

Case ID	WW Identifier	Narrative	MAH Comment
4.1(b)		This case was received via 4.1(b) (Reference number: 4.1(b)) on 12-Nov-2021 and was forwarded to Moderna on 12-Nov-2021. This regulatory authority case was reported by a consumer and describes the occurrence of FATIGUE (Fatigue/unusual tiredness), CHEST PAIN (Chest pain), DYSPNOEA (Shortness of breath), PALPITATIONS (Heart palpitations), TACHYCARDIA (Racing heart (tachycardia)), COLD SWEAT (clammy), MALAISE (generally unwell), ILLNESS (sickness), PERICARDITIS (Pericarditis) and MYOCARDITIS (Myocarditis) in a 24-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. On 29-Jul-2021, the patient received first dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 02-Nov-2021, received second dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 02-Nov-2021, the patient experienced FATIGUE (Fatigue/unusual tiredness) (seriousness criteria hospitalization, disability, medically significant and life threatening) and MALAISE (generally unwell) (seriousness criteria hospitalization, disability, medically significant and life threatening). On 03-Nov-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization, disability, medically significant and life threatening). On 04-Nov-2021, the patient experienced CHEST PAIN (Chest pain) (seriousness criteria hospitalization, disability, medically significant and life threatening), DYSPNOEA (Shortness of breath) (seriousness criteria hospitalization, disability,	24 years old male with unknown medical history who next day after the 2nd dose experienced chest pain, dyspnea, cold sweat, palpitations, tachycardia, and was found to have elevated troponin, abnormal ECG, SARS-CoV-2 negative, and was diagnosed with myopericarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and ECG results; a causal relationship cannot be excluded due to the missing information.

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		medically significant and life threatening), COLD SWEAT (clammy) (seriousness criteria hospitalization, disability, medically significant and life threatening) and ILLNESS (sickness) (seriousness criteria hospitalization, disability, medically significant and life threatening). On an unknown date, the patient experienced PALPITATIONS (Heart palpitations) (seriousness criteria hospitalization, disability, medically significant and life threatening), TACHYCARDIA (Racing heart (tachycardia)) (seriousness criteria hospitalization, disability, medically significant and life threatening) and PERICARDITIS (Pericarditis) (seriousness criteria hospitalization, disability, medically significant and life threatening). The patient was hospitalized for 5 days due to CHEST PAIN, COLD SWEAT, DYSPNOEA, FATIGUE, ILLNESS, MALAISE, MYOCARDITIS, PALPITATIONS, PERICARDITIS and TACHYCARDIA. At the time of the report, FATIGUE (Fatigue/unusual tiredness), CHEST PAIN (Chest pain), DYSPNOEA (Shortness of breath), PALPITATIONS (Heart palpitations), TACHYCARDIA (Racing heart (tachycardia)) and PERICARDITIS (Pericarditis) outcome was unknown, COLD SWEAT (clammy), MALAISE (generally unwell) and ILLNESS (sickness) had resolved and MYOCARDITIS (Myocarditis) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 04-Nov-2021, SARS-CoV-2 test: no - negative covid-19 test (Negative) No - Negative COVID-19 test. In November 2021, Blood test: 178 (High) Raised troponin 178, Troponin reference range 0-14. In November 2021, Electrocardiogram: presented as a heart attack presented as a heart attack.	

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		Patient attended Accident and Emergency, blood test taken and ECG, scan results presented as a heart attack. Patient was admitted to hospital with Myocarditis and Pericarditis. In hospital for 5 days. Awaiting MRI and ECHO and further blood tests. The diagnosis was made by a Cardiologist. Treatment included paracetamol and unspecified medication. Discharged with medication Bisoprolol and Ramipril. Concomitant product use was not provided by the reporter. Company Comment: This case concerns a 24-year-old male patient with no relevant medical history reported who experienced the unexpected and serious events of cold sweat, malaise, illness, fatigue, chest pain, dyspnoea, palpitations, tachycardia and the expected and AESI events of myocarditis and pericarditis. The events malaise and fatigue occurred the same day after the second dose of mRNA-1273 vaccine was administered, the event myocarditis the following day, the events cold sweats, illness and dyspnoea two days after and the rest of the events on an unknown day after vaccine was given. The rechallenge was not applicable as the events occurred after the second dose. Patient attended Accident and Emergency, blood test was taken (troponin was high 178 (0-14) and ECG, scan results presented as a heart attack. Patient was admitted to hospital due to myocarditis and pericarditis. He stayed in hospital for 5 days. Treatment included paracetamol and was discharged with bisoprolol and ramipril. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.	
4.1(b)		This regulatory authority case was reported by a physician and describes the occurrence of	39 years old male with medical history of 4.1(b) in 2019, who 3 days after the 2nd dose

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		MYOCARDITIS (Perimyocarditis) in a 39-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) (batch nos. 3002912 and 3002186) for COVID-19 immunisation. The patient's past medical history included 4.1(b) in September 2019. On 26-May-2021, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form. On 23-Jun-2021, received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) dosage was changed to 1 dosage form. On 26-Jun-2021, after starting mRNA-1273 (COVID-19 Vaccine Moderna), the patient experienced MYOCARDITIS (Perimyocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Perimyocarditis) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 26-Jun-2021, Blood creatine phosphokinase (Unknown-<190): 266 (High) 266 U/l. On 26-Jun-2021, Troponin I (Unknown-<100): 3453 (High) 3453 ng/l. On 29-Jun-2021, Blood creatine phosphokinase (Unknown-<190): 80 (normal) 80 U/l. On 29-Jun-2021, Troponin I (Unknown-<100): 600 (High) 600 ng/l. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered MYOCARDITIS (Perimyocarditis) to be possibly related. On 26-Jun-2021, patient suffered thoracic pain and was hospitalized. On an unknown date, tests showed elevation of ST segment, increased	experienced chest pain and was found to have elevated troponin, Ck, and abnormal ECG, and was diagnosed with myocarditis. Patient was discharged 3 days later. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and ECG results; a causal relationship cannot be excluded due to the missing information.

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		creatinine kinase (268 U/L) and coronary angiography was normal. Concomitant medications were not reported. Treatment included Irfen (Ibuprofen), Listril (Lisinopril), Metoprolol (exact preparation not known), Acetaminophen (exact preparation not known) and Pantoprazole (exact preparation not known). Patient showed good response. On 29-Jun-2021, patient was discharged from hospital. Company comment: This case concerns a 39-year-old, male patient with no relevant medical history, who experienced the serious expected AESI of Myocarditis. The event occurred 3 days after the second dose of mRNA-1273 vaccine. The lab information of increase in Blood creatine phosphokinase, and Troponin I and ST segment elevation support the diagnosis. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Event seriousness assessed as per Regulatory Authority reporting and retained for consistency with the RA report. Most recent FOLLOW-UP information incorporated above includes: On 15-Nov-2021: Translated document received on 17-NOV-2021. Updated case narrative and event verbatim.	
4.1(b)		This case was received via 4.1(b) (Reference number: 4.1(b) on 16-Nov-2021 and was forwarded to Moderna on 16-Nov-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of BLOOD TEST ABNORMAL (Blood test abnormal), CARDIAC MONITORING (Cardiac monitoring), CHEST X-RAY NORMAL (Chest X-ray normal), CHEST DISCOMFORT (Chest discomfort), CHEST PAIN (Chest pain), DYSPNOEA (Dyspnoea), ELECTROCARDIOGRAM	25 years old male with unknown medical history who next day after the 2nd dose experienced chest discomfort and chest pain, dyspnoea, painful respiration, and was found to have elevated troponin, and was diagnosed with myocarditis. EKG and other diagnostic test results are pending. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association

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		(Electrocardiogram), HYPOPNOEA (Hypopnoea), MONOCYTE COUNT INCREASED (Monocyte count increased), NEUTROPHIL COUNT INCREASED (Neutrophil count increased), PAINFUL RESPIRATION (Painful respiration), RESPIRATORY VIRAL PANEL (Respiratory viral panel), TROPONIN INCREASED (Troponin increased), WHITE BLOOD CELL COUNT INCREASED (White blood cell count increased) and MYOCARDITIS (Myocarditis) in a 25-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 939904 and 078C21A) for COVID-19 vaccination. No Medical History information was reported. On 01-Oct-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 01-Oct-2021, received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 02-Oct-2021, the patient experienced BLOOD TEST ABNORMAL (Blood test abnormal) (seriousness criteria hospitalization and life threatening), CARDIAC MONITORING (Cardiac monitoring) (seriousness criteria hospitalization and life threatening), CHEST X-RAY NORMAL (Chest X-ray normal) (seriousness criteria hospitalization and life threatening), CHEST DISCOMFORT (Chest discomfort) (seriousness criteria hospitalization and life threatening), CHEST PAIN (Chest pain) (seriousness criteria hospitalization and life threatening), DYSPNOEA (Dyspnoea) (seriousness criteria hospitalization and life threatening), ELECTROCARDIOGRAM (Electrocardiogram) (seriousness criteria hospitalization and life threatening), HYPOPNOEA (Hypopnoea) (seriousness criteria hospitalization and life threatening), MONOCYTE COUNT INCREASED	between the use of the product and the start of the events, as well as the elevated troponin results; a causal relationship cannot be excluded.

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		(Monocyte count increased) (seriousness criteria hospitalization and life threatening), NEUTROPHIL COUNT INCREASED (Neutrophil count increased) (seriousness criteria hospitalization and life threatening), PAINFUL RESPIRATION (Painful respiration) (seriousness criteria hospitalization and life threatening), RESPIRATORY VIRAL PANEL (Respiratory viral panel) (seriousness criteria hospitalization and life threatening), TROPONIN INCREASED (Troponin increased) (seriousness criteria hospitalization and life threatening), WHITE BLOOD CELL COUNT INCREASED (White blood cell count increased) (seriousness criteria hospitalization and life threatening) and MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization, medically significant and life threatening). At the time of the report, BLOOD TEST ABNORMAL (Blood test abnormal), CARDIAC MONITORING (Cardiac monitoring), CHEST X-RAY NORMAL (Chest X-ray normal), CHEST DISCOMFORT (Chest discomfort), CHEST PAIN (Chest pain), DYSPNOEA (Dyspnoea), ELECTROCARDIOGRAM (Electrocardiogram), HYPOPNOEA (Hypopnoea), MONOCYTE COUNT INCREASED (Monocyte count increased), NEUTROPHIL COUNT INCREASED (Neutrophil count increased), PAINFUL RESPIRATION (Painful respiration), RESPIRATORY VIRAL PANEL (Respiratory viral panel), TROPONIN INCREASED (Troponin increased), WHITE BLOOD CELL COUNT INCREASED (White blood cell count increased) and MYOCARDITIS (Myocarditis) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 02-Oct-2021, Chest X-ray: normal (normal) Normal.	

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		On 02-Oct-2021, Monocyte count (0.2-1.0): 2.6 (High) MONOCYTES ELEVATED AT 2.6 (RANGE .2-1.0). On 02-Oct-2021, Neutrophil count (0.00-0.04): 0.06 (High) IMMATURE NEUTROPHILS ELEVATED .06 (RANGE .00-.04). On 02-Oct-2021, Troponin: 176 (High) WITH A SECOND 2 HOUR TROPONIN ADDITIONALLY ELEVATED AT 176 and 159 (High) BLOODWORK RESULTS SHOWED AN ELEVATED TROPONIN AT 159(OVER 22 IS POSITIVE.). On 02-Oct-2021, White blood cell count (1.1-6.1): 16.1 (High) WBC BLOODWORK SHOWED ELEVATED AT 16.1 (RANGE 1.1-6.1). For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medication was given. Patient had to take shallow breaths due to pain in chest when a normal breath is taken Laboratory data was mentioned as patient done respiratory panel and EKG in ED but results was not given. As doctor suspect patient have myocarditis heart acho scheduled for tomorrow. No treatment medication was given. The patient presented to ED with chest pain, tightness and shortness of breath after receiving second covid shot 2 days ago. Patient had shallow breaths due to pain in chest when a normal breath is taken. The patient had bloodwork, respiratory panel, ekg, xray completed with bloodwork results showing an elevated troponin at 159(over 22 is positive.) with a second 2 hour troponin additionally elevated at 176. Impression from xray shows normal chest xray but findings reported image was obscured by overlying wires from heart monitor. WBC bloodwork showed elevated at 16.1 (range 1.1-6.1) monocytes elevated at 2.6	

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		(range .2-1.0) immature neutrophils elevated 0.06 (range .00-.04) MD suspected myocarditis and the patient was admitted with no communicated discharge date until echo results. Company Comment: This case concerns a 25-year-old, male patient with no relevant medical history, who experienced the unexpected events of Blood test abnormal, Cardiac monitoring, Chest X-ray normal, Chest discomfort, Dyspnoea, Electrocardiogram, Hypopnoea, Monocyte count increased, Neutrophil count increased, Painful respiration, Respiratory viral panel, Troponin increased, White blood cell count increased and expected event of Myocarditis. The events occurred approximately 1 day after the second dose of mRNA-1273. It was reported that both first and second dose was administered on the same date, which seems unlikely. The patient presented to ED with chest pain, tightness and shortness of breath after receiving second covid shot 2 days continued in company comment section.	
4.1(b)		This case was initially received via 4.1(b) (Reference number: 4.1(b)) on 16-Nov-2021. The most recent information was received on 18-Nov-2021 and was forwarded to Moderna on 18-Nov-2021. This regulatory authority case was reported by a consumer and describes the occurrence of ERECTILE DYSFUNCTION (Erection failure), URINARY RETENTION (Unable to urinate), HEART RATE (Heart rate), TACHYCARDIA (Racing heart), EJECTION FRACTION DECREASED (Ejection fraction low), HYPERHIDROSIS (Excess sweating), PARAESTHESIA (Tingling sensation), NIGHT SWEATS (excessive sweating), DYSPNOEA (Short of breathe), ARTHRALGIA (painful chest), PAIN (shooting pain),	29 years old male with unknown medical history with conflicting information regarding the TTO for all the described events. According to the information provided the patient had ejection fraction decreased and myocarditis 2 days after the 2nd dose of Spikevax, but the events of chest pain and tachycardia, dyspnea and elevated troponin were not until 32 days after the 2nd dose of Spikevax. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and

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		FATIGUE (Fatigue/unusual tiredness), CHEST PAIN (painful chest), PYREXIA (Fever), DYSPNOEA (Shortness of breath), PALPITATIONS (Heart palpitations), INCOHERENT (Incoherent), TACHYCARDIA (Tachycardia), HYPERHIDROSIS (Excess sweating), FATIGUE (Fatigue) and MYOCARDITIS (Myocarditis) in a 29-year-old male patient who received mRNA-1273 (COVID 19 Vaccine Moderna) for COVID-19 vaccination. No Medical History information was reported. On 17-Sep-2021, the patient received second dose of mRNA-1273 (COVID 19 Vaccine Moderna) (unknown route) 1 dosage form. On 19-Sep-2021, the patient experienced ERECTILE DYSFUNCTION (Erection failure) (seriousness criterion hospitalization), URINARY RETENTION (Unable to urinate) (seriousness criterion hospitalization), HEART RATE (Heart rate) (seriousness criterion hospitalization), EJECTION FRACTION DECREASED (Ejection fraction low) (seriousness criterion hospitalization), HYPERHIDROSIS (Excess sweating) (seriousness criterion hospitalization), PARAESTHESIA (Tingling sensation) (seriousness criterion hospitalization), INCOHERENT (Incoherent) (seriousness criterion hospitalization) and MYOCARDITIS (Myocarditis) (seriousness criterion hospitalization). 19-Sep-2021, the patient experienced HYPERHIDROSIS (Excess sweating) (seriousness criterion hospitalization) and FATIGUE (Fatigue) (seriousness criterion hospitalization). On 19-Oct-2021, the patient experienced TACHYCARDIA (Racing heart) (seriousness criterion hospitalization). 19-Oct-2021, the patient experienced TACHYCARDIA (Tachycardia) (seriousness criterion hospitalization). On an unknown date, the patient experienced NIGHT SWEATS (excessive sweating)	EKG results; a causal relationship cannot be excluded.

