARDIOGRAM ST SEGMENT ELEVATION (Electrocardiogram ST segment elevation), TROPONIN INCREASED (Troponin increased), VACCINATION COMPLICATION (Vaccination complication) and MYOCARDITIS (Myocarditis) in a 23-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for an unknown indication. No Medical History information was reported. On 10-Dec-2021, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 10-Dec-2021, the patient experienced CARDIOMYOPATHY (Cardiomyopathy) (seriousness criteria hospitalization, medically significant and life threatening), CATHETERISATION CARDIAC ABNORMAL (Catheterisation cardiac abnormal) (seriousness criteria hospitalization and life threatening), CHEST PAIN (Chest pain) (seriousness criteria hospitalization and life threatening), ECHOCARDIOGRAM	23 years old male with unknown medical history and who at an unknown TTO after the 3rd dose experienced chest pain, and was found to have elevated troponin, and abnormal EKG, Echo, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and EKG results; a causal relationship cannot be excluded.

		(Echocardiogram) (seriousness criteria hospitalization and life threatening), EJECTION FRACTION (Ejection fraction) (seriousness criteria hospitalization and life threatening), ELECTROCARDIOGRAM ST SEGMENT ELEVATION (Electrocardiogram ST segment elevation) (seriousness criteria hospitalization, medically significant and life threatening), TROPONIN INCREASED (Troponin increased) (seriousness criteria hospitalization and life threatening), VACCINATION COMPLICATION (Vaccination complication) (seriousness criteria hospitalization and life threatening) and MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization, medically significant and life threatening). At the time of the report, CARDIOMYOPATHY (Cardiomyopathy), CATHETERISATION CARDIAC ABNORMAL (Catheterisation cardiac abnormal), CHEST PAIN (Chest pain), ECHOCARDIOGRAM (Echocardiogram), EJECTION FRACTION (Ejection fraction), ELECTROCARDIOGRAM ST SEGMENT ELEVATION (Electrocardiogram ST segment elevation), TROPONIN INCREASED (Troponin increased), VACCINATION COMPLICATION (Vaccination complication) and MYOCARDITIS (Myocarditis) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Catheterisation cardiac: negative for obstruction (Negative) negative for obstruction. On an unknown date, Echocardiogram: 45% Echocardiogram with EF of 45%. On an unknown date, Troponin: 18 Peaked. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medications were reported. No treatment medications were reported. Soon after receiving vaccine, patient developed severe chest pain. Sought	

		care at the hospital, noted ST elevation. Urgent cardiac catheterization and echocardiogram showed Myopericarditis with cardiomyopathy due to Moderna booster vaccine and was hospitalized for 3 days.	
4.1(b)	4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b) on 28-Dec-2021 and was forwarded to Moderna on 28-Dec-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of CHEST PAIN (Chest pain), ANTICOAGULANT THERAPY (Anticoagulant therapy), BLOOD CREATINE PHOSPHOKINASE MB (Blood creatine phosphokinase MB), BLOOD CREATINE PHOSPHOKINASE ABNORMAL (Blood creatine phosphokinase abnormal), C-REACTIVE PROTEIN ABNORMAL (C-reactive protein abnormal), CHEST X-RAY (Chest X-ray), DIFFERENTIAL WHITE BLOOD CELL COUNT ABNORMAL (Differential white blood cell count abnormal), ECHOCARDIOGRAM (Echocardiogram), ELECTROCARDIOGRAM (Electrocardiogram), FIBRIN D DIMER INCREASED (Fibrin D dimer increased), FULL BLOOD COUNT ABNORMAL (Full blood count abnormal), INFLUENZA A VIRUS TEST (Influenza A virus test), INFLUENZA B VIRUS TEST (Influenza B virus test), LABORATORY TEST ABNORMAL (Laboratory test abnormal), N-TERMINAL PROHORMONE BRAIN NATRIURETIC PEPTIDE ABNORMAL (N-terminal prohormone brain natriuretic peptide abnormal), SARS-COV-2 TEST (SARS-CoV-2 test), TROPONIN I ABNORMAL (Troponin I abnormal) and MYOCARDITIS (Myocarditis) in a 31-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 069H21A) for an unknown indication. No Medical History information was reported. On 04-Dec-2021, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 09-Dec-2021, the	31 years old male with unknown medical history and who 5 days after the 3rd dose experienced chest pain, and was found to have elevated troponin, elevated fibrin d-dimer, elevated CRP, elevated NT-proBNP and abnormal EKG, Echo, and was diagnosed with myocarditis. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the well document information provided in the report; a causal relationship cannot be excluded.

