Case ID	WW Identifier	Narrative	MAH Comment
4.1(b)	4.1(b)	This case was received via 4.1(b) (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 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,	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 causal relationship cannot be excluded due to the lack of other information.

Case ID	WW Identifier	Narrative	MAH Comment
		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.	

Case ID	WW Identifier	Narrative	MAH Comment
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 (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). 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.	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 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.

Case ID	WW Identifier	Narrative	MAH Comment
		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.	

Case ID	WW Identifier	Narrative	MAH Comment
4.1(b)	4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b) on 04-Oct-2021 and was forwarded to Moderna on 08-Oct-2021. This case, reported by a pharmacist, was received by 4.1(b) 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.	20 years old male with unknown medical history who 2 days after the 2nd dose experienced chest pain and SOB 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.

Case ID	WW Identifier	Narrative	MAH Comment
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. 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.	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 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.

Case ID	WW Identifier	Narrative	MAH Comment
		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.	

Case ID	WW Identifier	Narrative	MAH Comment
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 09-Oct-2021. This case, reported by a physician, was received by 4.1(b) via Moderna's adverse reaction reporting site 4.1(b) and reported to th 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.

Case ID	WW Identifier	Narrative	MAH Comment
4.1(b)	4.1(b)	This case was received via 4.1(b) (Reference number 4.1(b) on 06-Oct-2021 and was forwarded to Moderna on 11-Oct-2021. This case, reported by a physician, was received by 4.1(b) via Moderna's adverse reaction reporting site 4.1(b) and reported to th 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.	22 years old male with unknown medical history 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.

Case ID	WW Identifier	Narrative	MAH Comment
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-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.	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 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.

Case ID	WW Identifier	Narrative	MAH Comment
		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 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.	

Case ID	WW Identifier	Narrative	MAH Comment
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 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 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	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.

Case ID	WW Identifier	Narrative	MAH Comment
		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.	

Case ID	WW Identifier	Narrative	MAH Comment
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), 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.	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.

Case ID	WW Identifier	Narrative	MAH Comment
		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.	

Case ID	WW Identifier	Narrative	MAH Comment
4.1(b)	4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b) on 06-Oct-2021 and was forwarded to Moderna on 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. 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.	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.

Case ID	WW Identifier	Narrative	MAH Comment
4.1(b)	4.1(b)	This case was received via 4.1(b) (Reference number 4.1(b) 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. 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..	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.

Case ID	WW Identifier	Narrative	MAH Comment
		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.	

Case ID	WW Identifier	Narrative	MAH Comment
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b) on 14-Oct-2021 and was forwarded to Moderna on 14-Oct-2021. This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Perimyocarditis), CHEST PAIN (Chest discomfort after the 2nd vaccination) and MALAISE (Malaise after the 2nd vaccination) in a 29-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 3004954 and 3004954) for COVID-19 immunisation. 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.	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. 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.

Case ID	WW Identifier	Narrative	MAH Comment
		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 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.	

Case ID	WW Identifier	Narrative	MAH Comment
4.1(b)	4.1(b)	This case was received via 4.1(b) (Reference number 4.1(b)) on 08-Oct-2021 and was forwarded to Moderna on 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. Company Comment: The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	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.

Case ID	WW Identifier	Narrative	MAH Comment
4.1(b)	4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b) on 08-Oct-2021 and was forwarded to Moderna on 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 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.	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.

Case ID	WW Identifier	Narrative	MAH Comment
		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.	

Case ID	WW Identifier	Narrative	MAH Comment
4.1(b) [redacted]	4.1(b) [redacted]	This regulatory authority case was reported by a physician and describes the occurrence of PERICARDITIS (Pericarditis) in a 33-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for SARS-CoV-2 immunisation. No Medical History information was reported. On 02-Aug-2021, the patient received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form. On *02-Aug-2021, after starting mRNA-1273 (COVID-19 Vaccine Moderna), the patient experienced PERICARDITIS* (Pericarditis) (seriousness criterion medically significant). At the time of the report, PERICARDITIS (Pericarditis) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 08-Aug-2021, Chest X-ray: normal (normal) Non-pathological, no pneumothorax. On 08-Aug-2021, Electrocardiogram: abnormal (abnormal) PR descending in DII, DIII and AVF, no repolarization disorders.. On 08-Aug-2021, Troponin T (Unknown-< 14): < 3 (abnormal) Troponin T- hs < 3 ng/L. On 10-Aug-2021, Echocardiogram: abnormal (abnormal) minimal pericardial effusion. On 10-Aug-2021, Ejection fraction: normal (normal) Normal. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered PERICARDITIS (Pericarditis) to be probably related. Lab tests C-reactive protein, Leucocyte count was done on 8-AUG-2021. The patient had good health, athletic, active smoker. Patient received 1st dose in July 2021, precise date unknown and the 2nd dose of the on Aug 2, 2021. In the night, a few hours after the vaccination, he was woken by a hot-cold sensation and intermittent oppressive chest pain for around 1 hour 30 minutes which decreased with anteflexion of the trunk. From slight unusual dyspnea during intense exercise. The chest pain almost disappeared. In the night of Aug 07, 2021, he was again woken by oppressive chest pain that lasted 2 hours before spontaneously resolving. A sitting position helped alleviate the pain. On Aug 8, 2021, he went to the emergency room with a feeling of very slight tightness in the chest. His vitals are within normal, the ECG shows no pathologies, same for the chest radiography. Troponins are negative (troponin T hs <3 ng/L, normal <14 ng/L). The cardiological status shows that the sounds are normal without murmur or perceived pericardial friction. The patient was in less pain with anteflexion of the trunk. Faced with the typical clinical case, a diagnosed with acute pericarditis, treatment with ibuprofen and dextromethorphan was started the same day. On Aug 10, 2021 during the cardiological exam, he described the disappearance of the retrosternal pains but the persistence of the cough and orthopnea. The transthoracic ultrasound showed a slight pericardial effusion. A regressive treatment of colchicine for 3 months and NSAIDs was introduced. This case refers to a 33-year-old male patient with no known medical history who experienced the expected event of Pericarditis on the same day after receiving the second dose of Moderna COVID-19 Vaccine. Rechallenge was assessed as not applicable. The event was considered related to the vaccine per the reporter's assessment. The benefit-risk relationship of Moderna COVID-19 Vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 15-Oct-2021: Translation received on 19-OCT-2021. Lab data added. Event verbatim updated. Narrative supplement updated.	