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		(seriousness criterion hospitalization), DYSPNOEA (Short of breathe) (seriousness criterion hospitalization), ARTHRALGIA (painful chest) (seriousness criterion hospitalization), PAIN (shooting pain) (seriousness criterion hospitalization), FATIGUE (Fatigue/unusual tiredness) (seriousness criterion hospitalization), CHEST PAIN (painful chest) (seriousness criterion hospitalization), PYREXIA (Fever) (seriousness criterion hospitalization), DYSPNOEA (Shortness of breath) (seriousness criterion hospitalization) and PALPITATIONS (Heart palpitations) (seriousness criterion hospitalization). At the time of the report, ERECTILE DYSFUNCTION (Erection failure), URINARY RETENTION (Unable to urinate), HEART RATE (Heart rate), TACHYCARDIA (Racing heart), EJECTION FRACTION DECREASED (Ejection fraction low), HYPERHIDROSIS (Excess sweating), PARAESTHESIA (Tingling sensation), TACHYCARDIA (Tachycardia), HYPERHIDROSIS (Excess sweating) and MYOCARDITIS (Myocarditis) had not resolved, NIGHT SWEATS (excessive sweating), DYSPNOEA (Short of breathe), ARTHRALGIA (painful chest), PAIN (shooting pain), FATIGUE (Fatigue/unusual tiredness), CHEST PAIN (painful chest), PYREXIA (Fever), DYSPNOEA (Shortness of breath) and PALPITATIONS (Heart palpitations) outcome was unknown and INCOHERENT (Incoherent) and FATIGUE (Fatigue) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Ejection fraction: 47 percent (Low) 47 percent. On an unknown date, SARS-CoV-2 test: negative (Negative) Negative. On an unknown date, Troponin: raised (High) raised.	

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		The action taken with mRNA-1273 (COVID 19 Vaccine Moderna) (Unknown) was unknown. Patient had shooting pain through the heart, Increased heart rate, unable to think clearly, unable to urinate without focusing, extreme tiredness and tingling sensation across his head and neck frequently. No concomitant drugs were provided. Patient underwent ECG, echocardiogram, 24 hour heart holter test, blood tests and the results were not provided. Patient referred to cardiologist. Cardiologist diagnosed regional myocarditis and LVEF in his heart working at 47% due to inflammation on his heart. Patient was hospitalized for 2 days Treatment medication reported included Ramparil and biosoprolol. More tests were pending Patient underwent troponin test ,which were raised. This case concerns a 29 year-old male patient with no reported medical history, who experienced the expected serious AESI of Myocarditis, and the unexpected serious events of Tachycardia, Ejection fraction decreased, Chest pain, Dyspnoea, and Pyrexia. The events of Myocarditis with Ejection fraction decreased occurred 2 days after the second dose of mRNA-1273 vaccine, the event of Tachycardia occurred 32 days after the second dose, and the events of Chest pain, Dyspnoea, and Pyrexia occurred an unknown number of days after the second dose. Troponin levels were found raised. Patient reported evaluation with ECG, echocardiogram, 24 hr Holter, but results were not provided. Additional information is not expected for this RA case. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes:	

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		On 18-Nov-2021: Follow-up received on 18-NOV-2021 contains significant information- Lab data updated.	
4.1(b)		This case was initially received via 4.1(b) (Reference number: 4.1(b) on 10-Nov-2021. The most recent information was received on 10-Nov-2021 and was forwarded to Moderna on 24-Nov-2021. This case, initially reported to the 4.1(b)) by a physician, was received via the 4.1(b) (Ref, 4.1(b) On 10-Nov-2021, this case, as follow-up information, reported by a vaccinator other than a physician, was received by 4.1(b) via Moderna's adverse reaction reporting site 4.1(b) and this case, initially reported to the 4.1(b)) by a vaccinator other than a physician, was received via the 4.1(b) (Ref, 4.1(b) On an unknown date, the patient received the 1st dose of this vaccine. On 07-Nov-2021, at 14:00, the patient received the 2nd dose of this vaccine. Pyrexia developed at night. Pyrexia did not subside with oral administration of acetaminophen. On 09-Nov-2021, pyrexia persisted, and in the morning, the patient experienced chest pain for about one hour. At 13:30, the patient visited the reporting hospital and was hospitalized. ST elevation was observed in the electrocardiogram. Blood test showed WBC: 9,450, CPR: 5.77, AST: 72, ALT: 28, LDH: 247, CK: 804, CK-MB: 35.7, myoglobin: 233, and troponin I: 17.8. Elevated cardiac enzymes were observed. Cardiac ultrasound showed diffuse hypokinesis of the left ventricular wall with EF of	16 years old male with unknown medical history who the same day after the 2nd dose experienced pyrexia, and two days later experienced chest pain and was found to have elevated troponin, CRP, CK-MB, abnormal EKG, and Echo, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and EKG and Echo results; a causal relationship cannot be excluded.

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		approximately 50%. The patient was transferred to another hospital with a diagnosis of myocarditis. On an unknown date, electrocardiogram showed widespread ST, CK, and CK-MB elevation; thus, acute myocarditis could not be ruled out. The patient was therefore hospitalized for follow-up and detailed examinations. Currently, the symptoms subsided. The outcome of myocarditis was reported as ongoing and unchanged. Follow-up investigation will be made. Follow-up received on 10-NOV-2021 Updated: Reporter Information, Patient Information, Other Relevant History, Lab Data, Product Information, Narrative Company Comment: The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	
4.1(b)		This case was received via 4.1(b) (Reference number: 4.1(b)) on 10-Nov-2021 and was forwarded to Moderna on 17-Nov-2021. This case, initially reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref, 4.1(b)) Myocarditis was assessed as serious by the MAH. On 21-Sep-2021, at 14:30, the patient received the 1st dose of this vaccine. On unknown date, Myalgia and pyrexia developed. On 19-Oct-2021, at 11:00, the patient received the 2nd dose of this vaccine.	18 years old male with unknown medical history who the next day after the 2nd dose experienced chest pain, chest discomfort, dyspnea, and the next day was found to have elevated troponin, and CK-MB, CRP, abnormal EKG, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and EKG results; a causal relationship cannot be excluded.

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		On 20-Oct-2021, myocarditis developed. Chest discomfort, chest pain, breathlessness, and the like developed. On 22-Oct-2021, as the symptoms were persisting, the patient visited a nearby hospital. The patient was referred to the reporting department because of positive TnT. Myocardial enzymes were positive with CK 279 U/L, CK-MB 28 U/L, TnT 0.30 pg/mL-MB 28 U/L, and TnT 0.30 pg/mL, and CRP was weakly positive at 1.19 mg/dL. Cardiac function slightly decreased to LVEF 50%, but there were no signs of heart failure. The myocarditis was suspected to be due to this vaccine, but there were almost no serious cases in the previous reports, and the patient was thus followed up at home. On 01-Nov-2021, the patient visited the hospital again. Myocardial enzymes became negative, LVEF normalized, and the symptoms resolved, and the treatment was terminated. The outcome of myalgia and pyrexia was unknown. The outcome of myocarditis was reported as resolved. Follow-up investigation will be made . Company Comment: The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	
4.1(b)		This case was received via 4.1(b) (Reference number: 4.1(b) on 16-Nov-2021 and was forwarded to Moderna on 16-Nov-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of ARTHRALGIA (Arthralgia), CHILLS (Chills), EYE PAIN (Eye pain), HEADACHE	20 years old male with unknown medical history who 24 day after the 2nd dose experienced chills, headache, pyrexia, myalgia, and was found to have elevated troponin, and was diagnosed with myocarditis. It was reported that the patient had recently arrived from traveling. No other information was provided. Important information is missing in the report including patient's medical

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		(Headache), MYALGIA (Myalgia), PYREXIA (Pyrexia), TROPONIN INCREASED (Troponin increased) and MYOCARDITIS (Myocarditis) in a 20-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. On 13-Jun-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 13-Jun-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 07-Jul-2021, the patient experienced ARTHRALGIA (Arthralgia) (seriousness criterion hospitalization), CHILLS (Chills) (seriousness criterion hospitalization), EYE PAIN (Eye pain) (seriousness criterion hospitalization), HEADACHE (Headache) (seriousness criterion hospitalization), MYALGIA (Myalgia) (seriousness criterion hospitalization), PYREXIA (Pyrexia) (seriousness criterion hospitalization), TROPONIN INCREASED (Troponin increased) (seriousness criterion hospitalization) and MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, ARTHRALGIA (Arthralgia), CHILLS (Chills), EYE PAIN (Eye pain), HEADACHE (Headache), MYALGIA (Myalgia), PYREXIA (Pyrexia), TROPONIN INCREASED (Troponin increased) and MYOCARDITIS (Myocarditis) outcome was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. No concomitant medications were reported. Patient developed fever, myalgia, headache, chills, joint pain, and pain behind the eye following recent travel	history as well as any other laboratory test conducted, including testing for SARS-CoV-2 which is very important due to the recent travel history. According to the WHO causality assessment this report is 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.

Case ID	WW Identifier	Narrative	MAH Comment
		and 20 days post second dose of Moderna vaccine. Troponin of 0.44/high, Troponin 507.94. Patient was managed for a broad differential including Myocarditis (viral vs. COVID vaccine) and received Vancomycin, Unasyn, Doxycycline, Ibuprofen and colchicine. Patient was currently stable and discharged after 3 days of admission. Company Comment: This case concerns a 20-years-old patient, with no relevant medical history reported, who experienced the serious expected event of MYOCARDITIS and the unexpected events of ARTHRALGIA, CHILLS, EYE PAIN, HEADACHE, MYALGIA and PYREXIA. The events occurred twenty-four days after the dose of the mRNA-1273 vaccine. The rechallenge was not applicable since the administration date for both doses was reported as the same. The benefit-risk relationship of the mRNA-1273 is not affected by this report.	
4.1(b)		This case was received via European Medicines Agency (Reference number: 4.1(b)) on 17-Nov-2021 and was forwarded to Moderna on 17-Nov-2021. This regulatory authority case was reported by a physician and describes the occurrence of NAUSEA (Nausea that lasted a day), DYSPNOEA (Woke up with Dyspnoea. Later the dyspnoea was only exertional and not at rest), CHILLS (Chills), DIZZINESS (Little dizzy after emerged chest pain), CHEST PAIN (Woke up with acute chest pain. Pressure-like pain over breastbone radiating to left arm was experienced. The Chest pain was aggravated by breathing and when the patient was in standing position), VOMITING (Vomiting that lasted a day), PYREXIA (Fever) and MYOCARDITIS (Myocarditis) in a 30-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 immunisation.	30 years old male with unknown medical history who 5 days after the 2nd dose experienced pyrexia, dyspnoea, chest pain, nausea, chills, and was found to have elevated troponin, abnormal EKG, abnormal CT scan and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and EKG results; a causal relationship cannot be excluded.

Case ID	WW Identifier	Narrative	MAH Comment
		Previously administered products included for COVID-19 immunisation: COVID-19 VACCINE MODERNA in 2021. Past adverse reactions to the above products included No adverse reaction with COVID-19 VACCINE MODERNA. On 08-Oct-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 13-Oct-2021, the patient experienced DYSPNOEA (Woke up with Dyspnoea. Later the dyspnoea was only exertional and not at rest) (seriousness criterion hospitalization), CHEST PAIN (Woke up with acute chest pain. Pressure-like pain over breastbone radiating to left arm was experienced. The Chest pain was aggravated by breathing and when the patient was in standing position) (seriousness criterion hospitalization) and MYOCARDITIS (Myocarditis) (seriousness criterion hospitalization). In October 2021, the patient experienced NAUSEA (Nausea that lasted a day) (seriousness criterion hospitalization), CHILLS (Chills) (seriousness criterion hospitalization), DIZZINESS (Little dizzy after emerged chest pain) (seriousness criterion hospitalization), VOMITING (Vomiting that lasted a day) (seriousness criterion hospitalization) and PYREXIA (Fever) (seriousness criterion hospitalization). In October 2021, NAUSEA (Nausea that lasted a day) and VOMITING (Vomiting that lasted a day) had resolved. At the time of the report, DYSPNOEA (Woke up with Dyspnoea. Later the dyspnoea was only exertional and not at rest), CHILLS (Chills), DIZZINESS (Little dizzy after emerged chest pain), CHEST PAIN (Woke up with acute chest pain. Pressure-like pain over breastbone radiating to left arm was experienced. The Chest pain was aggravated by breathing and when the patient was in standing position) and PYREXIA (Fever) outcome was unknown and	

Case ID	WW Identifier	Narrative	MAH Comment
		MYOCARDITIS (Myocarditis) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 13-Oct-2021, Auscultation: normal (normal) Regular heart rhythm and no murmurs. On 13-Oct-2021, Blood pressure measurement: 121/72 (normal) 121/72 mmHg. On 13-Oct-2021, Electrocardiogram: normal (normal) No signs of ischemia. Regular sinus rhythm and frequency of 71 Beats per minute. On 13-Oct-2021, Fibrin D dimer: < 0.3 (normal) < 0.3 Unit not specified. On 13-Oct-2021, Heart rate: 75 (normal) 75 Beats per minute. On 13-Oct-2021, International normalised ratio: 1.0 (normal) 1.0 Unit not specified. On 13-Oct-2021, Oxygen saturation: 98 (normal) 98 percent. On 13-Oct-2021, Physical examination: normal (normal) Do not seem acutely or chronically affected. Do not seem pain affected. On 13-Oct-2021, Respiratory rate: 16 (normal) 16 Breaths per minute. On 13-Oct-2021, Troponin T: 281 (High) 281 Unit not specified. In October 2021, Computerised tomogram: abnormal (abnormal) with heterogenous charge supporting myocarditis and normal (normal) Of heart, no cardiac sclerosis or stenosis. In October 2021, Electrocardiogram: normal (normal) No EKG changes during the hospitalisation. In October 2021, Troponin T: 529 (High) Maximum measured value of 529 Unit not specified. On 18-Oct-2021, Troponin T: low (Low) Immeasurable low. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medication reported. No Treatment Medication reported. On 13-OCT-2021, patient went for Blood test with unknown result	

Case ID	WW Identifier	Narrative	MAH Comment
		Company comment: This case concerns a 30-year-old male patient, with no reported relevant medical history, who experienced the unexpected serious events of NAUSEA, DYSPNOEA, CHILLS, DIZZINESS, CHEST PAIN, VOMITING, PYREXIA and MYOCARDITIS (AESI). The events occurred approximately 6 days after the administration of the second dose of mRNA-1273 Vaccine. The rechallenge was not applicable. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report.	
4.1(b)		This case was received via 4.1(b) (Reference number: 4.1(b) on 13-Nov-2021 and was forwarded to Moderna on 19-Nov-2021. This case, initially reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref, 4.1(b) On 31-Aug-2021, at 14:00, the patient received the 1st dose of the vaccine. On 28-Sep-2021, at 14:00, the patient received the 2nd dose of the vaccine. On 29-Sep-2021, at 17:00, acute myocarditis developed. On an unknown date, at the time of hospital visit, the patient had a high fever. Electrocardiogram showed ST elevation in I, aVL, and V2-6 with circumferential wall hypokinesia by echocardiography and increased CPK of 424 IU/L, and thus the patient was diagnosed with acute myocarditis. On 01-Oct-2021, the patient was hospitalized. On 08-Oct-2021, the patient was discharged from the hospital. On 12-Nov-2021, the symptom was resolving. Subsequent blood test denied virus as the cause, and based on the course of the disease, the	20 years old male with unknown medical history who 2 days after the 2nd dose experienced pyrexia, and was found to have elevated CPK and abnormal EKG, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated CRP and EKG results; a causal relationship cannot be excluded.