		patient experienced CHEST PAIN (Chest pain) (seriousness criterion hospitalization), ANTICOAGULANT THERAPY (Anticoagulant therapy) (seriousness criterion hospitalization), BLOOD CREATINE PHOSPHOKINASE MB (Blood creatine phosphokinase MB) (seriousness criterion hospitalization), BLOOD CREATINE PHOSPHOKINASE ABNORMAL (Blood creatine phosphokinase abnormal) (seriousness criterion hospitalization), C-REACTIVE PROTEIN ABNORMAL (C-reactive protein abnormal) (seriousness criterion hospitalization), CHEST X-RAY (Chest X-ray) (seriousness criterion hospitalization), DIFFERENTIAL WHITE BLOOD CELL COUNT ABNORMAL (Differential white blood cell count abnormal) (seriousness criterion hospitalization), ECHOCARDIOGRAM (Echocardiogram) (seriousness criterion hospitalization), ELECTROCARDIOGRAM (Electrocardiogram) (seriousness criterion hospitalization), FIBRIN D DIMER INCREASED (Fibrin D dimer increased) (seriousness criterion hospitalization), FULL BLOOD COUNT ABNORMAL (Full blood count abnormal) (seriousness criterion hospitalization), INFLUENZA A VIRUS TEST (Influenza A virus test) (seriousness criterion hospitalization), INFLUENZA B VIRUS TEST (Influenza B virus test) (seriousness criterion hospitalization), LABORATORY TEST ABNORMAL (Laboratory test abnormal) (seriousness criterion hospitalization), N-TERMINAL PROHORMONE BRAIN NATRIURETIC PEPTIDE ABNORMAL (N-terminal prohormone brain natriuretic peptide abnormal) (seriousness criterion hospitalization), SARS-COV-2 TEST (SARS-CoV-2 test) (seriousness criterion hospitalization), TROPONIN I ABNORMAL (Troponin I abnormal) (seriousness criterion hospitalization) and MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, CHEST PAIN (Chest pain), ANTICOAGULANT THERAPY (Anticoagulant therapy), BLOOD CREATINE PHOSPHOKINASE MB (Blood creatine phosphokinase MB),	

		BLOOD CREATINE PHOSPHOKINASE ABNORMAL (Blood creatine phosphokinase abnormal), C-REACTIVE PROTEIN ABNORMAL (C-reactive protein abnormal), CHEST X-RAY (Chest X-ray), DIFFERENTIAL WHITE BLOOD CELL COUNT ABNORMAL (Differential white blood cell count abnormal), ECHOCARDIOGRAM (Echocardiogram), ELECTROCARDIOGRAM (Electrocardiogram), FIBRIN D DIMER INCREASED (Fibrin D dimer increased), FULL BLOOD COUNT ABNORMAL (Full blood count abnormal), INFLUENZA A VIRUS TEST (Influenza A virus test), INFLUENZA B VIRUS TEST (Influenza B virus test), LABORATORY TEST ABNORMAL (Laboratory test abnormal), N-TERMINAL PROHORMONE BRAIN NATRIURETIC PEPTIDE ABNORMAL (N-terminal prohormone brain natriuretic peptide abnormal), SARS-COV-2 TEST (SARS-CoV-2 test), TROPONIN I ABNORMAL (Troponin I abnormal) and MYOCARDITIS (Myocarditis) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 09-Dec-2021, C-reactive protein: abnormal (abnormal) The result is abnormal Lab C-REACTIVE PROTEIN Physician Assistant. On 09-Dec-2021, Electrocardiogram: 12 (abnormal) Other type of result ECG 12 LEAD Physician Assistant. On 09-Dec-2021, Full blood count: abnormal (abnormal) The result is abnormal Lab CBC W/DIFFERENTIAL Physician Assistant. On 09-Dec-2021, Metabolic function test: abnormal (abnormal) The result is abnormal Lab COMPREHENSIVE METABOLIC PANEL Physician Assistant. On 09-Dec-2021, N-terminal prohormone brain natriuretic peptide: abnormal (abnormal) The result is abnormal Lab NT-PRO BNP Physician Assistant. On 09-Dec-2021, Troponin I: abnormal (abnormal) The result is abnormal Lab POC TROPONIN I (RESULTS ONLY) Physician Assistant. On 10-Dec-2021, Blood creatine phosphokinase MB: abnormal (abnormal)	

		The result is abnormal Lab CK TOTAL AND CKMB Doctor. On 10-Dec-2021, C-reactive protein: abnormal (abnormal) The result is abnormal Lab C-REACTIVE PROTEIN Doctor. On 10-Dec-2021, Electrocardiogram: 12 (abnormal) Other type of result ECG 12 LEAD Advance Registered Nurse Practitioner. On 10-Dec-2021, Full blood count: abnormal (abnormal) The result is abnormal Lab CBC NO DIFFERENTIAL Doctor. On 10-Dec-2021, Metabolic function test: abnormal (abnormal) The result is abnormal Lab BASIC METABOLIC PANEL Doctor. On 10-Dec-2021, Troponin I: abnormal (abnormal) The result is abnormal Lab TROPONIN I Doctor and abnormal (abnormal) The result is abnormal Lab TROPONIN I Doctor. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Concomitant product was not provided by the reporter Patient had Myocarditis and went to hospital on 09-DEC after experiencing chest pains 08-DEC and 09-DEC, discharged on 12-DEC. Pending follow-up with cardiologist and cardiac MRI. Treating with 975mg of Aspirin 3x daily.	
4.1(b)	4.1(b)	This spontaneous case was reported by a consumer and describes the occurrence of MYOCARDITIS (I'm one of the few unfortunate persons that experienced after the second dose of the Moderna vaccine), CHEST PAIN (I'm still experiencing strong chest pain), BACK PAIN (I'm still experiencing back pain), ABDOMINAL PAIN UPPER (I'm still experiencing stomach pain), PALPITATIONS (I'm still experiencing fast beating/I'm still experiencing pounding heart), DYSPNOEA (I'm still experiencing shortness of breath) and PYREXIA (Fever (39ºC)) in a 30-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination.	30 years old male with unknown medical history and who 3 days after the 2nd dose experienced chest pain, back pain, abdominal pain, palpiattions, dypsnea, and pyrexia, and was found to have elevated troponin, and abnormal MRI and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted. According to