Case ID	WW Identifier	Narrative	MAH Comment
4.1(b)	4.1(b)	This case was received via 4.1(b) (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 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.	

Case ID	WW Identifier	Narrative	MAH Comment
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 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.	

Case ID	WW Identifier	Narrative	MAH Comment
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.	

Case ID	WW Identifier	Narrative	MAH Comment
4.1(b)	4.1(b)	This case was received via 4.1(b) (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.	

Case ID	WW Identifier	Narrative	MAH Comment
4.1(b)	4.1(b)	This case was received via 4.1(b) (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.	

Case ID	WW Identifier	Narrative	MAH Comment
4.1(b)	4.1(b)	This case was received via 4.1(b) (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.

Case ID	WW Identifier	Narrative	MAH Comment
4.1(b)	4.1(b)	This case was received via 4.1(b) (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) 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.	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-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.

Case ID	WW Identifier	Narrative	MAH Comment
		On 13-Oct-2021, respiratory discomfort remained but tended to improve. 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.	

Case ID	WW Identifier	Narrative	MAH Comment
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) and MYOCARDITIS (Myocarditis) in an 18-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 038C21A) for COVID-19 vaccination. No Medical History information was reported. On 23-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 25-Jul-2021, the patient experienced CHEST PAIN (Chest pain) (seriousness criterion hospitalization) and MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). The patient was hospitalized on 25-Jul-2021 due to CHEST PAIN and MYOCARDITIS. The patient was treated with IBUPROFEN for Chest pain, at an unspecified dose and frequency. At the time of the report, CHEST PAIN (Chest pain) had resolved and MYOCARDITIS (Myocarditis) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 25-Jul-2021, Magnetic resonance imaging heart: abnormal (abnormal) visualized regions of epicardial delayed gadolinium enhancement consistent with myocarditis. On 25-Jul-2021, Pain assessment: 7/10 (High) Stabbing chest pain rated it a 7/10 on the pain scale.. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Concomitant medications was not reported.	

Case ID	WW Identifier	Narrative	MAH Comment
		On an unknown date, after receiving the first dose, 2 weeks later patient received the TDAP (tetanus, diphtheria, and pertussis) and typhoid vaccines. On 25-Jul-2021, the patient developed stabbing chest pain rated it as 7/10 on the pain scale at which point the patient went to the local ER (emergency room) and was transported to another medical facility for further evaluation and management due to concerns for myocarditis. Cardiology visualized regions of epicardial delayed gadolinium enhancement consistent with myocarditis. The patient had follow-up with cardiology in 2-3 weeks. Company comment This case concerns a 18-year-old, male with no reported medical history, who experienced the serious, unexpected event of chest pain and serious, expected and AESI event of myocarditis. The events occurred 2 days after second dose of Spikevax. The rechallenge was not applicable, as no additional dosing will be given. Previous vaccination with TDAP and Typhoid vaccines could be potentially confounders. The benefit-risk relationship of Spikevax is not affected by this report.	

Case ID	WW Identifier	Narrative	MAH Comment
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), 4.1(b) [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 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	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

Case ID	WW Identifier	Narrative	MAH Comment
		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+.	

Case ID	WW Identifier	Narrative	MAH Comment
		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.	

Case ID	WW Identifier	Narrative	MAH Comment
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 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 EFFUSION (Pericardial effusion) (seriousness criteria hospitalization and medically significant), PYREXIA (Pyrexia) (seriousness criterion hospitalization), SLEEP DISORDER (Sleep	21 years old male with unknown medical history who next day after the 2nd dose experienced chest pain, chest discomfort, dyspnoea, and was found to have elevated troponin, pericardial effusion, 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.

Case ID	WW Identifier	Narrative	MAH Comment
		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	

Case ID	WW Identifier	Narrative	MAH Comment
		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.	

Case ID	WW Identifier	Narrative	MAH Comment
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 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.	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. 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.

Case ID	WW Identifier	Narrative	MAH Comment
		This case concerns a 23-year-old, male patient with no relevant medical history, who experienced the unexpected events of chest pain and dyspnea and expected event of myocarditis. The events chest pain, dyspnea and myocarditis occurred 2 days after the second dose of mRNA-1273 vaccine administration. The rechallenge was unknown as there's no information available about the first dose. The patient's age and gender remain confounders. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.	

Case ID	WW Identifier	Narrative	MAH Comment
4.1(b)	4.1(b)	This case was received via 4.1(b) 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 4.1(b) 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. 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.	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.

Case ID	WW Identifier	Narrative	MAH Comment
		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.	