Case ID	WW Identifier	Narrative	MAH Comment
		patient was diagnosed with acute myocarditis due to the vaccine. The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. The outcome of acute myocarditis was reported as resolving. Follow-up investigation will be made. Company Comment: The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	
4.1(b)		This case was received via 4.1(b) (Reference number: 4.1(b) on 13-Nov-2021 and was forwarded to Moderna on 19-Nov-2021. This case, initially reported to the 4.1(b) by a (pharmacist), was received via the 4.1(b) (Ref, 4.1(b) On 21-Sep-2021, the patient received the 1st dose of the vaccine. On an unknown date, body temperature before the vaccination: 35.1 degrees Celsius. On 19-Oct-2021, at 16:15, the patient received the 2nd dose of the vaccine. On 20-Oct-2021, perimyocarditis developed. The patient experienced pyrexia of 39.0-39.9 degrees Celsius. On 21-Oct-2021, the patient had pyrexia of 38.0-38.9 degrees Celsius. At night, the patient experienced chest pain which was exacerbated during inspiration and feeling of dyspnea. On 22-Oct-2021, the patient had pyrexia of 37.8 degrees Celsius. Body temperature was reduced to 36.0-36.9 degrees Celsius after loxoprofen sodium hydrate was taken orally, but the patient felt that feeling	28 years old male with unknown medical history who 3 dayw after the 2nd dose experienced pyrexia, chest pain and was found to have elevated troponin, and CK-MB, and abnormal EKG, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and EKG results; a causal relationship cannot be excluded.

Case ID	WW Identifier	Narrative	MAH Comment
		of dyspnea and chest pain got worse than the previous day. The patient was urgently transported to a hospital. BP: 120/86, PR: 83, BT: 36.3 degrees Celsius, and SpO2: 98% (RA). Blood test showed CK/CKMB 323/19, CRP 7.5, and BNP 139. Electrocardiogram and echocardiography were performed, and left ventricular ejection fraction was 40% on echocardiography. The patient was referred and transported to the reporting hospital for suspected myocarditis. Chest pain reached its peak before the emergency transportation to the reporting hospital. At 14:00, on arrival at the reporting hospital, the patient had no chest pain. There was also no feeling of dyspnea in the supine position. The patient was hospitalized for fluid replacement, bed rest, and symptomatic treatment. On 23-Oct-2021, CK decreased to 242 while TnT slightly increased to 0.464. Although electrocardiogram showed 61 bpm and ST elevation in I, aVL, II, III, aVF, and V1-6, an improving tendency was seen in the findings compared to those on admission. Echocardiography also showed a slight improving tendency in wall motion. On 25-Oct-2021, subjective symptoms improved. Regarding the test values, CK was within the reference range, and electrocardiographic waveform showed an improving tendency of ST. On 27-Oct-2021, the clinical status had peaked out, and there was an improving tendency. The symptoms resolved, and the patient was discharged from the hospital. The outcome of perimyocarditis was reported as resolved. Follow-up investigation will be made.	

Case ID	WW Identifier	Narrative	MAH Comment
		Company Comment: The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	
4.1(b)		This case was received via 4.1(b) (Reference number: 4.1(b) on 13-Nov-2021 and was forwarded to Moderna on 19-Nov-2021. This case, initially reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref 4.1(b) On unknown date, the patient received the 1st dose of this vaccine. On 04-Nov-2021, around 16:30, the patient received the 2nd dose of this vaccine. A few hours after the vaccination, the patient experienced malaise and pyrexia. On 05-Nov-2021, around 17:30, pain in the left precordial region developed, and the patient visited the emergency outpatient department of the reporting hospital. Electrocardiogram showed ST elevation in I, aVL, and V1-5. On 06-Nov-2021, the patient was hospitalized with a diagnosis of acute pericarditis. On 09-Nov-2021, the disease was not complicated by heart failure, and no elevation of cardiac enzymes was noted. The symptoms improved only with oral medications such as analgesics, and thus the patient was discharged from the hospital. The outcome of malaise, pyrexia, acute pericarditis was reported as resolving. Follow-up investigation will be made. Company Comment:	17 years old male with unknown medical history who next day after the 2nd dose experienced chest pain and was found to have elevated cardiac enzymes and abnormal EKG and was diagnosed with pericarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated cardiac enzymes and EKG results; a causal relationship cannot be excluded due to the lack of other information.

Case ID	WW Identifier	Narrative	MAH Comment
		The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	
4.1(b)		This regulatory authority case was reported by a consumer and describes the occurrence of PERICARDITIS (Heart problems/pericarditis. The ECHO showed fluid accumulation of 12-14mm in the pericardium (pericardial effusion). Treatment: 0.5mg colchicine 2 tablets per day Course: there were...) in a 39-year-old female patient who received mRNA-1273 (COVID-19 Vaccine Moderna) (batch nos. 3003188 and 3002541) for an unknown indication. No medical history was reported. Concomitant products included ESTRADIOL, NORETHISTERONE ACETATE (SYSTEM CONTI) from 01-Jan-2021 to an unknown date for Menopause. On 01-Jun-2021, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form. On 29-Jun-2021, received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) dosage was changed to 1 dosage form. On 28-Jul-2021, after starting mRNA-1273 (COVID-19 Vaccine Moderna), the patient experienced PERICARDITIS (Heart problems/pericarditis. The ECHO showed fluid accumulation of 12-14mm in the pericardium (pericardial effusion). Treatment: 0.5mg colchicine 2 tablets per day Course: there were...) (seriousness criterion medically significant). At the time of the report, PERICARDITIS (Heart problems/pericarditis. The ECHO showed fluid accumulation of 12-14mm in the pericardium (pericardial effusion). Treatment: 0.5mg colchicine 2 tablets per day Course: there were..) had not resolved.	39 years old male with unknown medical history and concomitant use of contraceptives for the oast 6 months, who 29 days after the 2nd dose was found to have pericardial effusion on the Echo and was diagnosed with pericarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the abnormal Echo results; a causal relationship cannot be excluded due to the lack of other information.

Case ID	WW Identifier	Narrative	MAH Comment
		DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Echocardiogram: abnormal (abnormal) The ECHO showed fluid accumulation of On Jul 28, the patient had pericarditis with pericardial effusion (accumulation of 12-14 mm of fluid) revealed by ECHO. The patient was treated with colchicine 0.5 mg, 2 tablets per day. The patient reported that the fluid accumulation (3-4 mm) continues and that the treatment also continues, presumably at the time of the report. Heart problems/pericarditis. The ECHO showed fluid accumulation of 12- 14mm in the pericardium (pericardial effusion). Treatment: 0.5mg colchicine 2 tablets per day. Course: there was fluid accumulation of 12- 14mm, The treatment is still ongoing. At the time of reporting, the symptoms have not resolved. Reaction reported as non-serious. Further course unknown. Heart problems/pericarditis. The ECHO showed fluid accumulation of 12- 14mm in the pericardium (pericardial effusion). Treatment: 0.5mg colchicine 2 tablets per day Course: there was fluid accumulation of 3- 4mm. (deu). Company comment: This regulatory authority case concerns a 39-year-old female patient with no relevant medical history, who experienced the expected serious (medically significant) event/AESI of Pericarditis after mRNA- 1273 Moderna vaccine. The event occurred approximately 29 days after the second dose of mRNA- 1273 vaccine. Very limited information is available regarding clinical manifestations. Echocardiogram showed fluid accumulation of 12-14mm in the pericardium. Treatment with colchicine was prescribed with reduction of the pleural effusion to 3-	

Case ID	WW Identifier	Narrative	MAH Comment
		4mm. At the time of the report, treatment was ongoing and the event had not yet resolved. The rechallenge is not applicable, since the event was reported exclusively after the second dose. The benefit-risk relationship of mRNA- 1273 vaccine is not affected by this report Most recent FOLLOW-UP information incorporated above includes: On 19-Nov-2021: Translation received on 23-Nov-2021 contains translated event verbatim, lab test result, senders comment and reporters comment which is updated.	
4.1(b)		This case was received via 4.1(b) (Reference number: 4.1(b)) on 17-Nov-2021 and was forwarded to Moderna on 22-Nov-2021. This case, initially reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref, 4.1(b)) On an unknown date, the patient received the 1st dose of this vaccine. On an unknown date, body temperature before the vaccination: 37.2 degrees Celsius. On 05-Nov-2021, at 18:45, the patient received the 2nd dose of this vaccine. On 06-Nov-2021, in the morning, pyrexia and chest discomfort developed. The patient was considered to experience myocarditis. On 07-Nov-2021, at night, the symptoms were exacerbated, and the patient was unable to sleep. Analgesics were ineffective. On 08-Nov-2021, the patient visit a nearby physician. WBC: 7,500, and CRP: 4.9. Electrocardiogram of V2-6 showed ST elevation, and the patient was referred to the reporting hospital because myocarditis was suspected.	14 years old male with unknown medical history who the next day after the 2nd dose experienced pyrexia, and chest discomfort and 2 days later was found to have elevated troponin, CRP and CPK, and abnormal EKG, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and EKG results; a causal relationship cannot be excluded.

Case ID	WW Identifier	Narrative	MAH Comment
		CPK increased, and troponin I increased markedly to 4,952. The patient was hospitalized for treatment as myocarditis with electrocardiogram findings. On 15-Nov-2021, the symptoms were resolving, and the patient was discharged from the hospital. The outcome of myocarditis was reported as resolving. Follow-up investigation will be made. Company Comment: The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	
4.1(b)		This case was received via European Medicines Agency (Reference number: 4.1(b)) on 22-Nov-2021 and was forwarded to Moderna on 22-Nov-2021. This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (Myocarditis) in a 33-year-old female patient who received mRNA-1273 (Spikevax) (batch nos. 3004955 and 3006273) for an unknown indication. No Medical History information was reported. On 07-Sep-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 07-Sep-2021, received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. On 08-Sep-2021, after starting mRNA-1273 (Spikevax), the patient experienced MYOCARDITIS (Myocarditis) (seriousness criterion medically significant). At the time of the report, MYOCARDITIS (Myocarditis) was resolving. No concomitant medications were reported.	33 years old female with unknown medical history who next day after the 2nd dose was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events; a causal relationship cannot be excluded.

Case ID	WW Identifier	Narrative	MAH Comment
		No treatment information was provided. Company Comment : This regulatory case concerns a 33-year-old, female patient with no relevant medical history, who experienced the expected, serious AESI of myocarditis. The event occurred 1 day after administration of a dose of the Moderna mRNA-1273. Treatment information was not provided. However, the event was resolving at the time of the report. The rechallenge was not applicable as no additional dosing will be given. The benefit-risk relationship of the Moderna mRNA-1273 is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 22-Nov-2021: Translation received on 23-NOV-2021. Translated event verbatim updated.	
4.1(b)		This case was received via European Medicines Agency (Reference number: 4.1(b)) on 22-Nov-2021 and was forwarded to Moderna on 22-Nov-2021. This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Acute myocarditis) in a 34-year-old male patient who received mRNA-1273 (Spikevax) for Prophylactic vaccination. Previously administered products included for COVID-19 vaccination: COVID-19 VACCINE MODERNA in September 2021. Past adverse reactions to the above products included No adverse event with COVID-19 VACCINE MODERNA. On 26-Oct-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 27-Oct-2021, the patient experienced MYOCARDITIS (Acute myocarditis) (seriousness criterion hospitalization). At the time of the	34 years old male with unknown medical history who next day after the 2nd dose was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events; a causal relationship cannot be excluded.

Case ID	WW Identifier	Narrative	MAH Comment
		report, MYOCARDITIS (Acute myocarditis) had not resolved. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. No concomitant medication was reported. Treatment medication was not provided by the reporter. Company comment: This regulatory case concerns a 34-year-old, male patient with no relevant medical history, who experienced the expected AESI of myocarditis. The event, which resulted in hospitalization, occurred 1 day after administration of the second dose of the Moderna mRNA-1273. The rechallenge was not applicable as no additional dosing will be given. The patient's gender remains a confounder. The benefit-risk relationship of the Moderna mRNA-1273 is not affected by this report.	
4.1(b)		This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Retrosternal pressure) in a 17-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for SARS-CoV-2 immunization. No Medical History information was reported. On 05-Nov-2021, the patient received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form. On 09-Nov-2021, after starting mRNA-1273 (COVID-19 Vaccine Moderna), the patient experienced MYOCARDITIS (Retrosternal pressure) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Retrosternal pressure) outcome was unknown.	17 years old male with unknown medical history who 3 days after the 2nd dose experienced chest pressure, and was found to have elevated troponin, and CRP, and abnormal EKG with pericardial effusion, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin, CRP and EKG results; a causal relationship cannot be excluded.

Case ID	WW Identifier	Narrative	MAH Comment
		DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, C-reactive protein increased: 23 mg/l (abnormal) 23 mg/l. On an unknown date, Electrocardiogram: normal (normal) Rhythm normal, ST changes anterior wall (V1-V2).. On an unknown date, Troponin T: 872 ng/l (abnormal) 872 ng/l. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered MYOCARDITIS (Retrosternal pressure) to be possibly related. Concomitant medications was not reported. A small pericardial effusion was noted in the TTE. On Nov 08, 2021, Patinet felt slight pressure on his chest. He had then taken Dafalgan® (paracetamol, dose unknown). On the day following the second vaccination, the patient developed a mild headache. Company comment: This is a regulatory case concerning a 17 year-old male patient, with no relevant medical history reported, who experienced the serious unexpected and AESI event of Myocarditis 3 days after receiving the second dose of a proper vaccination schedule with mRNA-1273 vaccine. 3 days after the second dose, patient felt retrosternal pressure, laboratory showed increased levels of CRP and troponin, ECG showed ST change in V1-V2 (anterior wall) and a small pericardial effusion was found on TTE. The benefit-risk relationship of mRNA-1273 is not affected by this report Most recent FOLLOW-UP information incorporated above includes: On 22-Nov-2021: Translated document received on 23-Nov-2021	

Case ID	WW Identifier	Narrative	MAH Comment
		Contained Translated Relevant History, Lab section, Event verbatim, Case narrative and Reporter's comments section.	
4.1(b)		This case was received via 4.1(b) (Reference number: 4.1(b)) on 17-Nov-2021 and was forwarded to Moderna on 23-Nov-2021. This case, initially reported to the 4.1(b) by a (physician), was received via the 4.1(b) (Ref, 4.1(b)) On an unknown date, the patient received the 1st dose of the vaccine. On 02-Aug-2021, the patient received the 2nd dose of the vaccine. On 23-Aug-2021, disorder of skilled motor activities in the left upper limb suddenly developed. Around that time, the patient experienced epigastric pain and dyspnea. On 27-Aug-2021, paresthesia and incomplete paralysis in the left lower limb developed, and the patient visited a nearby neurosurgeon. Head MRI showed sporadic cerebral infarctions in the right cerebral hemisphere and left occipital lobe. On 28-Aug-2021, the patient was hospitalized. On 31-Aug-2021, on Day 4 of the onset of the disease, cardioembolic stroke was suspected. Electrocardiogram on admission showed sinus tachycardia of 104 bpm, small Q waves in the aVL and V5-V6 leads, and negative T waves in the III and aVF leads, which were non-specific findings. Biochemical examination of blood showed normal cardiac enzymes such as CK/CK-MB, but there were elevations of high-sensitivity troponin T of 0.682 ng/mL and NT-proBNP of 395 pg/mL, which were suggestive of some kind of myocardial damage. Transthoracic echocardiography showed sustained	38 years old male with unknown medical history who 29 days after the 2nd dose experienced epigastric pain, dyspnea, paresthesia, incomplete paralysis of the left lower limb. Head MRI showed sporadic cerebral infarctions, and a cardioembolic stroke was suspected. EKG was abnormal, CK/CK-MB were normal, but troponin were elevated, as well as NT-proBNP. cMRI showed findings consistent with myocarditis, and myocardial biopsy showed lymphocytes infiltration. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the well documented information provided in this report; a causal relationship cannot be excluded.