		No Medical History information was reported. On 13-Aug-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. In August 2021, the patient experienced CHEST PAIN (I'm still experiencing strong chest pain) (seriousness criterion hospitalization), BACK PAIN (I'm still experiencing back pain) (seriousness criterion hospitalization), ABDOMINAL PAIN UPPER (I'm still experiencing stomach pain) (seriousness criterion hospitalization), PALPITATIONS (I'm still experiencing fast beating/I'm still experiencing pounding heart) (seriousness criterion hospitalization), DYSPNOEA (I'm still experiencing shortness of breath) (seriousness criterion hospitalization) and PYREXIA (Fever (39ºC)) (seriousness criterion hospitalization). On 16-Aug-2021, the patient experienced MYOCARDITIS (I'm one of the few unfortunate persons that experienced after the second dose of the Moderna vaccine) (seriousness criteria hospitalization and medically significant). The patient was hospitalized from 07-Sep-2021 to 09-Sep-2021 due to ABDOMINAL PAIN UPPER, BACK PAIN, CHEST PAIN, DYSPNOEA, MYOCARDITIS, PALPITATIONS and PYREXIA. The patient was treated with IBUPROFEN in October 2021 for Adverse event, at an unspecified dose and frequency and PREDNISOLONE in September 2021 for Adverse event, at an unspecified dose and frequency. At the time of the report, MYOCARDITIS (I'm one of the few unfortunate persons that experienced after the second dose of the Moderna vaccine), CHEST PAIN (I'm still experiencing strong chest pain), BACK PAIN (I'm still experiencing back pain), ABDOMINAL PAIN UPPER (I'm still experiencing stomach pain), PALPITATIONS (I'm still experiencing fast beating/I'm still experiencing pounding heart), DYSPNOEA (I'm still experiencing shortness of breath) and PYREXIA (Fever (39ºC)) had not resolved.	the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and MRI results; a causal relationship cannot be excluded.

		DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In August 2021, Body temperature: high (High) 39 degree celsius. In August 2021, Troponin I: abnormal (abnormal) Abnormal. In October 2021, Troponin I: normal (normal) Normal. For mRNA-1273 (Spikevax) (Unknown), the reporter considered MYOCARDITIS (I'm one of the few unfortunate persons that experienced after the second dose of the Moderna vaccine) to be related. No further causality assessments were provided for CHEST PAIN (I'm still experiencing strong chest pain), BACK PAIN (I'm still experiencing back pain), ABDOMINAL PAIN UPPER (I'm still experiencing stomach pain), PALPITATIONS (I'm still experiencing fast beating/I'm still experiencing pounding heart), DYSPNOEA (I'm still experiencing shortness of breath) and PYREXIA (Fever (39°C)). The NFD test showed that the patient had myocarditis. The myocarditis was confirmed 3 days later by altered levels of "troponin I" and an MRT. The heart functionality got back to normal around the end of October No concomitant medications were reported.	
4.1(b)	4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b) on 28-Dec-2021 and was forwarded to Moderna on 28-Dec-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of CARDIAC FAILURE (Cardiac failure), CHEST X-RAY (Chest X-ray), CHEST PAIN (Chest pain), COMPUTERISED TOMOGRAM THORAX ABNORMAL (Computerised tomogram thorax abnormal), ELECTROCARDIOGRAM (Electrocardiogram), HAEMATOLOGY TEST (Haematology test), HILAR LYMPHADENOPATHY (Hilar	26-year-old male with medical history of supraventricular tachycardia, obesity, congenital diaphragmatic hernia and allergy, who 7 days after the 3rd dose of Spikevax experienced chest pain, pain, pain in extremity and was found to have pleural effusion that was consistent with pulmonary edema due to heart failure or associated viral mediastinitis, and troponin was also increased. This report is

		lymphadenopathy), LEFT ATRIAL ENLARGEMENT (Left atrial enlargement), LUNG DISORDER (Lung disorder), MEDIASTINITIS (Mediastinitis), PAIN (Pain), PAIN IN EXTREMITY (Pain in extremity), PLEURAL EFFUSION (Pleural effusion), PULMONARY OEDEMA (Pulmonary oedema), TISSUE INFILTRATION (Tissue infiltration), TROPONIN INCREASED (Troponin increased) and MYOCARDITIS (Myocarditis) in a 26-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for an unknown indication. The patient's past medical history included Asthma, Supraventricular tachycardia (SVT), Myopia, Obesity, Vitamin D deficiency and Congenital diaphragmatic hernia. Concurrent medical conditions included House dust mite allergy. On 06-Dec-2021, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 13-Dec-2021, the patient experienced CARDIAC FAILURE (Cardiac failure) (seriousness criteria hospitalization and medically significant), CHEST X-RAY (Chest X-ray) (seriousness criterion hospitalization), CHEST PAIN (Chest pain) (seriousness criterion hospitalization), COMPUTERISED TOMOGRAM THORAX ABNORMAL (Computerised tomogram thorax abnormal) (seriousness criterion hospitalization), ELECTROCARDIOGRAM (Electrocardiogram) (seriousness criterion hospitalization), HAEMATOLOGY TEST (Haematology test) (seriousness criterion hospitalization), HILAR LYMPHADENOPATHY (Hilar lymphadenopathy) (seriousness criterion hospitalization), LEFT ATRIAL ENLARGEMENT (Left atrial enlargement) (seriousness criterion hospitalization), LUNG DISORDER (Lung disorder) (seriousness criterion hospitalization), MEDIASTINITIS (Mediastinitis) (seriousness criteria hospitalization and medically significant),	heavily confounded due to the patient's medical history of supraventricular tachycardia, obesity, and congenital diaphragmatic hernia.Important information is missing in the report including patient’s medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and EKG results; a causal relationship cannot be excluded.