Case ID	WW Identifier	Narrative	MAH Comment
4.1(b)	4.1(b)	This case was received via 4.1(b) (Reference number 4.1(b) on 16-Oct-2021 and was forwarded to Moderna on 20-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 epilepsy and was taking levetiracetam. 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 13-Oct-2021, chest pain and queasy developed. On 15-Oct-2021, in the morning, the patient was raced to a hospital with a pain scale of 10/10. No pericardial effusion was confirmed by ultrasound. Electrocardiogram and blood test showed increased cardiac enzymes, and acute pericarditis was suspected. The patient was hospitalized. The outcome of chest pain, queasy, 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.	

Case ID	WW Identifier	Narrative	MAH Comment
4.1(b)	4.1(b)	This case was received via 4.1(b) (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.	

Case ID	WW Identifier	Narrative	MAH Comment
4.1(b)	4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b) on 16-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 an unknown date, body temperature before the vaccination: 36.5 degrees Celsius. On 07-Oct-2021, at 15:00, the patient received the 2nd dose of this vaccine. At 19:00, it was thought that acute myocarditis devloped. During the night, pyrexia and chest pain developed. On an unknown date, the symptoms did not improve, and the patient visited the reporting hospital emergently. On 10-Oct-2021, the patient was hospitalized for treatment. Acute myocarditis was diagnosed based on abnormal electrocardiogram and increased CK. On an unknown date, the symptoms improved with oral treatment with anti-inflammatory agent. On 14-Oct-2021, the symptoms improved, and the patient was discharged from the hospital. The outcome of acute 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.	

Case ID	WW Identifier	Narrative	MAH Comment
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.	

Case ID	WW Identifier	Narrative	MAH Comment
		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.	

Case ID	WW Identifier	Narrative	MAH Comment
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 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. 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,	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 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.

Case ID	WW Identifier	Narrative	MAH Comment
		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.. 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	

Case ID	WW Identifier	Narrative	MAH Comment
		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	

Case ID	WW Identifier	Narrative	MAH Comment
4.1(b) [redacted]	4.1(b) [redacted]	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 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.	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.

Case ID	WW Identifier	Narrative	MAH Comment
		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.	

Case ID	WW Identifier	Narrative	MAH Comment
4.1(b) [redacted]	4.1(b) [redacted]	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): 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	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 excluded due to the lack of other information.

Case ID	WW Identifier	Narrative	MAH Comment
		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: 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.	

Case ID	WW Identifier	Narrative	MAH Comment
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. 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.	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.

Case ID	WW Identifier	Narrative	MAH Comment
		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.	

Case ID	WW Identifier	Narrative	MAH Comment
4.1(b)	4.1(b)	This case was received via 4.1(b) (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 4.1(b) 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	

Case ID	WW Identifier	Narrative	MAH Comment
		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.	

Case ID	WW Identifier	Narrative	MAH Comment
		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.	

Case ID	WW Identifier	Narrative	MAH Comment
4.1(b)	4.1(b)	This case was received via 4.1(b) (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: The events 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 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.

Case ID	WW Identifier	Narrative	MAH Comment
4.1(b) [redacted]	4.1(b) [redacted]	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 (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.	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.

Case ID	WW Identifier	Narrative	MAH Comment
		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.	

Case ID	WW Identifier	Narrative	MAH Comment
4.1(b)	4.1(b)	This case was received via 4.1(b) Reference number: 4.1(b) on 24-Oct-2021 and was forwarded to Moderna on 24-Oct-2021. 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 4.1(b) 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. 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.	COnsumer report on a 40 years old male with unknown medical history 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.

Case ID	WW Identifier	Narrative	MAH Comment
		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 4.1(b) 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 4.1(b) syndrome, remains as a confounder. The benefit-risk relationship of Spikevax vaccine is not affected by this report.	

Case ID	WW Identifier	Narrative	MAH Comment
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), 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 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.	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 excluded due to the lack of other information.

Case ID	WW Identifier	Narrative	MAH Comment
		For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Concomitant medications was not reported.	

Case ID	WW Identifier	Narrative	MAH Comment
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. 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	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 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.

Case ID	WW Identifier	Narrative	MAH Comment
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) (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.	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 causal relationship cannot be excluded due to the lack of other information.

Case ID	WW Identifier	Narrative	MAH Comment
		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 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.	

Case ID	WW Identifier	Narrative	MAH Comment
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 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.	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.

Case ID	WW Identifier	Narrative	MAH Comment
4.1(b)	4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b) 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 4.1(b) by a pharmacist, was received via the 4.1(b) (Ref, 4.1(b) 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.	31 years old male with unknown medical history 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.

Case ID	WW Identifier	Narrative	MAH Comment
		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.	

Case ID	WW Identifier	Narrative	MAH Comment
4.1(b)	4.1(b)	This case was received via 4.1(b) (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. 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.	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.

Case ID	WW Identifier	Narrative	MAH Comment
		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.	

Case ID	WW Identifier	Narrative	MAH Comment
4.1(b)	4.1(b)	This case was received via 4.1(b) (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.	

Case ID	WW Identifier	Narrative	MAH Comment
4.1(b)	4.1(b)	This case was received via 4.1(b) (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.

Case ID	WW Identifier	Narrative	MAH Comment
4.1(b)	4.1(b)	This case was received via 4.1(b) (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 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.	27 years old male with unknown medical history who the next day after the the 2nd dose developed 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.

Case ID	WW Identifier	Narrative	MAH Comment
4.1(b)	4.1(b)	This case was received via 4.1(b) (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) 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.	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 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.

Case ID	WW Identifier	Narrative	MAH Comment
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. 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 4.1(b) 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..	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 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.

Case ID	WW Identifier	Narrative	MAH Comment
		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 4.1(b) [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.	