Case ID	WW Identifier	Narrative	MAH Comment
		left ventricular ejection fraction of 72%, but pericardial effusions were found circumferentially. Thus, acute myocarditis was strongly suspected. As a result of the medical interview, possibility of myocarditis associated with the vaccine was considered based on the timeline. Cardiac MRI showed a sporadic macular delayed image in the lateral side of both ventricles and near the apex of the interventricular septum, which were consistent with findings of myocarditis. No appreciable findings were found by the right heart catheter, without coronary artery stenosis. Myocardial biopsy of endocardium was performed at the right ventricular septum. Light microscopy showed infiltration of various inflammatory cells mainly consisting of lymphocytes, without remarkable aggregation, and degenerated cardiomyocytes were detected. Since the extreme phase of myocarditis had passed and hemodynamic disruption was not noted, the use of corticosteroids was avoided. No significant elevations were found in the pair serum of virus associated with myocarditis. Immunostaining for antibodies of the vaccine was performed using the myocardial biopsy specimens, and the result was positive. Based on the various findings, the symptoms were consistent with myocarditis associated with the vaccine. The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. On an unknown date, pericardial effusions decreased spontaneously. On 18-Sep-2021, high-sensitivity troponin T almost returned to normal. The symptoms were resolving with favorable course of the disease, and thus the patient was discharged from the hospital.	

Case ID	WW Identifier	Narrative	MAH Comment
		The outcome of myocarditis, sporadic cerebral infarction, and suspected cardioembolic stroke was reported as resolving. Follow-up investigation will be made . Company Comment: The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	
4.1(b)		This case was received via 4.1(b) (Reference number: 4.1(b) on 13-Nov-2021 and was forwarded to Moderna on 23-Nov-2021. This case, initially reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref, 4.1(b) On an unknown date, the patient received the 1st dose of this vaccine. On 07-Nov-2021, at 09:21, the patient received the 2nd dose of this vaccine. At 5 to 6 hours after the vaccination, headache and pyrexia of the highest 40.1 degrees Celsius. On 08-Nov-2021, the patient had a feeling of heaviness as if the chest was compressed, and antipyretics were taken every 6 hours. The onset of myocarditis and pericarditis were suspected. On 09-Nov-2021, because pyrexia in the 38s degrees Celsius and chest pain persisted, the patient visited a previous hospital. The patient was referred to our hospital with WBC of 10, 100/mcL and CRP of 10.3 mg/dL. Troponin T positive, CK 376, CK-MB 27, AST 39, CRP 8.63. Echocardiography showed no pericardial effusion and decreased cardiac function, or local changes.	14 years old male with unknown medical history who the same day after the 2nd dose experienced pyrexia and headache, next day experienced chest pressure and chest pain, and next days was found to have elevated troponin, CRP, and CK-MB, and abnormal Echo, and was diagnosed with myopericarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association 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.

Case ID	WW Identifier	Narrative	MAH Comment
		The patient was hospitalized for observation. On 12-Nov-2021, the patient recovered from the symptoms and was discharged from the hospital. The outcome of headache, pyrexia, chest pressure sensation, chest pain, suspected myocarditis and pericarditis was reported as resolved. Follow-up investigation will be made. Company Comment: The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	
4.1(b)		This case was received via 4.1(b) (Reference number: 4.1(b)) on 19-Nov-2021 and was forwarded to Moderna on 23-Nov-2021. This case, initially reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref 4.1(b)) On an unknown date, the patient received the 1st dose of this vaccine. On an unknown date, body temperature before vaccination: 36.4 degrees Celsius. On 06-Nov-2021, at 12:00 to 12:30, the patient received the 2nd dose of this vaccine. Around 21:00, pyrexia of 39 degrees Celsius developed. The patient took over-the-counter drugs. On 08-Nov-2021, breathlessness and chest pain developed. On 09-Nov-2021, the patient was diagnosed with myocarditis and underwent cardiac catheterization. The patient was hospitalized. There was no significant stenosis in the coronary artery, and myocardial	17 years old male with unknown medical history who the same day after the 2nd dose experienced pyrexia, and two days later experienced chest pain and dyspnea, and was found to have abnormal Echo, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the Echo results; a causal relationship cannot be excluded.

Case ID	WW Identifier	Narrative	MAH Comment
		biopsy was performed on the right ventricular apex considering myocarditis. Echocardiography showed a decrease in left ventricular ejection fraction of 40%, which improved over time. On 16-Nov-2021, the patient recovered from the symptoms and was discharged from the hospital. The outcome of pyrexia and myocarditis was reported as recovered. Follow-up investigation will be made . Company Comment: The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	
4.1(b)		This case was received via 4.1(b) Reference number: 4.1(b)) on 20-Nov-2021 and was forwarded to Moderna on 23-Nov-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 23-Oct-2021, the patient received the 2nd dose of this vaccine. On 25-Oct-2021, around 17:30, precordial pain appeared. Deep breathing aggravated the pain. There was no comfortable position for the patient. At 19:30, the patient visited an emergency outpatient department at the reporting hospital and was hospitalized for suspected myocarditis associated with the vaccine. There were no wall motion abnormalities in echocardiography, and wide range of ST elevation and positive Tn-T were shown in	22 years old male with unknown medical history who 2 days after the 2nd dose experienced chest pain, and was found to have elevated CRO, and abnormal EKG, Echo was normal, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated CRP and EKG results; a causal relationship cannot be excluded.

Case ID	WW Identifier	Narrative	MAH Comment
		electrocardiogram; therefore, the patient was diagnosed with myocarditis. The patient was hospitalized to be followed up. On an unknown date, the peak CPK was 25/39. The inflammatory response gradually decreased, and the patient's subjective symptoms almost disappeared. On 27-Oct-2021, echocardiography was performed, and there was no abnormality in a localized wall motion. On 29-Oct-2021, cardiac MRI was performed, and delayed imaging was not found. On 30-Oct-2021, the patient was discharged from the hospital as the symptoms improved. The outcome of myocarditis was reported as resolving. Follow-up investigation will be made. Company Comment: The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	
4.1(b)		This case was received via 4.1(b) (Reference number: 4.1(b) on 23-Nov-2021 and was forwarded to Moderna on 23-Nov-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of ABDOMINAL PAIN UPPER (Abdominal pain upper), ACTIVATED PARTIAL THROMBOPLASTIN TIME (Activated partial thromboplastin time), BLOOD TEST (Blood test), C-REACTIVE PROTEIN (C-reactive protein), CARDIAC MONITORING (Cardiac monitoring), CHEST X-RAY ABNORMAL (Chest X-ray abnormal), CHEST PAIN (Chest pain), DIARRHOEA (Diarrhoea),	26 years old male with medical history of gastritis who 3 days after the 3rd dose of Spikevax experienced diarrhea, abdominal pain, nausea, and vomiting and chest pain, and it was reported she had elevated troponin, and abnormal EKG, and was diagnosed with myocarditis but no laboratory or diagnostic test results were provided. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events; a

Case ID	WW Identifier	Narrative	MAH Comment
		ECHOCARDIOGRAM (Echocardiogram), ELECTROCARDIOGRAM (Electrocardiogram), ELECTROCARDIOGRAM ABNORMAL (Electrocardiogram abnormal), FULL BLOOD COUNT (Full blood count), HEADACHE (Headache), HUMAN CHORIONIC GONADOTROPIN (Human chorionic gonadotropin), INFLAMMATION (Inflammation), LIPASE (Lipase), METABOLIC FUNCTION TEST (Metabolic function test), MUSCLE INJURY (Muscle injury), NAUSEA (Nausea), PROTHROMBIN TIME (Prothrombin time), RED BLOOD CELL SEDIMENTATION RATE (Red blood cell sedimentation rate), RESPIRATORY VIRAL PANEL (Respiratory viral panel), SLEEP DISORDER (Sleep disorder), TROPONIN I (Troponin I), TROPONIN INCREASED (Troponin increased), URINE ANALYSIS (Urine analysis), VOMITING (Vomiting), MYOCARDITIS (Myocarditis) and PERICARDITIS (Pericarditis) in a 26-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 033F21A) for COVID-19 vaccination. The patient's past medical history included Gastritis. Concurrent medical conditions included Drug allergy (Doxycycline), Soy allergy, Food allergy (Sesame allergy) and Allergy to molds. On 05-Nov-2021, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 08-Nov-2021, the patient experienced ABDOMINAL PAIN UPPER (Abdominal pain upper) (seriousness criterion hospitalization), ACTIVATED PARTIAL THROMBOPLASTIN TIME (Activated partial thromboplastin time) (seriousness criterion hospitalization), BLOOD TEST (Blood test) (seriousness criterion hospitalization), C-REACTIVE PROTEIN (C-reactive	causal relationship cannot be excluded.

Case ID	WW Identifier	Narrative	MAH Comment
		protein) (seriousness criterion hospitalization), CARDIAC MONITORING (Cardiac monitoring) (seriousness criterion hospitalization), CHEST X-RAY ABNORMAL (Chest X-ray abnormal) (seriousness criterion hospitalization), CHEST PAIN (Chest pain) (seriousness criterion hospitalization), DIARRHOEA (Diarrhoea) (seriousness criterion hospitalization), ECHOCARDIOGRAM (Echocardiogram) (seriousness criterion hospitalization), ELECTROCARDIOGRAM (Electrocardiogram) (seriousness criterion hospitalization), ELECTROCARDIOGRAM ABNORMAL (Electrocardiogram abnormal) (seriousness criterion hospitalization), FULL BLOOD COUNT (Full blood count) (seriousness criterion hospitalization), HEADACHE (Headache) (seriousness criterion hospitalization), HUMAN CHORIONIC GONADOTROPIN (Human chorionic gonadotropin) (seriousness criterion hospitalization), INFLAMMATION (Inflammation) (seriousness criterion hospitalization), LIPASE (Lipase) (seriousness criterion hospitalization), METABOLIC FUNCTION TEST (Metabolic function test) (seriousness criterion hospitalization), MUSCLE INJURY (Muscle injury) (seriousness criterion hospitalization), NAUSEA (Nausea) (seriousness criterion hospitalization), PROTHROMBIN TIME (Prothrombin time) (seriousness criterion hospitalization), RED BLOOD CELL SEDIMENTATION RATE (Red blood cell sedimentation rate) (seriousness criterion hospitalization), RESPIRATORY VIRAL PANEL (Respiratory viral panel) (seriousness criterion hospitalization), SLEEP DISORDER (Sleep disorder) (seriousness criterion hospitalization), TROPONIN I (Troponin I) (seriousness criterion hospitalization), TROPONIN INCREASED (Troponin increased) (seriousness criterion hospitalization), URINE ANALYSIS	

Case ID	WW Identifier	Narrative	MAH Comment
		(Urine analysis) (seriousness criterion hospitalization), VOMITING (Vomiting) (seriousness criterion hospitalization), MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant) and PERICARDITIS (Pericarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, ABDOMINAL PAIN UPPER (Abdominal pain upper), ACTIVATED PARTIAL THROMBOPLASTIN TIME (Activated partial thromboplastin time), BLOOD TEST (Blood test), C-REACTIVE PROTEIN (C-reactive protein), CARDIAC MONITORING (Cardiac monitoring), CHEST X-RAY ABNORMAL (Chest X-ray abnormal), CHEST PAIN (Chest pain), DIARRHOEA (Diarrhoea), ECHOCARDIOGRAM (Echocardiogram), ELECTROCARDIOGRAM (Electrocardiogram), ELECTROCARDIOGRAM ABNORMAL (Electrocardiogram abnormal), FULL BLOOD COUNT (Full blood count), HEADACHE (Headache), HUMAN CHORIONIC GONADOTROPIN (Human chorionic gonadotropin), INFLAMMATION (Inflammation), LIPASE (Lipase), METABOLIC FUNCTION TEST (Metabolic function test), MUSCLE INJURY (Muscle injury), NAUSEA (Nausea), PROTHROMBIN TIME (Prothrombin time), RED BLOOD CELL SEDIMENTATION RATE (Red blood cell sedimentation rate), RESPIRATORY VIRAL PANEL (Respiratory viral panel), SLEEP DISORDER (Sleep disorder), TROPONIN I (Troponin I), TROPONIN INCREASED (Troponin increased), URINE ANALYSIS (Urine analysis), VOMITING (Vomiting), MYOCARDITIS (Myocarditis) and PERICARDITIS (Pericarditis) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):	

Case ID	WW Identifier	Narrative	MAH Comment
		On 08-Nov-2021, Troponin: 1 (High) Troponin 1 high-sensitivity. On 09-Nov-2021, Troponin: 1 (High) Troponin 1 high-sensitivity. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. On 08-NOV-2021 Lab tests ECG 12-Lead, PT- APTT, Lipase, Comprehensive metabolic panel, CBC, POC HCG Qualitative, Urinalysis Auto only, XR chest 1 view, C-reactive protein, Sedimentation rate, Troponin 1 high-sensitivity Transthoracic E., Respiratory virus comprehensive panel were done, results were not reported. On 09-NOV-2021 Lab tests Basic metabolic panel, CBC were done, results were not reported. Concomitant medication included Omeprazole, Zyrtec, Sucralfate, Montelukast, birth control pills, Fluticasone nasal spray, Acetaminophen. On 08-Nov-2021 around 2:30 am, Patient awoke to diarrhea stomach pains and began using the toilet and began to feel nauseas. She began vomiting while still using the restroom. Once she had finished using the restroom and vomiting, she began having chest pains. The chest pain would not subside, and it increased when she tried to lay back down. She went to ER where they discovered an abnormal EKG and elevated troponin levels. she was given Tramadol in the ER to help with the pain and chest x-ray then she was in the hospital and from 08-NOV-2021 to 09-NOV-2021. The doctors believed she was suffering from myocarditis or pericarditis. Her blood levels were examined every few hours and heart was monitored through an EKG. She was given morphine when her pain increased around 12 pm on 08-NOV-2021 and then tramadol at the end of	

Case ID	WW Identifier	Narrative	MAH Comment
		09-NOV-2021 when her head was throbbing. The cardiologist did an ultrasound of heart to see if the inflammation visible on the x-ray was pericarditis or myocarditis. On 09-NOV-2021 she was told the inflammation had decreased on its own which lead the doctors to believe it was the result of the booster covid vaccine. The cardiologist told she have microscopic damage to heart muscles based on the elevated troponin levels and she believed she had pericarditis. They prescribed Tramadol to take in case of more chest pain.	
4.1(b)		This case was received via 4.1(b) (Reference number: 4.1(b) on 19-Nov-2021 and was forwarded to Moderna on 24-Nov-2021. This case, initially reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref, 4.1(b) On an unknown date, the patient received the 1st dose of this vaccine. On an unknown date, body temperature before the vaccination: 36.5 degrees Celsius. On 28-Oct-2021, at 10:30, the patient received the 2nd dose of this vaccine. On 30-Oct-2021, at 04:00, chest pain was noted, and acute pericardial myocarditis developed. At 12:30, because the symptoms persisted, the patient made a visit to an emergency outpatient department. The patient was hospitalized because 12-lead ECG showed ST elevation in wide range of leads and blood data showed elevations in CPK of 425, CPK-MB of 34, troponin I of 4,247, and CRP of 4.31. On 31-Oct-2021, echocardiography showed hypokinesis of the localized area of the left ventricular wall and pericardial effusion. NSAIDS was administered, and the patient was hospitalized for a follow-up at rest. On 03-Nov-2021, the patient was discharged from the hospital as the symptoms resolved.	22 years old male with unknown medical history who 2 days after the 2nd dose experienced chest discomfort and was found to have elevated troponin, CRP and CK-MB, and abnormal EKG and Echo, and was diagnosed with myopericarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin, CRP, and EKG results; a causal relationship cannot be excluded.