		PAIN (Pain) (seriousness criterion hospitalization), PAIN IN EXTREMITY (Pain in extremity) (seriousness criterion hospitalization), PLEURAL EFFUSION (Pleural effusion) (seriousness criterion hospitalization), PULMONARY OEDEMA (Pulmonary oedema) (seriousness criteria hospitalization and medically significant), TISSUE INFILTRATION (Tissue infiltration) (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, CARDIAC FAILURE (Cardiac failure), CHEST X-RAY (Chest X-ray), CHEST PAIN (Chest pain), COMPUTERISED TOMOGRAM THORAX ABNORMAL (Computerised tomogram thorax abnormal), ELECTROCARDIOGRAM (Electrocardiogram), HAEMATOLOGY TEST (Haematology test), HILAR LYMPHADENOPATHY (Hilar lymphadenopathy), LEFT ATRIAL ENLARGEMENT (Left atrial enlargement), LUNG DISORDER (Lung disorder), MEDIASTINITIS (Mediastinitis), PAIN (Pain), PAIN IN EXTREMITY (Pain in extremity), PLEURAL EFFUSION (Pleural effusion), PULMONARY OEDEMA (Pulmonary oedema), TISSUE INFILTRATION (Tissue infiltration), TROPONIN INCREASED (Troponin increased) and MYOCARDITIS (Myocarditis) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 14-Dec-2021, Chest X-ray: result not reported Result not reported. On 14-Dec-2021, Haematology test: result not reported Result not reported. On 15-Dec-2021, Computerised tomogram thorax: abnormal The result showed combination of airspace disease, interlobular septal thickening, and bilateral simple attenuating pleural effusions that were most consistent with pulmonary edema due to heart failure. The left atrium was borderline enlarged.The findings were most consistent with the clinical diagnosis of	

		myo-pericarditis. There was a mildly enlarged bilateral hilar lymph nodes, likely related to pulmonary edema. Mediastinal soft tissue infiltration was likely related to patient's pulmonary edema or associated viral mediastinitis.. On 15-Dec-2021, Electrocardiogram: result not reported Result not reported. On 15-Dec-2021, Troponin: 22 22. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Concomitant medications were not reported. Treatment medications were not reported. The patient had burning chest pain radiating to arms.This is a regulatory case concerning a 26-year-old male patient with relevant medical history of supraventricular tachycardia, obesity, congenital diaphragmatic hernia and allergy, who experienced the serious expected AESI event of myocarditis, serious unexpected AESI events of cardiac failure, mediastinitis, pulmonary oedema, and serious unexpected events of chest X-ray, chest pain, computerised tomogram thorax abnormal, electrocardiogram, haematology test, hilar lymphadenopathy, left atrial enlargement, lung disorder, pain, pain in extremity, pleural effusion, tissue infiltration and troponin increased. The events occurred 8 days after the third dose of mRNA-1273 vaccine administration. The events were assessed as related to the product administration. The rechallenge was not applicable since the events occurred after the third dose and no further dosing is expected. The medical history of supraventricular tachycardia, obesity, congenital diaphragmatic hernia and allergy considered as 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 28-Dec-2021 and was forwarded to Moderna on 28-Dec-2021.	19 years old male with unknown medical history who the next day after the 2nd dose experienced chest pain and was found

		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), MYOCARDITIS (Myocarditis), PERICARDITIS (Pericarditis), CHEST PAIN (Chest pain), BLOOD CREATINE PHOSPHOKINASE MB INCREASED (Blood creatine phosphokinase MB increased), BLOOD CREATINE PHOSPHOKINASE NORMAL (Blood creatine phosphokinase normal), CHEST X-RAY NORMAL (Chest X-ray normal), COMPUTERISED TOMOGRAM THORAX NORMAL (Computerised tomogram thorax normal), ECHOCARDIOGRAM NORMAL (Echocardiogram normal), FULL BLOOD COUNT NORMAL (Full blood count normal), SARS-COV-2 TEST NEGATIVE (SARS-CoV-2 test negative) and TROPONIN INCREASED (Troponin increased) in a 19-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for an unknown indication. Concurrent medical conditions included Allergy to nuts and Oil allergy. On 27-Apr-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 27-Apr-2021, the patient experienced ELECTROCARDIOGRAM ST SEGMENT ELEVATION (Electrocardiogram ST segment elevation) (seriousness criteria hospitalization and medically significant), MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant), PERICARDITIS (Pericarditis) (seriousness criteria hospitalization and medically significant), CHEST PAIN (Chest pain) (seriousness criterion hospitalization), BLOOD CREATINE PHOSPHOKINASE MB INCREASED (Blood creatine phosphokinase MB increased) (seriousness criterion hospitalization), BLOOD CREATINE PHOSPHOKINASE NORMAL (Blood creatine phosphokinase	to have elevated troponin, and abnormal EKG, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and EKG results; a causal relationship cannot be excluded.