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 04-Sep-2021. The 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 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) 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). In August 2021, Blood creatinine: 87 (normal) 87 umol/L (micromole per litre)	19 years old female with unknown medical history who same day after the 2nd dose of the vaccine 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

Case ID	WW Identifier	Narrative	MAH Comment
		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 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) 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.	

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 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) 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)	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.

Case ID	WW Identifier	Narrative	MAH Comment
		4.1(b) had resolved. On 24-Aug-2021, DISCOMFORT 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,	

Case ID	WW Identifier	Narrative	MAH Comment
		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.	

Case ID	WW Identifier	Narrative	MAH Comment
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. 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	22 years old male with unknown medical history 4 days after the 2nd dose of the vaccine experienced chest pain, and was diagnosed with 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.

Case ID	WW Identifier	Narrative	MAH Comment
		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	

Case ID	WW Identifier	Narrative	MAH Comment
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. 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.	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.

Case ID	WW Identifier	Narrative	MAH Comment
		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.	

Case ID	WW Identifier	Narrative	MAH Comment
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. 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	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 including pateint's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2.

Case ID	WW Identifier	Narrative	MAH Comment
		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 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	

Case ID	WW Identifier	Narrative	MAH Comment
		significant information - updated inarrative.	

Case ID	WW Identifier	Narrative	MAH Comment
4.1(b)	4.1(b)	This regulatory authority case was reported by a consumer and describes the occurrence of PYREXIA (Fever) and MYOCARDITIS 4.1(b) 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, 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.	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 laboratory test conducted, including testing for SARS-CoV-2.

Case ID	WW Identifier	Narrative	MAH Comment
		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 translated and significant information from case narrative added.	

Case ID	WW Identifier	Narrative	MAH Comment
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 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 inferior leads and in V2-5, without PQ depression, with “J wave”. Pericarditis or “early repolarization” was discussed as a differential diagnosis. Transthoracic	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.

Case ID	WW Identifier	Narrative	MAH Comment
		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.	

Case ID	WW Identifier	Narrative	MAH Comment
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. 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 4.1(b) and sporty who drinks alcohol occasionally. Patient's medical history reported included consultation for palpitations on unspecified date of 2020 and 2021. After receiving	18 year old male patient who is a 4.1(b) 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 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

Case ID	WW Identifier	Narrative	MAH Comment
		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 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).	

Case ID	WW Identifier	Narrative	MAH Comment
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), 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)	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, 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

Case ID	WW Identifier	Narrative	MAH Comment
		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. 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.	

Case ID	WW Identifier	Narrative	MAH Comment
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 (Spikevax) (batch no. 3003604) for Vaccination. 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)) (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 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.	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 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

Case ID	WW Identifier	Narrative	MAH Comment
		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 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.	

Case ID	WW Identifier	Narrative	MAH Comment
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. 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.	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

Case ID	WW Identifier	Narrative	MAH Comment
		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.	

Case ID	WW Identifier	Narrative	MAH Comment
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) (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	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 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

Case ID	WW Identifier	Narrative	MAH Comment
		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 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	

Case ID	WW Identifier	Narrative	MAH Comment
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): 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	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

Case ID	WW Identifier	Narrative	MAH Comment
		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.	

Case ID	WW Identifier	Narrative	MAH Comment
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 (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 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 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 (4.1(b) 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	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 the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2.

Case ID	WW Identifier	Narrative	MAH Comment
		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 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	

Case ID	WW Identifier	Narrative	MAH Comment
4.1(b)	4.1(b)	This case was received via 4.1(b) (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.

Case ID	WW Identifier	Narrative	MAH Comment
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): In August 2021, C-reactive protein: 19 (High) 19 mg/L. In August 2021, Echocardiogram: normal (normal) No finding of pathological	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

Case ID	WW Identifier	Narrative	MAH Comment
		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.	

Case ID	WW Identifier	Narrative	MAH Comment
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 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	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.

Case ID	WW Identifier	Narrative	MAH Comment
		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.	

Case ID	WW Identifier	Narrative	MAH Comment
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. 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	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 as well as any other laboratory test conducted, including testing for SARS-CoV-2.

Case ID	WW Identifier	Narrative	MAH Comment
		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 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.	

Case ID	WW Identifier	Narrative	MAH Comment
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): 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	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.

Case ID	WW Identifier	Narrative	MAH Comment
		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.	

Case ID	WW Identifier	Narrative	MAH Comment
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 21-Sep-2021 and was forwarded to Moderna on 21-Sep-2021. This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (4.1(b) in a 22-year-old male patient who received mRNA-1273 (Spikevax) (batch no. FE9174) for 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.	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 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

Case ID	WW Identifier	Narrative	MAH Comment
		For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Patient was hospitalized 2 days after vaccination with Spikevax. First dose 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.	

Case ID	WW Identifier	Narrative	MAH Comment
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b) on 21-Sep-2021 and was forwarded to Moderna on 21-Sep-2021. 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) (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	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 is confounded by the administration of the other mRNA vaccine

Case ID	WW Identifier	Narrative	MAH Comment
		(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. 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.	

Case ID	WW Identifier	Narrative	MAH Comment
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): 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.	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

Case ID	WW Identifier	Narrative	MAH Comment
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. 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.	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

Case ID	WW Identifier	Narrative	MAH Comment
		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.	

Case ID	WW Identifier	Narrative	MAH Comment
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 (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 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.	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

Case ID	WW Identifier	Narrative	MAH Comment
		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.	

Case ID	WW Identifier	Narrative	MAH Comment
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 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:	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.