Case ID	WW Identifier	Narrative	MAH Comment
		The outcome of acute pericardial myocarditis was reported as resolving. Follow-up investigation will be made. Company Comment: The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	
4.1(b)		This case was received via 4.1(b) (Reference number: 4.1(b) on 23-Nov-2021 and was forwarded to Moderna on 23-Nov-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of CHEST PAIN (Left Chest pain), MALAISE (Malaise), HYPERHIDROSIS (Hyperhidrosis), FATIGUE (Fatigue), CHILLS (Chills), NAUSEA (Nausea), HEADACHE (Headache), PYREXIA (Pyrexia), ANXIETY (Anxiety), C-REACTIVE PROTEIN INCREASED (C-reactive protein increased), CARDIAC IMAGING PROCEDURE ABNORMAL (Cardiac imaging procedure abnormal), CHEST DISCOMFORT (Chest discomfort), COUGH (Cough), EAR PAIN (Ear pain), ECHOCARDIOGRAM NORMAL (Echocardiogram normal), EJECTION FRACTION NORMAL (Ejection fraction normal), ELECTROCARDIOGRAM T WAVE INVERSION (Electrocardiogram T wave inversion), ELECTROCARDIOGRAM ABNORMAL (Electrocardiogram abnormal), LEFT VENTRICULAR DILATATION (Left ventricular dilatation), MAGNETIC RESONANCE IMAGING HEART (Magnetic resonance imaging heart), MYOCARDIAL OEDEMA (Myocardial oedema), N-TERMINAL PROHORMONE BRAIN NATRIURETIC PEPTIDE INCREASED (N-terminal prohormone brain natriuretic peptide increased), PAIN (Pain), PERICARDIAL	39 years old female with unknown medical history who the same day after the 3rd dose of Spikevax experienced left chest pain, malaise, diaphoresis, that progressed in the 48 hours to fatigue, chills, fever, nausea, headache. Symptoms resolved after 48 hours with rest and 500-650 mg Tylenol 2-3x/day, except chest pain, pleuritic at times, associated at times with nausea, retching, cough, fatigue. Three days after the 3rd dose the patient went to the ED and she was found to have elevated troponin, CRP, NT-proBNP, abnormal EKG, and cardiac MRI identified myopericarditis. Admitted for 1 night. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the well documented information provided in this report; a causal relationship cannot be excluded.

Case ID	WW Identifier	Narrative	MAH Comment
		FIBROSIS (Pericardial fibrosis), PLEURITIC PAIN (Pleuritic pain), RED BLOOD CELL SEDIMENTATION RATE INCREASED (Red blood cell sedimentation rate increased), RETCHING (Retching), SLEEP DISORDER (Sleep disorder), TROPONIN INCREASED (Troponin increased), VENTRICULAR HYPOKINESIA (Ventricular hypokinesia), VOMITING (Vomiting) and MYOCARDITIS (Myocarditis) in a 39-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 014F21A) for COVID-19 vaccination. Concurrent medical conditions included Penicillin allergy (caused hives in patient) and Allergy to NSAIDs (avoiding due to history of idiopathic angioedema). On 05-Nov-2021, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 05-Nov-2021, the patient experienced CHEST PAIN (Left Chest pain) (seriousness criterion hospitalization), MALAISE (Malaise) (seriousness criterion hospitalization), HYPERHIDROSIS (Hyperhidrosis) (seriousness criterion hospitalization), FATIGUE (Fatigue) (seriousness criterion hospitalization), CHILLS (Chills) (seriousness criterion hospitalization), NAUSEA (Nausea) (seriousness criterion hospitalization), HEADACHE (Headache) (seriousness criterion hospitalization), PYREXIA (Pyrexia) (seriousness criterion hospitalization), ANXIETY (Anxiety) (seriousness criterion hospitalization), C-REACTIVE PROTEIN INCREASED (C-reactive protein increased) (seriousness criterion hospitalization), CARDIAC IMAGING PROCEDURE ABNORMAL (Cardiac imaging procedure abnormal) (seriousness criterion hospitalization), CHEST DISCOMFORT (Chest discomfort) (seriousness criterion hospitalization),	

Case ID	WW Identifier	Narrative	MAH Comment
		COUGH (Cough) (seriousness criterion hospitalization), EAR PAIN (Ear pain) (seriousness criterion hospitalization), ECHOCARDIOGRAM NORMAL (Echocardiogram normal) (seriousness criterion hospitalization), EJECTION FRACTION NORMAL (Ejection fraction normal) (seriousness criterion hospitalization), ELECTROCARDIOGRAM T WAVE INVERSION (Electrocardiogram T wave inversion) (seriousness criteria hospitalization and medically significant), ELECTROCARDIOGRAM ABNORMAL (Electrocardiogram abnormal) (seriousness criterion hospitalization), LEFT VENTRICULAR DILATATION (Left ventricular dilatation) (seriousness criterion hospitalization), MAGNETIC RESONANCE IMAGING HEART (Magnetic resonance imaging heart) (seriousness criterion hospitalization), MYOCARDIAL OEDEMA (Myocardial oedema) (seriousness criteria hospitalization and medically significant), N-TERMINAL PROHORMONE BRAIN NATRIURETIC PEPTIDE INCREASED (N-terminal prohormone brain natriuretic peptide increased) (seriousness criterion hospitalization), PAIN (Pain) (seriousness criterion hospitalization), PERICARDIAL FIBROSIS (Pericardial fibrosis) (seriousness criteria hospitalization and medically significant), PLEURITIC PAIN (Pleuritic pain) (seriousness criterion hospitalization), RED BLOOD CELL SEDIMENTATION RATE INCREASED (Red blood cell sedimentation rate increased) (seriousness criterion hospitalization), RETCHING (Retching) (seriousness criterion hospitalization), SLEEP DISORDER (Sleep disorder) (seriousness criterion hospitalization), TROPONIN INCREASED (Troponin increased) (seriousness criterion hospitalization), VENTRICULAR HYPOKINESIA (Ventricular hypokinesia) (seriousness criteria	

Case ID	WW Identifier	Narrative	MAH Comment
		hospitalization and medically significant), VOMITING (Vomiting) (seriousness criterion hospitalization) and MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, CHEST PAIN (Left Chest pain), MALAISE (Malaise), HYPERHIDROSIS (Hyperhidrosis), FATIGUE (Fatigue), CHILLS (Chills), NAUSEA (Nausea), HEADACHE (Headache) and PYREXIA (Pyrexia) had not resolved and ANXIETY (Anxiety), C-REACTIVE PROTEIN INCREASED (C-reactive protein increased), CARDIAC IMAGING PROCEDURE ABNORMAL (Cardiac imaging procedure abnormal), CHEST DISCOMFORT (Chest discomfort), COUGH (Cough), EAR PAIN (Ear pain), ECHOCARDIOGRAM NORMAL (Echocardiogram normal), EJECTION FRACTION NORMAL (Ejection fraction normal), ELECTROCARDIOGRAM T WAVE INVERSION (Electrocardiogram T wave inversion), ELECTROCARDIOGRAM ABNORMAL (Electrocardiogram abnormal), LEFT VENTRICULAR DILATATION (Left ventricular dilatation), MAGNETIC RESONANCE IMAGING HEART (Magnetic resonance imaging heart), MYOCARDIAL OEDEMA (Myocardial oedema), N-TERMINAL PROHORMONE BRAIN NATRIURETIC PEPTIDE INCREASED (N-terminal prohormone brain natriuretic peptide increased), PAIN (Pain), PERICARDIAL FIBROSIS (Pericardial fibrosis), PLEURITIC PAIN (Pleuritic pain), RED BLOOD CELL SEDIMENTATION RATE INCREASED (Red blood cell sedimentation rate increased), RETCHING (Retching), SLEEP DISORDER (Sleep disorder), TROPONIN INCREASED (Troponin increased), VENTRICULAR HYPOKINESIA (Ventricular hypokinesia), VOMITING (Vomiting)	

Case ID	WW Identifier	Narrative	MAH Comment
		and MYOCARDITIS (Myocarditis) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 08-Nov-2021, C-reactive protein: 29.9 (High) 29.9. On 08-Nov-2021, Electrocardiogram: normal (normal) inverted T waves in V1-2, no ST segment abnormalities. On 08-Nov-2021, Magnetic resonance imaging heart: abnormal (abnormal) hypokinesis of LV mid to distal inferior walls, mid myocardial and subepicardial late gadolinium enhancement at basal to apical inferior, basal to mid inferolateral, and mid anterolateral segments of LV, myocardial edema, focal thickening of pericardium with late gadolinium enhancement of the pericardium adjacent to the inferior, inferolateral and anterolateral walls, consistent with acute peri myocarditis. On 08-Nov-2021, N-terminal prohormone brain natriuretic peptide: 657 (High) 657. On 08-Nov-2021, Red blood cell sedimentation rate: 65 (High) 65. On 08-Nov-2021, Troponin: 344 (High) greater than 352, greater than 351, greater than 296. On 09-Nov-2021, Echocardiogram: normal (normal) LV systolic function normal, no segmental LV wall motion abnormalities, EF 60%, global longitudinal strain normal. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Concomitant medications included Calcium/Vitamin D. It was reported that patient developed left chest pain within a few hours of shot, along with malaise, diaphoresis. Accompanied by fatigue, chills, fever, nausea, headache over next 48 hours. Other symptoms resolved after 48 hours with rest and 500-650 mg	

Case ID	WW Identifier	Narrative	MAH Comment
		Tylenol 2-3x/day, except chest pain, pleuritic at times, associated at times with nausea, retching, cough, fatigue. Chest pain was 3-5/10 and intermittent, until escalated to 10/10 and awoke patient from sleep 60 hours after shot, no longer pleuritic but crushing, associated with sense of doom, nausea/vomiting, and radiation to left ear. This episode lasted about an hour and returned to 1-2/10 pain after 650 mg Tylenol by the time patient reached the ED. Found to have elevated troponin, and cardiac MRI identified myopericarditis. Admitted for 1 night. Being treated with colch	
4.1(b)		This case was received via 4.1(b) (Reference number: 4.1(b)) on 23-Nov-2021 and was forwarded to Moderna on 23-Nov-2021. This regulatory authority case was reported by a consumer and describes the occurrence of FATIGUE (Fatigue/unusual tiredness), CHEST PAIN (Chest pain), DYSPNOEA (Shortness of breath), TACHYCARDIA (Racing heart (tachycardia)) and MYOCARDITIS (Myocarditis) in a 19-year-old female patient who received mRNA-1273 (COVID 19 Vaccine Moderna) (batch no. 3004222) for COVID-19 immunisation. No Medical History information was reported. On 10-Sep-2021, the patient received second dose of mRNA-1273 (COVID 19 Vaccine Moderna) (unknown route) 1 dosage form. On 13-Sep-2021, after starting mRNA-1273 (COVID 19 Vaccine Moderna), the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). On an unknown date, the patient experienced FATIGUE (Fatigue/unusual tiredness) (seriousness criteria hospitalization and medically significant), CHEST PAIN (Chest pain) (seriousness	Consumer report for a 19 years old female with unknown medical history who at an unknown TTO after the 2nd dose experienced fatigue, chest pain, dyspnea, tachycardia, and was found to have elevated troponin and was diagnosed with myocarditis. Other diagnostic test were conducted but results were not provided. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events. A causal relationship cannot be excluded due to the lack of information.

Case ID	WW Identifier	Narrative	MAH Comment
		criteria hospitalization and medically significant), DYSPNOEA (Shortness of breath) (seriousness criteria hospitalization and medically significant) and TACHYCARDIA (Racing heart (tachycardia)) (seriousness criteria hospitalization and medically significant). At the time of the report, FATIGUE (Fatigue/unusual tiredness), CHEST PAIN (Chest pain), DYSPNOEA (Shortness of breath) and TACHYCARDIA (Racing heart (tachycardia)) outcome was unknown and MYOCARDITIS (Myocarditis) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Troponin: 160 (High) 160 and raised (High) Raised. Patient reported that her symptoms lead to hospital stay, duration was 4 days and diagnosis was made by Cardiologist. Hospitalized with crushing chest pain there for 4 days. Multiple blood tests, echocardiogram (EEG), chest X-ray. Fatigue, myocarditis, shortness of breath and tachycardia. Additional lab tests include: Later Heart MRO outpatient, blood tests that signal heart muscle damage and other imaging tests. No Concomitant medication information was reported. No treatment medications were provided.	
4.1(b)		This case was received via 4.1(b) (Reference number: 4.1(b)) on 18-Nov-2021 and was forwarded to Moderna on 24-Nov-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.	25 years old male with unknown medical history who the next day after the 2nd dose experienced headache and pyrexia, and two days later experienced chest pain and was found to have elevated troponin, and CK, and abnormal EKG, abnormal myocardial biopsy and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO

Case ID	WW Identifier	Narrative	MAH Comment
		On 19-Oct-2021, the patient received the 2nd dose of this vaccine. The patient was hospitalized. On 20-Oct-2021, headache and pyrexia developed. On 21-Oct-2021, chest pain developed. On 23-Oct-2021, the symptoms did not improve, and the patient visited a nearby physician. Although electrocardiographic changes and predominant findings in the echocardiography were not indicated, the patient was urgently transferred to the reporting hospital due to suspected myocarditis after the vaccination with this vaccine because of positive troponin. After admission, coronary angiography showed no ischemic lesion. Left ventriculography, myocardial biopsy, and hemodynamic evaluation were performed, and the patient was diagnosed with myocarditis and admitted to the ICU. On the monitor, AF rhythm, which developed during myocardial biopsy, persisted, but it was confirmed that troponin T peaked out on the same day. At 14:27 CK: 264 U/L, and highly sensitive TNT: 0.358 ng/mL. At 20:00 CK: 258 U/L, and highly sensitive TNT: 0.486 ng/mL. At 23:00 CK: 227 U/L, and highly sensitive TNT: 0.481 ng/mL. On 24-Oct-2021, the patient returned to sinus rhythm. Cardiac ultrasonography showed no significant findings. At 08:09, CK: 166 U/L, and highly sensitive TNT: 0.341 ng/mL. On 25-Oct-2021, at 06:48, CK: 84 U/L, and highly sensitive TNT: 0.140 ng/mL.	causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and EKG results; a causal relationship cannot be excluded.