		normal) (seriousness criterion hospitalization), CHEST X-RAY NORMAL (Chest X-ray normal) (seriousness criterion hospitalization), COMPUTERISED TOMOGRAM THORAX NORMAL (Computerised tomogram thorax normal) (seriousness criterion hospitalization), ECHOCARDIOGRAM NORMAL (Echocardiogram normal) (seriousness criterion hospitalization), FULL BLOOD COUNT NORMAL (Full blood count normal) (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, ELECTROCARDIOGRAM ST SEGMENT ELEVATION (Electrocardiogram ST segment elevation), MYOCARDITIS (Myocarditis), PERICARDITIS (Pericarditis), CHEST PAIN (Chest pain), BLOOD CREATINE PHOSPHOKINASE MB INCREASED (Blood creatine phosphokinase MB increased), BLOOD CREATINE PHOSPHOKINASE NORMAL (Blood creatine phosphokinase normal), CHEST X-RAY NORMAL (Chest X-ray normal), COMPUTERISED TOMOGRAM THORAX NORMAL (Computerised tomogram thorax normal), ECHOCARDIOGRAM NORMAL (Echocardiogram normal), FULL BLOOD COUNT NORMAL (Full blood count normal), SARS-COV-2 TEST NEGATIVE (SARS-CoV-2 test negative) and TROPONIN INCREASED (Troponin increased) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Blood creatine phosphokinase: 149 (normal) 149. On an unknown date, Blood creatine phosphokinase MB: 153.3 (High) 153.3. On an unknown date, Chest X-ray: no acute disease (normal) No acute disease. On an unknown date, Computerised tomogram: negative (Negative) negative. On an unknown date, Echocardiogram: normal (normal) normal LV function, no right side cavity strain, no pleural	

		effusion. Working diagnosis is acute pericarditis with myocarditis. On an unknown date, Electrocardiogram: diffuse st elevation diffuse ST elevation. On an unknown date, Full blood count: wnl (normal) WNL. On an unknown date, SARS-CoV-2 test: negative (Negative) negative. On an unknown date, Troponin: 30.760 (High) 30.760 and 31.893 (High) 31.893. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Concomitant product use was not provided by the reporter. The patient received the second Moderna vaccine in the series in outside location. He began having chest pain that day after receiving the vaccine and came to the hospital on day 3 of chest pain. No prior similar events, no cardiovascular risk factors. Patient was better with sitting up and leaning forward was admitted to the hospital and started on Ibuprofen and Colchicine. Patient was discharged after 3 days with significant improvement in his status. On discharge pain was 0 out of 10. To continue Ibuprofen for 1 week and colchicine for 6 weeks. Cardiology cleared patient for discharge. Treatment medications included Ibuprofen and Colchicine.	
4.1(b) [redacted]	4.1(b) [redacted]	This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 28-Dec-2021 and was forwarded to Moderna on 28-Dec-2021. This regulatory authority case was reported by a physician and describes the occurrence of CHEST PAIN (Precordial pain extended to left and right scapula) and PERICARDITIS (Pericarditis) in a 39-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 immunisation. Concurrent medical conditions included Hypothyroidism (Medication-T4 50 mcg once daily).	39 years old female with medical history of hypothyroidism who 5 days after the 2nd dose experienced chest pain and was found to have normal EKG, abnormal Echo and cMRI with mild pericardial effusion and was diagnosed with pericarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2.

		Concomitant products included LEVOTHYROXINE SODIUM (T4) for an unknown indication. On 14-Jul-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 19-Jul-2021, the patient experienced CHEST PAIN (Precordial pain extended to left and right scapula) (seriousness criterion medically significant) and PERICARDITIS (Pericarditis) (seriousness criterion medically significant). At the time of the report, CHEST PAIN (Precordial pain extended to left and right scapula) and PERICARDITIS (Pericarditis) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 19-Jul-2021, Echocardiogram: normal (normal) Ejection fraction 60% without pericardial effusion. On 19-Jul-2021, Electrocardiogram: normal (normal) Within normal limits. On 24-Aug-2021, Magnetic resonance imaging heart: abnormal (abnormal) Acute pericarditis in remission, no indication of structural cardiomyopathy and myocarditis, ejection fraction 56%, mild pericardial effusion. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Treatment medications were not provided.	According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the Echo and cMRI results; a causal relationship cannot be excluded.
4.1(b)	4.1(b)	This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Post-vaccine myopericarditis) in a 15-year-old female patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination. No Medical History information was reported. On 10-Oct-2021, the patient received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1	15-year-old girl, with no reported chronic diseases (in particular no reported cardiovascular disease), who 7 days after the 2nd dose of Spikevax experienced chest pain, flu-like symptoms, and nausea, and was found to have normal ECG, normal Echo, elevated troponin, CK and CK-MB. A cardiac MRI was conducted 46 days and it showed small sequelae of the