Case ID	WW Identifier	Narrative	MAH Comment
		On 23-Sep-2021: Translation Document received on 27-SEP-2021 and does not contain any new information.	

Case ID	WW Identifier	Narrative	MAH Comment
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 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.	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.

Case ID	WW Identifier	Narrative	MAH Comment
		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.	

Case ID	WW Identifier	Narrative	MAH Comment
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. 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	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.

Case ID	WW Identifier	Narrative	MAH Comment
		information ECG, transthoracic echocardiogram, coronary angiography added in lab data.in history alcohol use, tobacco use added narrative updated.	

Case ID	WW Identifier	Narrative	MAH Comment
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)), 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 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	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.

Case ID	WW Identifier	Narrative	MAH Comment
		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 [redacted] and HEADACHE [redacted] to be probably related and CHEST PAIN [redacted] LIMB DISCOMFORT [redacted] ABDOMINAL PAIN [redacted] and MYOCARDITIS [redacted] 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.	

Case ID	WW Identifier	Narrative	MAH Comment
		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.	

Case ID	WW Identifier	Narrative	MAH Comment
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)) (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	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, including testing for SARS-CoV-2. Report confounded by the normal tests including the chest x-raym the EKG and the ultrasensitive troponin assay.

Case ID	WW Identifier	Narrative	MAH Comment
		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. 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.	

Case ID	WW Identifier	Narrative	MAH Comment
4.1(b)	4.1(b)	This case was received via 4.1(b) (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. 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.	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.

Case ID	WW Identifier	Narrative	MAH Comment
4.1(b)	4.1(b)	This case was received via 4.1(b) (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. 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.	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.

Case ID	WW Identifier	Narrative	MAH Comment
4.1(b)	4.1(b)	This case was received via 4.1(b) (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. 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.	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.

Case ID	WW Identifier	Narrative	MAH Comment
4.1(b)	4.1(b)	This case was received via 4.1(b) (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. 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.	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.

Case ID	WW Identifier	Narrative	MAH Comment
4.1(b)	4.1(b)	This case was received via 4.1(b) (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: The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	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.

Case ID	WW Identifier	Narrative	MAH Comment
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): 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.	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.

Case ID	WW Identifier	Narrative	MAH Comment
		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.	

Case ID	WW Identifier	Narrative	MAH Comment
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 29-Sep-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 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 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.	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.

Case ID	WW Identifier	Narrative	MAH Comment
		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.	

Case ID	WW Identifier	Narrative	MAH Comment
		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.	

Case ID	WW Identifier	Narrative	MAH Comment
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 29-Sep-2021. This case was reported by a physician via the Drug Information Center. 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.	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 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.

Case ID	WW Identifier	Narrative	MAH Comment
4.1(b) [redacted]		This case was received via 4.1(b) 4.1(b) [redacted] (Reference number: 4.1(b) [redacted] 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 (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	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.

Case ID	WW Identifier	Narrative	MAH Comment
		(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)	

Case ID	WW Identifier	Narrative	MAH Comment
		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	

Case ID	WW Identifier	Narrative	MAH Comment
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 (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	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.

Case ID	WW Identifier	Narrative	MAH Comment
		(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)	

Case ID	WW Identifier	Narrative	MAH Comment
		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	

Case ID	WW Identifier	Narrative	MAH Comment
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): 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.	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.

Case ID	WW Identifier	Narrative	MAH Comment
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): 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.	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.

Case ID	WW Identifier	Narrative	MAH Comment
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 (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 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.	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

Case ID	WW Identifier	Narrative	MAH Comment
		For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Treatment information was not provided.	

Case ID	WW Identifier	Narrative	MAH Comment
4.1(b)	4.1(b)	This case was received via 4.1(b) (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 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.	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.

Case ID	WW Identifier	Narrative	MAH Comment
4.1(b)	4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b) on 27-Sep-2021 and was forwarded to Moderna on 01-Oct-2021. This case, reported by a physician, was received by 4.1(b) 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 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 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.	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.

Case ID	WW Identifier	Narrative	MAH Comment
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) [redacted]. 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.	

Case ID	WW Identifier	Narrative	MAH Comment
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.	

Case ID	WW Identifier	Narrative	MAH Comment
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.	

Case ID	WW Identifier	Narrative	MAH Comment
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 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/I. 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.	

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 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 (Myokarditis) 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.	

Case ID	WW Identifier	Narrative	MAH Comment
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.	

Case ID	WW Identifier	Narrative	MAH Comment
4.1(b)	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 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.	

Case ID	WW Identifier	Narrative	MAH Comment
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	

Case ID	WW Identifier	Narrative	MAH Comment
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.	

Case ID	WW Identifier	Narrative	MAH Comment
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 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 4.1(b) [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.	

Case ID	WW Identifier	Narrative	MAH Comment
4.1(b)	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 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.	

Case ID	WW Identifier	Narrative	MAH Comment
4.1(b) [redacted]		This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted] 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)	

Case ID	WW Identifier	Narrative	MAH Comment
4.1(b)		This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS 4.1(b))) and CHEST PAIN 4.1(b) 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) (seriousness criteria hospitalization and medically significant) and CHEST PAIN 4.1(b) (seriousness 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) and CHEST PAIN 4.1(b) had resolved.	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 possible according to the WHO causality assessment.

Case ID	WW Identifier	Narrative	MAH Comment
		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 taken and De-challenge for suspect product and updated narrative	

Case ID	WW Identifier	Narrative	MAH Comment
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. 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.	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 WHO causality assessment.