Case ID	WW Identifier	Narrative	MAH Comment
		On 26-Oct-2021, the patient was transferred to a general ward for stable symptoms. Since then, there was no chest pain, and there was no remarkable change in examination findings. At 07:35, CK: 83 U/L, and highly sensitive TNT: 0.028 ng/mL. At 08:46, highly sensitive TNT: 0.007 ng/mL. On 01-Nov-2021, at 08:25, highly sensitive TNT: 0.003 ng/mL On 02-Nov-2021, the symptoms were resolving, and the patient was discharged from the hospital. The outcome of chest pain and acute myocarditis was reported as resolving. Follow-up investigation will be made. Company Comment: The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	
4.1(b)		This case was received via 4.1(b) (Reference number: 4.1(b)) on 19-Nov-2021 and was forwarded to Moderna on 24-Nov-2021. This case, initially reported to the 4.1(b) by a (physician), was received via the 4.1(b) (Ref, 4.1(b)) The patient has a history of bundle branch block right. On 29-Sep-2021, the patient received the 1st dose of this vaccine. On an unknown date, body temperature before vaccination: 36.7 degrees Celsius. On 27-Oct-2021, at 15:30, the patient received the 2nd dose of this vaccine.	21 years old male with medical history of bundle branch block right who 3 days after the 2nd dose experienced chest pain and was found to have elevated troponin, CK and CK-MB, and abnormal EKG, and was diagnosed with myopericarditis. cMRI was performed 6 days later and confirmed the diagnosis of myopericarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and EKG results; a causal relationship cannot be excluded

Case ID	WW Identifier	Narrative	MAH Comment
		On 30-Oct-2021, from the morning, the patient experienced left precordial pain and cold sweat. At 10:00, acute pericardial myocarditis developed. On 31-Oct-2021, in the morning, the patient had chest pain and made an emergency visit to the reporting hospital. The patient originally had right bundle branch block, and electrocardiogram showed ST elevation in I, II, III, aVF, and V4-6 leads, and the results of a blood test showed elevation of cardiac enzymes (CK, CKMB, and Tropl). Echocardiography showed diffuse hypokinesis mainly in the inferior wall. The patient was hospitalized to receive treatments, and analgesics were used. On an unknown date, improvements were shown in electrocardiogram, cardiac enzymes, and echocardiography. On 04-Nov-2021, the patient was discharged with improvement of the symptoms. On 06-Nov-2021, cardiac MRI was performed, and the findings were consistent with myocarditis. The outcome of acute pericardial myocarditis was reported as resolving. Follow-up investigation will be made. Company Comment: The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	
4.1(b)		This case was received via 4.1(b) (Reference number: 4.1(b) on 22-Nov-2021 and was forwarded to Moderna on 25-Nov-2021. This case, initially reported to the 4.1(b) by a	30-year-old male patient with unknown medical history, who next day after the 2nd dose of Spikevax experienced pyrexia and back pain, and two days later experienced convulsions while sleeping, and after the ambulance arrived, it was noted that the patient had ventricular

Case ID	WW Identifier	Narrative	MAH Comment
		(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 10-Nov-2021, the patient received the 2nd dose of this vaccine. On 11-Nov-2021, high fever and back pain developed. On 13-Nov-2021, around 07:25, the patient developed convulsions while sleeping, and the family member who noticed the convulsions called an ambulance. With verbal guidance, a family member started chest compressions on the patient. At 07:30, when the ambulance arrived, the patient had ventricular fibrillation, so defibrillation was performed once, and cardiac arrest and pulseless electrical activity were repeated. At 08:07, the patient arrived at the reporting hospital and extracorporeal cardiopulmonary resuscitation was performed. Coronary angiography showed no significant stenosis in the coronary arteries. Myocardial biopsy was not performed. Acute myocarditis after vaccination was suspected based on the clinical history and clinical course. The patient was complicated by hypoxic encephalopathy and there was a high possibility that the patients life could not be saved. On 19-Nov-2021, the symptoms were ongoing and unchanged. The outcome of convulsion, ventricular fibrillation, asystole, pulseless electrical activity, suspected acute myocarditis and hypoxic encephalopathy was reported as ongoing and unchanged. Follow-up investigation will be made.	fibrillation, so defibrillation was performed once, and cardiac arrest and pulseless electrical activity were repeated. The patient was hospitalized and extracorporeal cardiopulmonary resuscitation was performed. Coronary angiography showed no significant stenosis in the coronary arteries. Myocardial biopsy was not performed. Acute myocarditis after vaccination was suspected based on the clinical history and clinical course, as reported. The patient was complicated by hypoxic encephalopathy. No other information was provided. Important information is missing in the report including patient's medical history as well as any diagnostic or laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events. A causal relationship cannot be excluded due to the lack of information.

Case ID	WW Identifier	Narrative	MAH Comment
		Company Comment: The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. Company comment- This case concerns a 30-year-old male patient with no relevant medical history provided, who experienced the unexpected serious events of Seizure, Ventricular fibrillation, Cardiac arrest, Pulseless electrical activity, Hypoxic-ischaemic encephalopathy, as well as serious expected events of Myocarditis. All reported events occurred three days following the administration of the second dose of the mRNA-1273 vaccine. The patient initially developed convulsions while sleeping, and after the ambulance arrived, it was noted that the patient had ventricular fibrillation, so defibrillation was performed once, and cardiac arrest and pulseless electrical activity were repeated. The patient was hospitalized and extracorporeal cardiopulmonary resuscitation was performed. Coronary angiography showed no significant stenosis in the coronary arteries. Myocardial biopsy was not performed. Acute myocarditis after vaccination was suspected based on the clinical history and clinical course, as reported. The patient was complicated by hypoxic encephalopathy. At the time of the report, all events were ongoing and unchanged. The re-challenge is not applicable, in line with the source document (no rechallenge was done and recurrence is not applicable). The events were considered related to the product per the reporter's and MAH assessment. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report.	
4.1(b)		This case was received via 4.1(b) (Reference number: 4.1(b)) on 17-Nov-2021	34 years old male with unknown medical history who the next day after the 2nd dose experienced pyrexia, chest tightness and

Case ID	WW Identifier	Narrative	MAH Comment
		and was forwarded to Moderna on 25-Nov-2021. This case, initially reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref 4.1(b)) On 21-Sep-2021, the patient received the 1st dose of the vaccine. On 22-Sep-2021, the patient merely had a low-grade fever of 37s degrees Celsius. From 28-Sep-2021 to 01-Oct-2021, the patient experienced pyrexia of 38s degrees Celsius, chest discomfort, malaise, and headache. On an unknown date, the patient visited an ENT physician, and the symptoms improved with oral administration of prescribed medication. Chest discomfort during activities remained. On an unknown date, body temperature before the vaccination: 36.5 degrees Celsius. On 20-Oct-2021, at 17:00, the patient received the 2nd dose of the vaccine. On 21-Oct-2021, the patient had pyrexia of 38s degrees Celsius. Chest tightness and breathlessness began to appear during activities. Particularly at inspiration, the patient sometimes had dry cough because of difficulty breathing in. Although the patient took acetaminophen and over-the-counter ibuprofen, body temperature was not reduced. On 25-Oct-2021, the patient visited the previous physician for the first time. Pyrexia of 38s degrees Celsius and dyspnea on exertion were noted. The results of a blood test showed elevations of WBC and CRP. Chest X-ray showed no obvious image of pneumonia, but CTR was expanded	dyspnea, and 4 days later was admitted to the hospital for suspected myopericarditis. This is a well documented case showing findings of Wenckebach type second degree atrioventricular block, but the results of blood tests showed no elevation in cardiac enzymes such as CK and troponin, and echocardiography showed no myocardial oedema or markedly abnormal wall motions, with a small amount of pericardial fluid. But CRP and BNP were elevated. Patient also had thrombocytosis and increased D-dimer. BMIPP myocardial scintigraphy was performed for evaluation of myocardial damages. The uptake into the myocardia was uniformly favorable except for a part in the anterior wall. Therefore, myocardial damage was not completely ruled out. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the well documented information provided in this report; a causal relationship cannot be excluded.

Case ID	WW Identifier	Narrative	MAH Comment
		to 58%, which was suggestive of accumulation of pleural fluid. The patient visited the reporting department by ambulance with a referral for suspected myocarditis and pericarditis after vaccination with the vaccine. [Actual symptoms on admission] Body temperature: 38.8 degrees Celsius, pulse rate: regular with 96 beats/min, blood pressure: (right) 125/79 mmHg, (left) 141/82 mmHg, SpO2: 96% (RA). <head and neck> No anemia in the bulbar conjunctiva, no conjunctiva bulbi coloring yellow, no lymph node swelling, no thyroid gland enlargement, no carotid bruit, and no stiffness in the neck. No Jolt accentuation. <Chest> Cardiac sound: regular without cardiac murmur, respiratory sounds: clear on both lungs. <Abdomen> Flat and soft, and favorable bowel sounds on auscultation. No tenderness and no pain on percussion. No Murphy signs. <Limbs and joints> Peripheral vessels were well palpable. No peripheral coldness, no oedema, and no warmth and swelling in joints. Pain in the shoulder joints was noted when pyrexia developed. Based on the episode and symptoms, myocarditis and/or pericarditis associated with the COVID-19 vaccine was suspected. The results of blood tests showed no elevation in cardiac enzymes such as CK and troponin, and echocardiography showed no myocardial oedema or markedly abnormal wall motions, with a small amount of pericardial fluid. There was an impression that a large amount of adipose tissues was found. There was some awkwardness in the movement of the heart, and since	

Case ID	WW Identifier	Narrative	MAH Comment
		pericardial effusion was suspected based on the CT image provided by the previous physician, it was decided to perform detailed examinations and medical treatments in hospitalization for suspected pericarditis and myocarditis. BNP was elevated to 92.3 pg/mL, and the cardiac shadow was clearly enlarged compared to that of chest X-ray in 2019. WBC increased predominantly in neutrophils and CRP was high, but PCT was not markedly elevated. Urinalysis, chest CT, and X-ray showed no evidence of respiratory infection. Considering the possibility of changes associated with pericarditis or myocarditis, administration of three tablets of acetaminophen 500 mg in three divided doses was started. Thrombocytosis, increased D-dimer, and low albumin, which had not been found in 2019, were considered to be caused by the inflammation that was found this time. Leg vein echography was performed, and the obvious leg vein thrombus was not found. On 26-Oct-2021, the patient had no pyrexia, and the chest symptom was gradually relieved over time. BMIPP myocardial scintigraphy was performed for evaluation of myocardial damages. The uptake into the myocardia was uniformly favorable except for a part in the anterior wall. Therefore, myocardial damage was not completely ruled out. On 28-Oct-2021, although the inflammatory responses decreased in the results of follow-up blood sampling, platelet and D-dimer levels showed a further increasing tendency. Since the risk of thrombus formation was also considered, continuous infusion of 10,000 units of heparin was started. The patient was diagnosed with thrombocytosis. In reference to ACT and APTT, the dose of heparin was increased to 20,000 units, but the inflammatory response decreased and both platelet	

Case ID	WW Identifier	Narrative	MAH Comment
		count and D-dimer tended to decrease. On 31-Oct-2021, findings of Wenckebach type second degree atrioventricular block were intermittently found in the monitor electrocardiogram. There were no subjective symptoms. On 01-Nov-2021, the result of a blood test showed findings that suggested hepatic disorder due to acetaminophen. Decreased pericardial effusion was confirmed by echocardiography, and administration of acetaminophen after dinner was discontinued on the same day. From 02-Nov-2021 to 03-Nov-2021, holter electrocardiography was performed for detailed examination. Pause of 2 seconds or more was observed 7 times a day, and the maximum RR interval was 2.4 seconds, both of which were waveforms of Wenckebach type second degree atrioventricular block. On 04-Nov-2021, the result of a blood test revealed that hepatic disorder was exacerbated even after discontinuation of acetaminophen. It was considered to be due to heparin. Chest CT showed a tendency of decrease in pericardial effusion. On 05-Nov-2021, oral administration of 1 tablet of aspirin 100 mg was started, and the dose of heparin was gradually reduced to 10,000 units. As the patient complained of numbness in the right lower limb, echography of the lower limb artery showed no occlusion or stenosis of the artery. On 07-Nov-2021, the dose of heparin was gradually decreased to 5,000 units. On 08-Nov-2021, blood tests confirmed that both platelets and D-dimer had decreased sufficiently and hepatic dysfunction was also	

Case ID	WW Identifier	Narrative	MAH Comment
		improving. Electrocardiography and echocardiography showed no findings of exacerbation, and it was concluded that outpatient follow-up was possible. The symptoms were resolving, and the patient was discharged from the hospital. On discharge, the patient was prescribed 1 tablet of aspirin (100) and 1 capsule of esomeprazole magnesium hydrate (10) in one dose after breakfasts for each. Administration of aspirin was going to be continued after the discharge from the hospital. The outcome of pyrexia, malaise, and headache was reported as resolved. The outcome of chest discomfort was unknown. The outcome of myocarditis, pericarditis, thrombocytosis, Wenckebach type second degree atrioventricular block, and numbness in the right lower limb was reported as resolving. Follow-up investigation will be made. Laboratory test continuation: Leg vein echography: No visible thrombosis was found in the lower extremity venous within the observable range. Abdominal echography: Bile ducts: The right and left intrahepatic bile ducts and common bile ducts are not dilated, and there is no apparent wall thickening. Cholangitis seems to be negative on the echo. Gallbladder: swelling, atrophy, and wall thickening were not observed. No stones or masses are found in the gallbladder lumen. Liver: Enlarged (especially in the right lobe), smooth surface but blunted liver margin, and elevated liver parenchymal echo levels. The	

Case ID	WW Identifier	Narrative	MAH Comment
		vessels in the liver are indistinct without no deep attenuation, and the liver parenchyma is heterogeneous. The low echo area was found around the gallbladder. There is no apparent mass. Hepatic cyst was found. Others: kidneys, spleen, and pancreas were normal. No ileus, no ascites. Plain chest CT: No evidence of respiratory infection. Blood pressure: (right) 125/79 mmHg, (left) 141/82 mmHg. APTT: 3	
4.1(b)		This regulatory authority case was reported by a physician and describes the occurrence of FATIGUE (Mild fatigue), PYREXIA (Fever up to 38 degrees), ARTHRALGIA (Limb pain) and MYOCARDITIS (Myocarditis) in a 21-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for an unknown indication. No Medical History information was reported. In September 2021, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form. On 08-Oct-2021, received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) dosage was changed to 1 dosage form. On 09-Oct-2021, the patient experienced FATIGUE (Mild fatigue) (seriousness criteria hospitalization and medically significant), PYREXIA (Fever up to 38 degrees) (seriousness criteria hospitalization and medically significant) and ARTHRALGIA (Limb pain) (seriousness criteria hospitalization and medically significant). On 11-Oct-2021, after starting mRNA-1273 (COVID-19 Vaccine Moderna), the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). On 10-Oct-2021,	21 years old male with unknown medical history who next day after the 2nd dose experienced pyrexia, fatigue and arthralgia, and two days later experienced chest pain and was found to have elevated troponin, and CRP, and abnormal EKG, normal Echo, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and EKG results; a causal relationship cannot be excluded.