		dosage form once a day. On 15-Oct-2021, after starting mRNA-1273 (COVID-19 Vaccine Moderna), the patient experienced MYOCARDITIS (Post-vaccine myopericarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Post-vaccine myopericarditis) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 17-Oct-2021, Electrocardiogram: normal (normal) Regular sinus rhythm at 82 bpm, normal axis at 64. On 18-Oct-2021, Echocardiogram: normal (normal) Left ventricle not dilated, not hypertrophied. On 20-Oct-2021, Echocardiogram: normal (normal) Sinus rhythm 85/min, normal axis, no hypertension. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered MYOCARDITIS (Post-vaccine myopericarditis) to be possibly related. Concomitant product use was not provided by the reporter. The patient was in usual good health. On 17-Oct-2021 patient was hospitalized for finding of perimyocarditis and admitted to intensive care on due to post-vaccination myopericarditis. Patient was subsequently developed a slight flu-like syndrome at 3.10 pm as well as transfixing chest pains with regard to the xyphoid appendix, of varying intensity, associated with nausea. The electrocardiogram and the cardiac enzyme assessment are compatible with myopericarditis. Simple pain relief was introduced. The transthoracic echocardiography showed a contractile segmentation and global normal function of the left ventricle and an absence of pericardial panicum. A beta-blocker treatment was introduced in small doses. A ban from moderate to intensive sport for 3 to 6 months was recommended. The patient was transferred from intensive care to pediatrics at 19-Oct-2021 and then	myocardium typical for myocarditis confirming the diagnosis of myocarditis. According to the WHO causality assessment this report is probable based on temporal association between the use of the product and the start of the events, a causal relationship cannot be excluded.

		following a cardiological consultation in the hospital at 20-Oct-2021. Pediatric cardiologist on 20-Oct-2021 stated that the patient showed a practically normal echocardiography, just with the most sensitive measurements (strain) there was the suspicion of a slight decrease in systolic function in the posterolateral regions of the left ventricle. With the elevation of troponin (672 ng/L), CK (632 U/L) and CK-MB (67 U/L) cardiac MRI was recommended. On 03-Dec-2021 the referring physician also reported again, confirmation from the doctor who on MRI stated that this examination showed small sequelae of the myocardium typical for myocarditis. The diagnosis of vaccine myocarditis therefore be confirmed. Patient took beta-blocker as a treatment medication. Most recent FOLLOW-UP information incorporated above includes: On 30-Dec-2021: Translation received on 04-Jan-2022 that contains patient laboratory data and inarrative 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 30-Dec-2021 and was forwarded to Moderna on 30-Dec-2021. This regulatory authority case was reported by a consumer and describes the occurrence of DYSPNOEA (I missed my breath), CHEST DISCOMFORT (weight on the sternum), FATIGUE (weariness) and PERICARDITIS (pericarditis) in a 38-year-old female patient who received mRNA-1273 (COVID-19 Vaccine Moderna) (batch nos. 3003660 and 3003660) for COVID-19 vaccination. The patient's past medical history included Thrombosis (deep vein thrombosis in 2017 and 2020 in the lower limbs). Concurrent medical conditions included Lactose intolerance. On 09-Jun-2021, the patient received dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form once a day.	Consumer report for a 38 year-old female with medical history of two episodes of deep vein thrombosis, who 17 days after the 2nd dose of Spikevax experienced dyspnoea, chest discomfort and fatigue and was found to have an abnormal ECG. No other information was provided. Important information is missing in the report including patient's full medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events. A causal relationship cannot be

		On 20-Jul-2021, received dose of mRNA-1273 (COVID-19 Vaccine Moderna) (unknown route) dosage was changed to 1 dosage form. On 06-Aug-2021, the patient experienced DYSPNOEA (I missed my breath) (seriousness criterion medically significant), CHEST DISCOMFORT (weight on the sternum) (seriousness criterion medically significant), FATIGUE (weariness) (seriousness criterion medically significant) and PERICARDITIS (pericarditis) (seriousness criterion medically significant). At the time of the report, DYSPNOEA (I missed my breath), CHEST DISCOMFORT (weight on the sternum), FATIGUE (weariness) and PERICARDITIS (pericarditis) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 20-Aug-2021, Electrocardiogram: pericardite (abnormal) pericardite. No concomitant medication was provided by reporter. Patient was without allergy (slight lactose intolerance), with a history of deep vein thrombosis (anticoagulants taken until October 2020). No therapy was currently underway. Not a smoker and alcohol consumer rarely. About 10 days after the second dose, walking in the mountains she missed her breath and felt a burden on the sternum. The patient thought it was simply due to post-vaccine tiredness, but the feeling comes up even if only by stairs. On 20-Aug-2021 she went to the doctor as the symptomatology persists and with an ECG the doctor diagnoses a pericarditis in the healing phase and treats it with 10 days of ibuprofen 600 mg 2 times a day. The patient was said to be active and often goes to the mountains and specifies that in maggio 2020 he had done an exertion of the heart that showed no pathologies. The symptomatology was getting better. Company comment: This is a regulatory case concerning a 38 year-old, female patient with a history of two episodes of deep vein thrombosis, who experienced	excluded due to the lack of information.