Case ID	WW Identifier	Narrative	MAH Comment
		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-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.	

Case ID	WW Identifier	Narrative	MAH Comment
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. 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.	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.

Case ID	WW Identifier	Narrative	MAH Comment
		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.	

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 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-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.	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; 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.

Case ID	WW Identifier	Narrative	MAH Comment
		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 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] 102 mg/dL, Urea 36.7 mg/dL, [redacted] 0.82 mg/dL, [redacted] 136 mmol/L, [redacted] 3.7 mmol/L, [redacted] 103 mmol/L, [redacted] 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 [redacted] 0.60(<5.20)ng/mL. On 27-Aug-2021, Pharyngeal exudate: Bordetella pertussis [redacted] parapertussis, Chlamydia pneumoniae, Mycoplasma pneumoniae: [redacted] RT-PCR [redacted] VRS [redacted]), Virus Influenza A, Influenza B, Virus [redacted], Coronavirus: [redacted] PCR [redacted] ADN [redacted] Adenovirus y ARN [redacted] Coronavirus (NL63, OC43, 229E, HKU1 y MERS-CoV), Enterovirus/Rinovirus, Metapneumovirus [redacted] Virus Parainfluenza (1, 2, 3 y 4): [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,	

Case ID	WW Identifier	Narrative	MAH Comment
		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	

Case ID	WW Identifier	Narrative	MAH Comment
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): 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	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.

Case ID	WW Identifier	Narrative	MAH Comment
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 04-Jun-2021. The most recent information was received on 05-Jul-2021 and was forwarded to Moderna on 05-Jul-2021. This spontaneous case was reported by a consumer and describes the occurrence of MYOCARDITIS (Myocarditis/ acute myocarditis) in a 28-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 006c21a) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concomitant products included FISH OIL from 05-Jan-2021 to an unknown date and SIMVASTATIN from 05-Jan-2021 to an unknown date for Cholesterol low, VITAMIN D [VITAMIN D NOS] from 10-Jan-2021 to an unknown date for Vitamin D increased. On 23-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 21-May-2021 at 8:30 AM, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 21-May-2021, the patient experienced MYALGIA (Body ache), CHILLS (Chills) and PYREXIA (Fever). On 24-May-2021, the patient experienced MYOCARDITIS (Myocarditis/ acute myocarditis) (seriousness criteria hospitalization and medically significant). The patient was hospitalized on 24-May-2021 due to CHEST PAIN and MYOCARDITIS. On 23-May-2021, MYALGIA (Body ache), CHILLS (Chills) and PYREXIA (Fever) had resolved. On 25-May-2021, MYOCARDITIS (Myocarditis/ acute myocarditis) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 25-Apr-2021, Magnetic resonance imaging: inconclusive (Inconclusive) Results are Unknown. On 24-May-2021, Angiogram: inconclusive (Inconclusive) Results are Unknown. On 24-May-2021, Electrocardiogram: abnormal (abnormal) Abnormal.	This is a 28 years old male with unknown medical history but who was taking Simvastatin, which suggest hypercholesterolemia. The patient 3 days after the 2nd dose of the vaccine developed chest pain and he was diagnosed with myocarditis. According to the CDC definition this case is a probable case of myocarditis; according to the Brigton collaboratuoin is a Level 4 case, and according to the WHO causality assessment, this case is considered possible. Important risk factors associated with this report is the medical history of hypercholesteronemia as well as use of Simvastatin, which is labelled for myopathy manifested as muscle pain, tenderness or weakness with creatine kinase (CK) above ten times the upper limit of normal (ULN).

Case ID	WW Identifier	Narrative	MAH Comment
		On 24-May-2021, Ultrasound scan: inconclusive (Inconclusive) Results are Unknown. On an unknown date, SARS-CoV-2 test: negative (Negative) Negative. By that evening, patient felt the usual symptoms of fever, body ache and chills, which continued for the next 48 hours. By Sunday, 05/23, he was feeling back to normal and in good health. The next morning, Monday, 05/24, he woke up with chest pain, a crushing pain in his heart and to the ER[redacted]). An EKG was taken, and the cardiologist mentioned that it was abnormal and that a catheter angiogram needed to be done to check the arteries. Treatment included overnight monitoring by the cardiology team. Next morning, the cardiologist told the patient that he has myocarditis, and that it is showing up in younger adults who have taken the vaccine. He is currently on medication over the course of the next month, till his follow up visit with the cardiologist. (Per source document). 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. Further information has been requested. Most recent FOLLOW-UP information incorporated above includes: On 05-Jul-2021: Updated Concomitant medication, lab data COVID- 19 test and event of Myocarditis end date were provided.	

Case ID	WW Identifier	Narrative	MAH Comment
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 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.	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.

Case ID	WW Identifier	Narrative	MAH Comment
		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).	

Case ID	WW Identifier	Narrative	MAH Comment
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, 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):	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.

Case ID	WW Identifier	Narrative	MAH Comment
		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.	

Case ID	WW Identifier	Narrative	MAH Comment
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, 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):	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.

Case ID	WW Identifier	Narrative	MAH Comment
		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.	

Case ID	WW Identifier	Narrative	MAH Comment
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. 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.	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.

Case ID	WW Identifier	Narrative	MAH Comment
		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.	

Case ID	WW Identifier	Narrative	MAH Comment
4.1(b)		This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Miocarditis aguda) 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): 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	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.

Case ID	WW Identifier	Narrative	MAH Comment
		investigation results and suspect vaccine details.	

Case ID	WW Identifier	Narrative	MAH Comment
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 (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.	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 information missing regarding other laboratory tests conducted, treatment, medical course, etc.