Case ID	WW Identifier	Narrative	MAH Comment
		FATIGUE (Mild fatigue), PYREXIA (Fever up to 38 degrees) and ARTHRALGIA (Limb pain) had resolved. At the time of the report, MYOCARDITIS (Myocarditis) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 12-Oct-2021, Echocardiogram: normal (normal) TTE of Oct 12, 2021 was reported as unremarkable. In October 2021, Blood test: high (High) Trop Peak 1500 ng/l, CRP 200mg/l, CK 147. In October 2021, Electrocardiogram: abnormal (abnormal) EKG result was reported as ST-elevation in II, III, aVF, V3-V6, ST reduction.. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered FATIGUE (Mild fatigue), PYREXIA (Fever up to 38 degrees) and ARTHRALGIA (Limb pain) to be probably related and MYOCARDITIS (Myocarditis) to be possibly related. No concomitant medications were reported. Treatment drug administered included aspirin, then ibuprofen and colchicine. The patient was not known for any pathologies or allergies, kidney, or liver disease, and doesn't smoke or use alcohol. The first dose vaccine administration date was not indicated, but presumably administered in September. On 10 Oct 2021, 3 days after the second dose of Spikevax, the patient experienced chest pain during the night and severe fatigue. The patient was admitted to the hospital and was diagnosed with myocarditis, treated with aspirin, then ibuprofen and colchicine. In particular, the evaluation described that it got subsided the following day i.e., 10 Oct 2021. During the night of 10 Oct 2021 till 11 Oct 2021 the patient awoke during the night due to	

Case ID	WW Identifier	Narrative	MAH Comment
		severe retrosternal pain, which intensified with strong inspiration and no radiation to the arms was reported. Likewise, the patient indicated a decrease in general performance but had no loss of consciousness, dizziness or palpitations. He had no known cardiac conditions or thromboses and was in good general condition. BP of 128/80, pulse 130/min, oxygen 97 percent under ambient air, temperature 27.5 degree Celsius and AF of 14/ min was reported. The findings for heart were reported as tachycardic, rhythmic cardiac action without secondary murmurs and no peripheral pulse deficit. For lungs vesicular breath sounds over all lung fields, with no leg swelling. ECG results showed ST elevations ubiquitous, and high suspicion of myocarditis. Thereupon hospitalization was confirmed. The symptoms improved and the patient was discharged on 15 Oct 2021. The reaction reported was serious and reporter described as unknown further course of patient. Most recent FOLLOW-UP information incorporated above includes: On 26-Nov-2021: Translated document received on 01 Dec 2021. Added senders comment. Event verbatim and narrative was updated.	
4.1(b)		This regulatory authority case was reported by a physician and describes the occurrence of CHEST DISCOMFORT (Feeling of pressure in the sternum), DYSPNOEA (Dyspnea), PAIN IN EXTREMITY (Limb pain), PYREXIA (Flu-like feeling) and MYOCARDITIS (Perimyocarditis) in a 23-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 immunisation. Concurrent medical conditions included Obstructive sleep apnea syndrome, Nicotine abuse (Infrequent	23 years old male with medical history obstructive sleep apnea who 27 days after the 2nd dose experienced pyrexia, pain in extremity, chest discomfort, dyspnea, 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

Case ID	WW Identifier	Narrative	MAH Comment
		nicotine consumption) and Alcohol use (Infrequent alcohol consumption). On 18-Sep-2021, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form. On 16-Oct-2021, received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) dosage was changed to 1 dosage form. On 12-Nov-2021, the patient experienced PAIN IN EXTREMITY (Limb pain) (seriousness criteria hospitalization and medically significant), PYREXIA (Flu-like feeling) (seriousness criteria hospitalization and medically significant) and MYOCARDITIS (Perimyocarditis) (seriousness criteria hospitalization and medically significant). On 15-Nov-2021, the patient experienced CHEST DISCOMFORT (Feeling of pressure in the sternum) (seriousness criteria hospitalization and medically significant) and DYSPNOEA (Dyspnea) (seriousness criteria hospitalization and medically significant). At the time of the report, CHEST DISCOMFORT (Feeling of pressure in the sternum), DYSPNOEA (Dyspnea), PAIN IN EXTREMITY (Limb pain), PYREXIA (Flu-like feeling) and MYOCARDITIS (Perimyocarditis) was resolving. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered CHEST DISCOMFORT (Feeling of pressure in the sternum), DYSPNOEA (Dyspnea), PAIN IN EXTREMITY (Limb pain), PYREXIA (Flu-like feeling) and MYOCARDITIS (Perimyocarditis) to be possibly related. Patient had suffered from a febrile sensation with limb pain on 12-NOV-2021 had intermittent episodes of sensation of pressure in the sternum with mild dyspnea on 15-NOV-2021 The patient had to be hospitalized	the start of the events; a causal relationship cannot be excluded.

Case ID	WW Identifier	Narrative	MAH Comment
		and a tentative diagnosis of perimyocarditis was made. On 16-NOV-2021 the patient's condition was reported as improved. Concomitant product use was not provided. Treatment information was not provided Most recent FOLLOW-UP information incorporated above includes: On 29-Nov-2021: Translation received on 01-Dec-2021, past medical history ,event information and senders comments was updated.	
4.1(b)		This case was received via 4.1(b) (Reference number: 4.1(b) on 30-Nov-2021 and was forwarded to Moderna on 30-Nov-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of PERICARDITIS (Pericarditis) in a 27-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 004F21A) for an unknown indication. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Penicillin allergy, Drug allergy and Seasonal allergy. On 10-Sep-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 10-Sep-2021, the patient experienced PERICARDITIS (Pericarditis) (seriousness criterion medically significant), C-REACTIVE PROTEIN (C-reactive protein), CHEST X-RAY (Chest X-ray), CHEST PAIN (Chest pain), DIFFERENTIAL WHITE BLOOD CELL COUNT (Differential white blood cell count), DIZZINESS (Dizziness), ELECTROCARDIOGRAM (Electrocardiogram), FIBRIN D DIMER (Fibrin D dimer), FULL	27 years old female with unknown medical history who the same day after the 2nd dose experienced chest pain, fatigue and dizziness, and was diagnosed with myopericarditis. Diagnostic and laboratory test results were not provided. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events; a causal relationship cannot be excluded.

Case ID	WW Identifier	Narrative	MAH Comment
		BLOOD COUNT (Full blood count), MAGNETIC RESONANCE IMAGING ABNORMAL (Magnetic resonance imaging abnormal), MAGNETIC RESONANCE IMAGING HEART (Magnetic resonance imaging heart), METABOLIC FUNCTION TEST (Metabolic function test), TROPONIN (Troponin) and FATIGUE (Fatigue). At the time of the report, PERICARDITIS (Pericarditis), C-REACTIVE PROTEIN (C-reactive protein), CHEST X-RAY (Chest X-ray), CHEST PAIN (Chest pain), DIFFERENTIAL WHITE BLOOD CELL COUNT (Differential white blood cell count), DIZZINESS (Dizziness), ELECTROCARDIOGRAM (Electrocardiogram), FIBRIN D DIMER (Fibrin D dimer), FULL BLOOD COUNT (Full blood count), MAGNETIC RESONANCE IMAGING ABNORMAL (Magnetic resonance imaging abnormal), MAGNETIC RESONANCE IMAGING HEART (Magnetic resonance imaging heart), METABOLIC FUNCTION TEST (Metabolic function test), TROPONIN (Troponin) and FATIGUE (Fatigue) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 29-Oct-2021, Magnetic resonance imaging heart: abnormal (abnormal) Confirmed Diagnosis of Pericarditis. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. No concomitant medications were provided. Patient had C-Reactive Protein and Sedimentation Rate - 22-Oct-2021 (Primary Care Office Visit) , CBC with Differential - 20-Oct-2021 (ER Visit), XR Chest 1 VW Portable - 20-Oct-2021 (ER Visit), D-Dimer, Quantitative - 20-Oct-2021 (ER Visit), Comprehensive Metabolic Panel - 20-	

Case ID	WW Identifier	Narrative	MAH Comment
		Oct-2021 (ER Visit) , High-Sensitivity Troponin - 20-Oct-2021 (ER Visit), ECG 12-LEAD - 20-Oct-2021 (ER Visit). Patient experienced Chest Pain (Diagnosed as Pericarditis) (persistent-continuing as of 13-Nov-2021) ,Light-headedness (intermittent - occasional onsets as of 13-Nov-2021), Fatigue (persistent - continuing as of 13-Nov-2021). Treatment medication included Indomethacin and Colchicine.	
4.1(b)		This case was received via 4.1(b) (Reference number: 4.1(b) on 30-Nov-2021 and was forwarded to Moderna on 30-Nov-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of PERICARDITIS (Pericarditis) in a 32-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 011F21A) for an unknown indication. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 05-Nov-2021, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 11-Nov-2021, the patient experienced PERICARDITIS (Pericarditis) (seriousness criterion medically significant), BLOOD TEST (Blood test), BREAST PAIN (Breast pain), CHEST PAIN (Chest pain), COMPUTERISED TOMOGRAM (Computerised tomogram), ELECTROCARDIOGRAM (Electrocardiogram), MUSCULOSKELETAL PAIN (Musculoskeletal pain) and PAIN (Pain). At the time of the report, PERICARDITIS (Pericarditis), BLOOD TEST (Blood test), BREAST PAIN (Breast pain), CHEST PAIN (Chest pain), COMPUTERISED	32 years old female with unknown medical history who 6 days after the 3rd dose experienced left shoulder pain radiated to left chest under her breast that increased when lying down and with inspiration. Diagnostic and laboratory test results were not provided. Patient 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. A causal relationship cannot be excluded due to the lack of information.

Case ID	WW Identifier	Narrative	MAH Comment
		TOMOGRAM (Computerised tomogram), ELECTROCARDIOGRAM (Electrocardiogram), MUSCULOSKELETAL PAIN (Musculoskeletal pain) and PAIN (Pain) had not resolved. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Lab tests CT, EKG, bloodwork was done, results were not provided. Patient had pain in left shoulder blade radiating to left chest under breast. Pain increased when she was lying down and taking deep breaths. Pain decreased when she was leaning forward. Pain started on 11/11/21 and became worse. ER visit made on 11/17/21 and diagnosed with Pericarditis. No fluid buildup or blood clots. Prescribed Naproxen and encouraged to rest. Concomitant medication of the patient was not reported. Company comment This case concerns a 32-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) with no relevant medical history who experienced the serious expected event (AESI) of pericarditis 6 six days after the third dose of the vaccine. Rechallenge is not applicable, since no further dosing is expected. The benefit-risk relationship is not affected by this report.	
4.1(b)		This case was received via 4.1(b) (Reference number: 4.1(b) on 30-Nov-2021 and was forwarded to Moderna on 30-Nov-2021. This regulatory authority case was reported by a health care professional and describes the occurrence of ANGINA PECTORIS (Angina pectoris), CATHETERISATION CARDIAC (Catheterisation cardiac),	22 years old male with unknown medical history who 3 days after the 2nd dose experienced angina pectoris and was diagnosed with myocarditis. Diagnostic and laboratory test results were not provided. No other information was provided. Important information is missing in the report including patient's full medical history as well as any diagnostic or laboratory test conducted, including testing for

Case ID	WW Identifier	Narrative	MAH Comment
		ECHOCARDIOGRAM (Echocardiogram), MYOCARDITIS (Myocarditis), SLEEP DISORDER (Sleep disorder) and TROPONIN I (Troponin I) in a 22-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 010M20A) for an unknown indication. Concurrent medical conditions included Penicillin allergy. On 10-Feb-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 13-Feb-2021, the patient experienced ANGINA PECTORIS (Angina pectoris) (seriousness criterion hospitalization), CATHETERISATION CARDIAC (Catheterisation cardiac) (seriousness criterion hospitalization), ECHOCARDIOGRAM (Echocardiogram) (seriousness criterion hospitalization), MYOCARDITIS (Myocarditis) (seriousness criterion hospitalization), SLEEP DISORDER (Sleep disorder) (seriousness criterion hospitalization) and TROPONIN I (Troponin I) (seriousness criterion hospitalization). At the time of the report, ANGINA PECTORIS (Angina pectoris), CATHETERISATION CARDIAC (Catheterisation cardiac), ECHOCARDIOGRAM (Echocardiogram), MYOCARDITIS (Myocarditis), SLEEP DISORDER (Sleep disorder) and TROPONIN I (Troponin I) had resolved. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Other Meds : Occasional ibuprofen or ferrous sulfate pill. Most symptoms faded within 4 hours, possibly due to hospital intervention.	SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events. A causal relationship cannot be excluded due to the lack of information.

Case ID	WW Identifier	Narrative	MAH Comment
		Lab Data: 02/13/2021: Heart catheterization, Troponin I levels 02/14/2021: Troponin I levels 06/07/2021: Echocardiogram. results are unknown. Company Comment. This case concerns a 22-year-old male subject, with no relevant medical history, who experienced the serious, expected, and AESI event of Myocarditis, and the serious and unexpected events of Angina pectoris, Catheterisation cardiac, Sleep disorder, among others. The events occurred 3 days after the second dose of mRNA-1273 vaccine. The rechallenge is not applicable, as no additional dosing will be given. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.	
4.1(b)		This case was received via 4.1(b) (Reference number: 4.1(b) on 30-Nov-2021 and was forwarded to Moderna on 30-Nov-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of CARDITIS (Carditis) and MYOCARDITIS (Myocarditis) in a 34-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 05T21A) for an unknown indication. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Allergy to chemicals (Sulphur). On 03-Nov-2021, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 04-Nov-2021, the patient experienced CARDITIS (Carditis) (seriousness criterion medically significant), MYOCARDITIS (Myocarditis) (seriousness criterion medically significant), CHEST DISCOMFORT (Chest discomfort), CHEST PAIN (Chest pain),	34 years old female with unknown medical history who next day after the 3rd dose experienced chest pain and chest discomfort and was found to have elevated troponin, CRP, and abnormal EKG, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin, CRP, and EKG results; a causal relationship cannot be excluded.

Case ID	WW Identifier	Narrative	MAH Comment
		DYSпноEA (Dyspnoea), PAIN IN EXTREMITY (Pain in extremity), PARAESTHESIA (Paraesthesia), HYPOAESTHESIA (Hypoaesthesia), LYMPHADENOPATHY (Lymphadenopathy), TROPONIN INCREASED (Troponin increased), ELECTROCARDIOGRAM ABNORMAL (Electrocardiogram abnormal), C-REACTIVE PROTEIN INCREASED (C-reactive protein increased), CHEST X-RAY NORMAL (Chest X-ray normal), ECHOCARDIOGRAM (Echocardiogram) and LABORATORY TEST (Laboratory test). At the time of the report, CARDITIS (Carditis), MYOCARDITIS (Myocarditis), CHEST DISCOMFORT (Chest discomfort), CHEST PAIN (Chest pain), DYSпноEA (Dyspnoea), PAIN IN EXTREMITY (Pain in extremity), PARAESTHESIA (Paraesthesia), HYPOAESTHESIA (Hypoaesthesia), LYMPHADENOPATHY (Lymphadenopathy), TROPONIN INCREASED (Troponin increased), ELECTROCARDIOGRAM ABNORMAL (Electrocardiogram abnormal), C-REACTIVE PROTEIN INCREASED (C-reactive protein increased), CHEST X-RAY NORMAL (Chest X-ray normal), ECHOCARDIOGRAM (Echocardiogram) and LABORATORY TEST (Laboratory test) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, C-reactive protein: high (High) High. On an unknown date, Electrocardiogram: abnormal (abnormal) abnormalities. On an unknown date, Troponin: high (High) High. On an unknown date, X-ray: normal (normal) Nothing in lungs. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did	

Case ID	WW Identifier	Narrative	MAH Comment
		not provide any causality assessments. Patient other Medications included Vyvanse and lexapro It was reported that patient developed sore arms and chest pains on her left side and patient went to her doctor because she had shortness of breath and chest pain, Swollen lymph nodes of the left. Friday it got worst, all on her left breast area, got lab work done. Last week it came back really bad on Wednesday, patient went to ER, chest tight and pain sharp pain, tightening in chest. Did labs and test acute carditis and was given meds. On Sunday, Patient went back in ER for tingling and numbness on right foot. Carditis was the same but had confirmed that it was a reaction to the med that was given. Patient was advised to stop taking these meds. These were Colchicine, Indomethacin, Pantoprazole. Patient still having chest pains and hard to breath with inflammation of the heart. ER visit was twice. Laboratory data included Echocardiogram with unknown results.	
4.1(b)		This case was received via 4.1(b) (Reference number: 4.1(b) on 30-Nov-2021 and was forwarded to Moderna on 30-Nov-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of BLOOD CREATINE PHOSPHOKINASE INCREASED (Blood creatine phosphokinase increased), C-REACTIVE PROTEIN INCREASED (C-reactive protein increased), CHEST PAIN (Chest pain), DYSPNOEA (Dyspnoea), ECHOCARDIOGRAM (Echocardiogram), EJECTION FRACTION (Ejection fraction), MYALGIA (Myalgia), PYREXIA (Pyrexia), TROPONIN INCREASED (Troponin increased) and	19 years old male with medical history of glomerulonephritis who 2 days after the 2nd dose experienced chest pain, dyspnoea, pyrexia, myalgia, and was found to have elevated troponin, CRP, CKP, and normal Echo, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin, and CRP; a causal relationship cannot be excluded.