		the serious (due to medically important condition) expected, according CCDS, AESI of pericarditis and the serious (due to medically important condition) unexpected, according CCDS, events of dyspnoea, chest discomfort and fatigue. The events occurred approximately 17 days after the second dose of mRNA-1273 vaccine. The outcome of the events was reported as recovering. An electrocardiogram was performed and a diagnosis of pericarditis was made, patient received treatment with ibuprofen. The rechallenge was not applicable, as the events were reported exclusively after the second dose and no information on additional dosing is available. The medical history, of two episodes of deep vein thrombosis remains a confounder. 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 PERICARDITIS (pericarditis) in a 31-year-old patient of an unknown gender who received mRNA-1273 (Moderna CoviD-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. In August 2021, the patient received first dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (Intramuscular) 1 dosage form once a day. On 01-Sep-2021, received second dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 24-Oct-2021, the patient experienced PERICARDITIS (pericarditis) (seriousness criterion medically significant). At the time of the report, PERICARDITIS (pericarditis) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Blood test: gb = 7320 including 54% pnn, crp <5 rets bs normal GB = 7320 including 54% PNN, CRP <5 rets BS normal.	31 years old of unknown gender and unknown medical history who 54 days after the 2nd dose of Spikevax was found to have pericardial friction with mitral focus, ECG abnormal, CRP elevated, troponin elevated and fibrin d-dimmer elevated and was diagnosed with pericarditis. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and ECG results; a causal relationship cannot be excluded.

		On an unknown date, Electrocardiogram: sinus, regular. discrete sus st (<2mm) sinus, regular. discrete sus ST (<2mm). For mRNA-1273 (Moderna CoviD-19 Vaccine) (Intramuscular), the reporter considered PERICARDITIS (pericarditis) to be related. Concomitant product use was not provided by the reporter. Patient is 31 years old, unknown sex, weight 75 kg, height 185 cm. Performed the second dose of Spikevax on 01-Sep-2021. First dose presumably performed in August 2021 (date not indicated). On 24-Oct-2021 the patient experienced pericarditis. The doctor's examination reports: patient was conscious, oriented. No sensitivomotor deficit. Glasgow Score 4Y + 5V + 6M = 15. Symmetrical and reactive pupils. Headache. Examine cardios: Regular heart sounds, no murmur, pericardial friction with mitral focus +++ Distal pulses present and symmetrical . Tests performed ECG: sinus, regular. discrete sus ST (<2mm) in V2 / V3 -blood tests: GB = 7320 including 54% PNN, CRP <5 rets BS normal, too <10 and DDimeres = 211 <500. Reaction reported as severe. The symptoms are not resolved at the time of reporting. Further course not known. No treatment information was provided.	
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 30-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination. Concurrent medical conditions included Smoker (Smoking:yes). On 15-Sep-2021, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form once a day. On 13-Oct-2021, received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) dosage was changed to 1 dosage form once a day. In October 2021, the patient experienced MYOCARDITIS (4.1(b)	30 years old male with unknown medical history who at an unknown TTO after the 2nd dose was found to have elevated troponin, and abnormal EKG, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the

		(seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (4.1(b) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In October 2021, Echocardiogram: not reported (Inconclusive) test_result: 4.1(b) In October 2021, Electrocardiogram: abnormal (abnormal) test_result: 4.1(b) ;. In October 2021, Troponin: high (High) test_result: 4.1(b) For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered MYOCARDITIS (4.1(b) to be possibly related. No concomitant medications were reported. Patient had No known pathologies, known smoker and rarely drinks alcohol. First dose presumably performed in September. In close time correlation with the vaccine (report sent on 19/10) he experiences myocarditis called 4.1(b) not serious'. Patient relevant Examinations performed was reported as Low ECG modification, increased troponin (high), irrelevant TTE. The reaction is reported to be severe and that caused hospitalization. The symptoms are not resolved at the time of reporting. Further course not known.	product and the start of the events, as well as the elevated troponin and EKG results; a causal relationship cannot be excluded.
4.1(b)	4.1(b)	This regulatory authority case was reported by a physician and describes the occurrence of CHEST PAIN (Chest Pain), PERICARDIAL RUB (pericardial), TACHYCARDIA (tachycardia), COUGH (tachycardia), PYREXIA (fever), FATIGUE (tiredness) and MYOCARDITIS (myocarditis) in an 18-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) (batch nos. 1. + 2.4.1(b) 300 29 18 and 1. + 2.4.1(b) 300 29 18) for COVID-19 vaccination. No Medical History information was reported.	18 years old male with unknown medical history who 2 days after the 2nd dose of Spikevax experienced fever, fatigue, chest pain, tachycardia, cough and found to have elevated troponin, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test

		On 18-Jun-2021, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form once a day. On 16-Jul-2021, received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) dosage was changed to 1 dosage form. On 16-Jul-2021, the patient experienced CHEST PAIN (Chest Pain) (seriousness criterion medically significant), PERICARDIAL RUB (pericardial) (seriousness criterion medically significant), TACHYCARDIA (tachycardia) (seriousness criterion medically significant), COUGH (tachycardia) (seriousness criterion medically significant), PYREXIA (fever) (seriousness criterion medically significant), FATIGUE (tiredness) (seriousness criterion medically significant) and MYOCARDITIS (myocarditis) (seriousness criterion medically significant). On 05-Aug-2021, CHEST PAIN (Chest Pain), PERICARDIAL RUB (pericardial), TACHYCARDIA (tachycardia), COUGH (tachycardia), PYREXIA (fever), FATIGUE (tiredness) and MYOCARDITIS (myocarditis) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In 2021, Fibrin D dimer: negative (Negative) test_result = negativa;. In 2021, Laboratory test: test 10061576 (24.1) troponin (2021): troponin; te TEST 10061576 (24.1) troponin (2021): troponin; TEST 10016577 (24.1) D-dimers (2021): D-dimers neg.. In 2021, Troponin: negative (Negative) test_result = negativa;. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered CHEST PAIN (Chest Pain), PERICARDIAL RUB (pericardial), TACHYCARDIA (tachycardia), COUGH (tachycardia), PYREXIA (fever), FATIGUE (tiredness) and MYOCARDITIS (myocarditis) to be related.	conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin; a causal relationship cannot be excluded.