Case ID	WW Identifier	Narrative	MAH Comment
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) in a 19-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. EW0176) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concomitant products included SERTRALINE HYDROCHLORIDE (ZOLOFT) for an unknown indication. On 08-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 10-Jun-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criterion medically significant), TACHYCARDIA (Tachycardia), DYSPNOEA (shortness of breath), CHEST PAIN (Left sided chest pain) and BACK PAIN (radiating chest pain to the back x 7 days). The patient was treated with METHYLPREDNISOLONE (MEDROL DOSEPAK) at a dose of 1 dosage form. At the time of the report, MYOCARDITIS (Myocarditis), TACHYCARDIA (Tachycardia), DYSPNOEA (shortness of breath), CHEST PAIN (Left sided chest pain) and BACK PAIN (radiating chest pain to the back x 7 days) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 17-Jun-2021, Echocardiogram: mild st elevation (abnormal) mild ST elevation. On 17-Jun-2021, Metabolic function test: normal (normal) Comprehensive metabolic profile blood work normal. On 18-Jun-2021, Echocardiogram: normal (normal) normal. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments.	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 information missing regarding other laboratory tests conducted, treatment, medical course, etc.

Case ID	WW Identifier	Narrative	MAH Comment
		Treatment information also included rest. Was diagnosed from cardiologist as 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. No further information is expected at this time.	

Case ID	WW Identifier	Narrative	MAH Comment
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 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.	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.

Case ID	WW Identifier	Narrative	MAH Comment
		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.	

Case ID	WW Identifier	Narrative	MAH Comment
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 (FOCALIN XR ER), DEXMETHYLPHENIDATE HYDROCHLORIDE (FOCALIN [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) 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.	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.

Case ID	WW Identifier	Narrative	MAH Comment
		No treatment information was provided. Very limited information regarding these events has been provided at this time. Additional information required.	

Case ID	WW Identifier	Narrative	MAH Comment
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 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	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.

Case ID	WW Identifier	Narrative	MAH Comment
		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.	

Case ID	WW Identifier	Narrative	MAH Comment
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 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	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 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.

Case ID	WW Identifier	Narrative	MAH Comment
		normal coronary arteries & normal left ventricular function on LV gram. Treatment for the event included unspecified pain medication. 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.	

Case ID	WW Identifier	Narrative	MAH Comment
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 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.	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.

Case ID	WW Identifier	Narrative	MAH Comment
		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.	

Case ID	WW Identifier	Narrative	MAH Comment
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. 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 %.	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.

Case ID	WW Identifier	Narrative	MAH Comment
		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.	

Case ID	WW Identifier	Narrative	MAH Comment
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 36-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-May-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-May-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization, medically significant and life threatening). On an unknown date, the patient experienced VACCINATION SITE REACTION (COVID arm). At the time of the report, MYOCARDITIS (Myocarditis) had not resolved and VACCINATION SITE REACTION (COVID arm) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 27-May-2021, Angiogram: unknown (Inconclusive) Unknown. On 27-May-2021, Electrocardiogram: unknown (Inconclusive) Unknown. On 27-May-2021, Troponin: 9.0 (High) to over 9.0. On 27-May-2021, Ultrasound scan: unknown (Inconclusive) Unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Action taken with mRNA-1273 in response to the events was not applicable. Concomitant medications were not reported. Treatment information was not provided.	This is a 36 years old male with very limited information who 3 days after receiving the 2nd dose of the vaccine patient was diagnosed 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.

Case ID	WW Identifier	Narrative	MAH Comment
		It was reported that the patient experienced COVID arm after the first shot. Company comment: Based on the current available information and temporal association between the use of the product and the start date of the event of Myocarditis, a causal relationship cannot be excluded. Very limited information regarding the event of COVID arm has been provided at this time. No further information is expected.	

Case ID	WW Identifier	Narrative	MAH Comment
4.1(b)		This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS 4.1(b) and HYPERTHYROIDISM (Hyperthyroidism) in a 33-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) (batch no. 3003183) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Nicotine dependence and Overweight. On 05-Jun-2021, the patient received first dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 16-Jun-2021, received second dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 16-Jun-2021, after starting mRNA-1273 (Moderna CoviD-19 Vaccine), the patient experienced INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (Inappropriate schedule of product administration). On 17-Jun-2021, the patient experienced MYOCARDITIS 4.1(b) (seriousness criteria hospitalization and medically significant). On an unknown date, the patient experienced HYPERTHYROIDISM (Hyperthyroidism) (seriousness criterion medically significant). The patient was hospitalized from sometime in June 2021 to 23-Jun-2021 due to MYOCARDITIS. At the time of the report, MYOCARDITIS 4.1(b) had not resolved and HYPERTHYROIDISM (Hyperthyroidism) and INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (Inappropriate schedule of product administration) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 18-Jun-2021, Arteriogram coronary normal: normal Invasive exclusion of coronary heart disease.. On 18-Jun-2021, Echocardiogram: showed slightly impaired global LV function with baso-inferior and inferolateral hypokinesia.. On 18-Jun-2021, Magnetic resonance imaging heart: normal Heart MRI confirmed myocarditis.. On 18-Jun-2021, Troponin: (High) Urine revealed significantly elevated troponin..	This is a 33 years old male overweight and with very limited information provided who the next day 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 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.

Case ID	WW Identifier	Narrative	MAH Comment
		No concomitant product information was provided. No treatment information was provided. Patient reported that Invasive Exclusion of coronary heart disease using coronary angiography was performed on 18-Jun-2021. Also mentioned that a differential diagnosis was performed to rule out a viral cause of the myocarditis the result was still pending. 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 follow up is possible. Most recent FOLLOW-UP information incorporated above includes: On 14-Jul-2021: Translation document uploaded: Lab data, event and discharge date added.	

Case ID	WW Identifier	Narrative	MAH Comment
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 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.	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. 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.

Case ID	WW Identifier	Narrative	MAH Comment
		Findings corresponding to active inflammation/myocarditis.. On 26-Jun-2021, Serology test: negative (Negative) Negative. 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.	

Case ID	WW Identifier	Narrative	MAH Comment
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 (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) verhoogd / 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:	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, treatment, medical course, etc.

Case ID	WW Identifier	Narrative	MAH Comment
		On 15-Jul-2021: Significant follow-up received. Added batch number of second dose.	

Case ID	WW Identifier	Narrative	MAH Comment
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 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.	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 information missing regarding other laboratory tests conducted, treatment, medical course, etc.

Case ID	WW Identifier	Narrative	MAH Comment
4.1(b)		This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS 4.1(b) in a 36-year-old male patient who received mRNA-1273 (COVID 19 Vaccine Moderna) (batch nos. 3003183 and 3002183) for COVID-19 vaccination. No Medical History information was reported. On 11-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, 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): In 2021, Troponin: elevated (High) troponin elevation. The concomitant medications were not reported. The treatment information was not provided. The lab tests were reported as ecocardiogram and elevated troponin performed on an unspecified date confirmed the suspected myocarditis in the patient. Myocardial infarction and NSTEMI were ruled out. Most recent FOLLOW-UP information incorporated above includes: On 13-Jul-2021: Translation document was received on 20 July 2021 and had significant information. Added DOB of patient and batch number of first dose of drug, Lab data.	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 information missing regarding other laboratory tests conducted, treatment, medical course, etc.

Case ID	WW Identifier	Narrative	MAH Comment
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, 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.	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 hypertension and hyperlipidemia. There is also important information missing regarding other laboratory tests conducted, treatment, medical course, etc.

Case ID	WW Identifier	Narrative	MAH Comment
		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. 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.	

Case ID	WW Identifier	Narrative	MAH Comment
4.1(b)		This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS 4.1(b) in a 35-year-old male patient who received mRNA-1273 (COVID 19 Vaccine Moderna) (batch nos. 3002913 and 3002183) for COVID-19 vaccination. No Medical History information was reported. On 17-May-2021, the patient received first dose of mRNA-1273 (COVID 19 Vaccine Moderna) (Intramuscular) 1 dosage form. On 21-Jun-2021, received second dose of mRNA-1273 (COVID 19 Vaccine Moderna) (Intramuscular) dosage was changed to 1 dosage form. On 22-Jun-2021, the patient experienced MYOCARDITIS 4.1(b) (seriousness criteria hospitalization and medically significant). The patient was hospitalized on 22-Jun-2021 due to MYOCARDITIS. At the time of the report, MYOCARDITIS 4.1(b) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In June 2021, Troponin: increased (High) Reported as troponin increase. An acute myocardial infarction and hemorrhage disorder were excluded.. Concomitant medications were not reported. 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 event, a causal relationship cannot be excluded. Most recent FOLLOW-UP information incorporated above includes: On 13-Jul-2021: Translation received on 19-Jul-2021 and added relevant diagnostic testing findings and added lot number of first dose of vaccine.	This is a 35 years old male with very limited information provided who the next day 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 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.

Case ID	WW Identifier	Narrative	MAH Comment
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): 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.	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.

Case ID	WW Identifier	Narrative	MAH Comment
		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	

Case ID	WW Identifier	Narrative	MAH Comment
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 (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):	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 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.

Case ID	WW Identifier	Narrative	MAH Comment
		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. 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.	

Case ID	WW Identifier	Narrative	MAH Comment
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. 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.	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.

Case ID	WW Identifier	Narrative	MAH Comment
		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.	

Case ID	WW Identifier	Narrative	MAH Comment
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 (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),	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.

Case ID	WW Identifier	Narrative	MAH Comment
		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.	

Case ID	WW Identifier	Narrative	MAH Comment
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 (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.	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 regarding treatment, medical course, etc.

Case ID	WW Identifier	Narrative	MAH Comment
		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.	

Case ID	WW Identifier	Narrative	MAH Comment
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), 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.	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 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.

Case ID	WW Identifier	Narrative	MAH 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.	

Case ID	WW Identifier	Narrative	MAH Comment
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. 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.	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.

Case ID	WW Identifier	Narrative	MAH 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.	

Case ID	WW Identifier	Narrative	MAH Comment
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 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.	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.

Case ID	WW Identifier	Narrative	MAH Comment
		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 inform ation and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.	

Case ID	WW Identifier	Narrative	MAH Comment
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 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.	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.

Case ID	WW Identifier	Narrative	MAH 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.	

Case ID	WW Identifier	Narrative	MAH Comment
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 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.	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.

Case ID	WW Identifier	Narrative	MAH Comment
		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.	

Case ID	WW Identifier	Narrative	MAH Comment
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 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.	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.

Case ID	WW Identifier	Narrative	MAH Comment
		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.	

Case ID	WW Identifier	Narrative	MAH Comment
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. 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.	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 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.

Case ID	WW Identifier	Narrative	MAH 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 27-Jul-2021: Translated document received on 27-JUL-2021 contains significant information, Laboratory investigation and Anatomical Location, batch number for dose one updated. On 27-Jul-2021: Follow-up received on 27-JUL-2021 Contain No new information.	