		Concomitant product was not provided by the reporter Patient was of 18 years, no pathology, pharmacotherapy, allergy, non-smoker and non-alcohol user, received Spikevax on 18-JUN-2021 and 16-JUL-2021 Two days after the last injection, on 16-JUL-2021, had developed myocarditis with fever, fatigue, chest pain, tachycardia, cough and Perikardreiben The patient, after 21 days, was said to had recovered. ADDITIONAL DOCUMENTS: Source of this Case Safety Report in E2B (R3) Format: Additional documents:; Source of this Case Safety Report in E2B (R2) Format Lab data was provided as unknown with result as TEST 10061576 (24.1) troponin (2021): troponin; TEST 10016577 (24.1) D-dimers (2021): D-dimers neg on unknown date Treatment product was not provided by the reporter Company comment: This regulatory authority case concerns a 18-year-old male patient with no relevant medical history who experienced serious unexpected events of chest pain, pericardial rub, tachycardia, cough, pyrexia, fatigue and expected myocarditis, that occurred on the same day after the 2nd dose of the mRNA-1273 . No further details regarding the events were provided. The patient recovered 3 weeks later. The rechallenge was not applicable due to occurrence after the 2nd 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 Takeda Pharmaceuticals (Reference number: 4.1(b)) on 09-Dec-2021 and was forwarded to Moderna on 14-Dec-2021. This case, initially reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref, 4.1(b)). The patient was receiving insulin degludec and insulin aspar as insulin injections. On an unspecified date in Jul-2021, the patient initiated the treatment with	38 years old male with medical history of Diabetes mellitus; Diabetic nephropathy; Diabetic retinopathy; Hypertension; and Dyslipidaemia and who was on dialysis for diabetic nephropathy. Patient 7 days after the 1st dose of Spikevax experienced dyspnea and was cardiopulmonary arrest on his way to the hospital. Patient's ECG showed ventricular fibrillation, he was hypotense, and had

		maintenance dialysis for diabetic nephropathy and continued maintenance dialysis. On 02-Sep-2021, the patient received the 1st dose of this vaccine. On 09-Sep-2021, around 21:15, the patient complained of a strong feeling of dyspnoea and the family member called for an ambulance. When the ambulance arrived, the patient was in cardiopulmonary arrest. The patient was transported to the reporting hospital while resuscitation was performed. When the patient arrived at the reporting hospital, he was still in cardiopulmonary arrest and his ECG waveform showed asystole. The patient was intubated, chest compressions were performed, adrenaline was administered, the ECG showed ventricular fibrillation, defibrillation was performed, and the heart rate resumed. Subsequently, blood pressure decreased, and a large amount of pericardial effusion was detected by echocardiography, so a diagnosis of cardiac tamponade was made. Pericardiocentesis was performed, and blood pressure was stabilized. With elevated troponin T and CKMB, acute pericarditis and myocarditis were diagnosed and the patient was hospitalized. On 10-Sep-2021, cardiac catheterization was performed. There was no significant stenosis in the coronary arteries, and myocardial biopsy was performed. The blood pressure was not stable and the patient was suffering from severe hypoxic encephalopathy and was not expected to regain consciousness, so it was decided not to provide any treatment including dialysis. Gradually, the blood pressure decreased. On 13-Sep-2021, at 21:18, The patient died of multi-organ failure. Cardiac tamponade from acute pericarditis and myocarditis was considered to be the cause of cardiopulmonary arrest. The outcome of cardio-respiratory arrest was unknown. The outcome of cardiac	pericardial effusion detected by echo; had elevated troponin T and CKMB. He was diagnosed with a cardiac tamponade, myocarditis and pericarditis. The next day patient was found to have severe hypoxic encephalopathy and died two days later. The cause of death was reported to be multi-organ failure, and cardiac tamponade from acute pericarditis and myocarditis was considered to be the cause of the cardiopulmonary arrest. It is unknown if an autopsy was performed. No other information was provided. Important information is missing in the report including patient clinical course of the current conditions, as well as any laboratory test conducted, including SARS-CoV-2 test. Pericardial disease is common in patients with renal disease. Approximately 20% of uremic patients requiring chronic dialysis develop uremic pericarditis or dialysis pericarditis. In all forms of uremic pericarditis, cardiac tamponade is the main danger, and can be life-threatening, as it was in this patient, also is more common in dialyzed than in nondialyzed patients with chronic renal failure. The medical history of the patient of diabetic nephropathy and dialysis initiated just two months before the ocurrence of the events are important risk factors that provide a more plausible explanation for the occurrence of the reported

		tamponade, acute pericarditis and myocarditis, hypoxic encephalopathy, and multi-organ failure was reported as fatal. Follow-up investigation will be made. Company Comment: The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	events. According to the WHO causality assessment this report is considered possible