Case ID	WW Identifier	Narrative	MAH Comment
		MYOCARDITIS (Myocarditis) in a 19-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for an unknown indication. The patient's past medical history included Glomerulonephritis. On 15-Nov-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 17-Nov-2021, the patient experienced BLOOD CREATINE PHOSPHOKINASE INCREASED (Blood creatine phosphokinase increased) (seriousness criterion hospitalization), C-REACTIVE PROTEIN INCREASED (C-reactive protein increased) (seriousness criterion hospitalization), CHEST PAIN (Chest pain) (seriousness criterion hospitalization), DYSPNOEA (Dyspnoea) (seriousness criterion hospitalization), ECHOCARDIOGRAM (Echocardiogram) (seriousness criterion hospitalization), EJECTION FRACTION (Ejection fraction) (seriousness criterion hospitalization), MYALGIA (Myalgia) (seriousness criterion hospitalization), PYREXIA (Pyrexia) (seriousness criterion hospitalization), TROPONIN INCREASED (Troponin increased) (seriousness criterion hospitalization) and MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, BLOOD CREATINE PHOSPHOKINASE INCREASED (Blood creatine phosphokinase increased), C-REACTIVE PROTEIN INCREASED (C-reactive protein increased), CHEST PAIN (Chest pain), DYSPNOEA (Dyspnoea), ECHOCARDIOGRAM (Echocardiogram), EJECTION FRACTION (Ejection fraction), MYALGIA (Myalgia), PYREXIA (Pyrexia), TROPONIN INCREASED (Troponin increased) and MYOCARDITIS (Myocarditis) outcome was unknown.	

Case ID	WW Identifier	Narrative	MAH Comment
		DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 18-Nov-2021, Blood creatine phosphokinase: 406 (High) 406 at 06:22 and 1038 (High) 1038 at 18:08. On 18-Nov-2021, C-reactive protein increased: 48.7 (High) 48.7. On 18-Nov-2021, Echocardiogram: (normal) Normal left ventricular size, thickness and systolic function with no regional wall motion abnormalities. The left ventricular ejection fraction is 70 % of note. On 18-Nov-2021, Troponin: (High) 0.42 at 05:58 and (High) 1.70 at 18:08. On 19-Nov-2021, Blood creatine phosphokinase: 1061 (High) 1061 at 05:22. On 19-Nov-2021, Troponin: (High) 2.65 at 05:22. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Patient had fever and myalgia following the vaccine. Symptoms got better but on day 3 he has developed chest pain and progressed with SOB. He presented to the ED and working diagnosis is perimyocarditis. Patient was still hospitalized. cMRI was not available in our hospital. No concomitant medications provided. No treatment medications provided.	
4.1(b)		This case was received via 4.1(b) (Reference number: 4.1(b) on 30-Nov-2021 and was forwarded to Moderna on 30-Nov-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of BLOOD CREATINE PHOSPHOKINASE INCREASED (Blood creatine phosphokinase increased), CHEST PAIN (Chest pain), CHILLS (Chills), DIARRHOEA	15 years old male with medical history of latent TB s/p 9 mths INH tx with persistent GI symptoms who the next days after the 3rd dose of Spikevax experienced pyrexia, chills, fatigue, and two days later experienced chest discomfort and persistent fever and was found to have elevated troponin, and CK-MB, and abnormal EKG, with normal Echo, and negative SARA-CoV-2 test. Patient was diagnosed with myopericarditis. No other information

Case ID	WW Identifier	Narrative	MAH Comment
		(Diarrhoea), ECHOCARDIOGRAM NORMAL (Echocardiogram normal), ELECTROCARDIOGRAM ST SEGMENT ELEVATION (Electrocardiogram ST segment elevation), ELECTROCARDIOGRAM ABNORMAL (Electrocardiogram abnormal), FATIGUE (Fatigue), HYPERHIDROSIS (Hyperhidrosis), PYREXIA (Pyrexia), SARS-COV-2 TEST NEGATIVE (SARS-CoV-2 test negative), TROPONIN I INCREASED (Troponin I increased), VIRAL TEST NEGATIVE (Viral test negative), VOMITING (Vomiting), PERICARDITIS (Pericarditis) and MYOCARDITIS (Myocarditis) in a 26-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 032M20A, 045A21A and 033F21A) for COVID-19 vaccination. The patient's past medical history included TB in 2009. On 05-Nov-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 05-Nov-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form and third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 08-Nov-2021, the patient experienced BLOOD CREATINE PHOSPHOKINASE INCREASED (Blood creatine phosphokinase increased) (seriousness criterion hospitalization prolonged), CHEST PAIN (Chest pain) (seriousness criterion hospitalization prolonged), CHILLS (Chills) (seriousness criterion hospitalization prolonged), DIARRHOEA (Diarrhoea) (seriousness criterion hospitalization prolonged), ECHOCARDIOGRAM NORMAL (Echocardiogram normal) (seriousness criterion hospitalization prolonged), ELECTROCARDIOGRAM ST	was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin, CRP and EKG results; a causal relationship cannot be excluded.

Case ID	WW Identifier	Narrative	MAH Comment
		SEGMENT ELEVATION (Electrocardiogram ST segment elevation) (seriousness criteria hospitalization prolonged and medically significant), ELECTROCARDIOGRAM ABNORMAL (Electrocardiogram abnormal) (seriousness criterion hospitalization prolonged), FATIGUE (Fatigue) (seriousness criterion hospitalization prolonged), HYPERHIDROSIS (Hyperhidrosis) (seriousness criterion hospitalization prolonged), PYREXIA (Pyrexia) (seriousness criterion hospitalization prolonged), SARS-COV-2 TEST NEGATIVE (SARS-CoV-2 test negative) (seriousness criterion hospitalization prolonged), TROPONIN I INCREASED (Troponin I increased) (seriousness criterion hospitalization prolonged), VIRAL TEST NEGATIVE (Viral test negative) (seriousness criterion hospitalization prolonged), VOMITING (Vomiting) (seriousness criterion hospitalization prolonged), PERICARDITIS (Pericarditis) (seriousness criteria hospitalization prolonged and medically significant) and MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization prolonged and medically significant). At the time of the report, BLOOD CREATINE PHOSPHOKINASE INCREASED (Blood creatine phosphokinase increased), CHEST PAIN (Chest pain), CHILLS (Chills), DIARRHOEA (Diarrhoea), ECHOCARDIOGRAM NORMAL (Echocardiogram normal), ELECTROCARDIOGRAM ST SEGMENT ELEVATION (Electrocardiogram ST segment elevation), ELECTROCARDIOGRAM ABNORMAL (Electrocardiogram abnormal), FATIGUE (Fatigue), HYPERHIDROSIS (Hyperhidrosis), PYREXIA (Pyrexia), SARS-COV-2 TEST NEGATIVE (SARS-CoV-2 test negative), TROPONIN I INCREASED (Troponin I increased), VIRAL TEST NEGATIVE (Viral test negative), VOMITING (Vomiting), PERICARDITIS (Pericarditis) and	

Case ID	WW Identifier	Narrative	MAH Comment
		MYOCARDITIS (Myocarditis) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 08-Nov-2021, Blood creatine phosphokinase: increased (High) increased. On 08-Nov-2021, Echocardiogram: normal (normal) normal. On 08-Nov-2021, Troponin: increased (High) 0507, 6266. On 08-Nov-2021, Viral test: negative (Negative) Negative. On 09-Nov-2021, Troponin: increased (High) 0910, 2762. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Other Meds : Cetirizine QD prn, Fluticasone Nasal QD, Montelukast 10 mg QD, Loestrin 1.5/30 QD, Omeprazole 40 mg QD. Symptom Text : Moderna COVID-19 Vaccine EUA: Pericarditis / Myocarditis Patient with latent TB s/p 9 mths INH tx with persistent GI symptoms, received Moderna Vaccines on 3/3/2021, 3/31/2021, and 11/05/2021. On 11/6/2021 patient began to have chills, fatigue, 1; fever as high as 4.1(b) Early on the morning of 11/8/2021 around 2 a.m. she began diarrhea, vomiting and chest pain which was made worse by lying down. Persistent fevers as well as sweats prompted to come to the ER. EKG was abnormal (diffuse ST elevation), echocardiogram obtained which was stable. Patient began to improve over the next few hours and was discharged in stable condition on 11/9/2021. Covid test negative	
4.1(b)	4.1(b)	This case was initially received via 4.1(b) (Reference number: 4.1(b)) on 02-Dec-2021. The most recent information was received on 12-Dec-	36 years old female, participant in a clinical trial and with medical history of COVID 19 infection a year before receiving the 3rd dose with Spikevax and previously receiving the Astrazeneca vaccine who

Case ID	WW Identifier	Narrative	MAH Comment
		2021 and was forwarded to Moderna on 12-Dec-2021. This regulatory authority case was reported by a consumer and describes the occurrence of SEIZURE (Convulsion), TREMOR (Shaking), TACHYCARDIA (Pulse rapid), HEART RATE IRREGULAR (Heartbeats irregular), LYMPHADENOPATHY (Swollen lymph nodes), RESPIRATION ABNORMAL (Abnormal breathing), DYSPNOEA (Shortness of breath), EYE PAIN (Eye pain), PALPITATIONS (Heart racing), FATIGUE (Fatigue/unusual tiredness), CHEST PAIN (Chest pain), PYREXIA (Fever), HYPERTENSION (Hypertension) and MYOCARDITIS (Myocarditis) in a 36-year-old female patient who received mRNA-1273 (COVID 19 Vaccine Moderna) (batch no. A6X5W) for COVID-19 vaccination. The patient's past medical history included Allergic reaction (Allergic reaction to food but never medication), Suspected COVID-19 in November 2020, Clinical trial participant (National statistics) and Back pain. Concomitant products included CODEINE PHOSPHATE, PARACETAMOL (CO-CODAMOL) for Back pain, COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (COVID-19 VACCINE ASTRAZENECA) for COVID-19 vaccination. On 27-Nov-2021, the patient received third dose of mRNA-1273 (COVID 19 Vaccine Moderna) (unknown route) 1 dosage form. On 27-Nov-2021, the patient experienced SEIZURE (Convulsion) (seriousness criteria hospitalization, disability and medically significant), TREMOR (Shaking) (seriousness criteria hospitalization, disability and medically significant), TACHYCARDIA (Pulse rapid) (seriousness criteria hospitalization,	immediately after receiving her booster dose experienced a fast pacing heart followed by shortness of breath and increased pulse rate. 25 minutes later, her hands started to shake and blood pressure was elevated to 200/160. She started to have what was described as a convulsion and paramedics were called. An ECG was taken at the time showing abnormal QRS changes. She also had abnormal breathing, chest pain, eye pain, fatigue, fever, irregular heartbeats, swollen lymph nodes. Patient was taken to the hospital where a second ECG done 3 days later again showed R wave abnormalities. Blood test done showed abnormal serum chloride levels. No other information was provided. Important information is missing in the report including patient's full medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. ECG results are conflicting showing more results for a myocardial infarction than for myocarditis. Also the abrupt TTO does not correspond with the already described presentation of case of myocarditis after vaccination with Spikevax. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events. A causal relationship cannot be excluded due to the lack of information.

Case ID	WW Identifier	Narrative	MAH Comment
		disability and medically significant), HEART RATE IRREGULAR (Heartbeats irregular) (seriousness criteria hospitalization, disability and medically significant), LYMPHADENOPATHY (Swollen lymph nodes) (seriousness criteria hospitalization, disability and medically significant), RESPIRATION ABNORMAL (Abnormal breathing) (seriousness criteria hospitalization, disability and medically significant), DYSPNOEA (Shortness of breath) (seriousness criteria hospitalization, disability and medically significant), EYE PAIN (Eye pain) (seriousness criteria hospitalization, disability and medically significant), PALPITATIONS (Heart racing) (seriousness criteria hospitalization, disability and medically significant) and HYPERTENSION (Hypertension) (seriousness criteria hospitalization, disability and medically significant). On an unknown date, the patient experienced FATIGUE (Fatigue/unusual tiredness) (seriousness criteria hospitalization, disability and medically significant), CHEST PAIN (Chest pain) (seriousness criteria hospitalization, disability and medically significant), PYREXIA (Fever) (seriousness criteria hospitalization, disability and medically significant) and MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization, disability and medically significant). At the time of the report, SEIZURE (Convulsion) and TREMOR (Shaking) had resolved, TACHYCARDIA (Pulse rapid), LYMPHADENOPATHY (Swollen lymph nodes), RESPIRATION ABNORMAL (Abnormal breathing), DYSPNOEA (Shortness of breath), EYE PAIN (Eye pain) and MYOCARDITIS (Myocarditis) had not resolved, HEART RATE IRREGULAR (Heartbeats irregular) and PALPITATIONS (Heart racing) was resolving and FATIGUE (Fatigue/unusual tiredness), CHEST PAIN (Chest pain), PYREXIA (Fever)	

Case ID	WW Identifier	Narrative	MAH Comment
		and HYPERTENSION (Hypertension) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 20-Oct-2020, SARS-CoV-2 test: yes - positive covid-19 test (Positive) Yes - Positive COVID-19 test. On 27-Nov-2021, Electrocardiogram: abnormal (abnormal) abnormal. On 01-Dec-2021, Blood test: abnormal (abnormal) abnormal serum cholride levels. On 01-Dec-2021, Electrocardiogram: abnormal (abnormal) showed abnormalities on the R wave. On an unknown date, Blood pressure measurement: 200/160 (High) 200/160 with a pulse of around 150. Immediately post-vaccination, patient's heart started to race, this was followed by shortness of breath and increased pulse rate. Around 25 minutes later, her hands started to shake and blood pressure was in the red zone. Afterwards, her whole body started to have convulsions and this was ongoing for around an hour until the paramedics gave her intravenous medication to stop the shaking. An ECG was taken at the time and heart was abnormal. She also had abnormal breathing, chest pain, eye pain, fatigue, fever, irregular heartbeats, swollen lymph nodes. Blood pressure eventually taken into cubicle for further treatment, three over the course of around 10 minutes, all read high one being 200/160 with a pulse of around 150, ambulance was called. ECG upon ambulance arrival showing abnormal QRS changes, 10 ml of chlorphenamine via canula given. Heart pain treatment still ongoing. GP has advised 6 weeks complete rest as a minimum. Cocodamol for pain under arm. This regulatory case concerns a 36-year-old, female patient with relevant	

Case ID	WW Identifier	Narrative	MAH Comment
		history of concomitant administration of the AstraZeneca COVID-19 vaccine, who experienced the unexpected, serious AESI of myocarditis and seizure and the unexpected, serious events of tremor, tachycardia, heart rate irregular, lymphadenopathy, respiration abnormal, dyspnoea, eye pain, palpitations, fatigue, chest pain, pyrexia and hypertension. The events seizure, tremor, tachycardia, heart rate irregular, lymphadenopathy, respiration abnormal, dyspnoea, eye pain, palpitations and hypertension occurred on the same day after administration of the booster dose of the Moderna mRNA-1273 vaccine. The start dates of the other events were not provided. The patient was attended by the paramedics and was given intravenous medication (unspecified) and 10 ml of chlorphenamine via canula. She spoke to her physician on 29Nov2021 and was advised that she is suffering from myocarditis. A second ECG done on 01Dec2021 again showed R wave abnormalities. Blood test done showed abnormal serum chloride levels. She was then referred to a specialist. The events seizure and tremor had resolved while the events heart rate irregular and palpitations were resolving at the time of the report. The events myocarditis, tachycardia, lymphadenopathy, respiration abnormal, dyspnoea and eye pain had not resolved, and the outcomes of the other events were unknown at the time of the report. The history of concomitant administration of the AstraZeneca COVID-19 vaccine remains a confounder. The benefit-risk relationship of the Moderna mRNA-1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 12-Dec-2021: Follow-up received on 12-DEC-2021 contained significant information Medical	

Case ID	WW Identifier	Narrative	MAH Comment
		History, Lab data, Concomitant product, Event details were updated.	
4.1(b)	4.1(b)	This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCARDITIS (Myocarditis) in a 34-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for an unknown indication. No Medical History information was reported. On 01-Nov-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 03-Nov-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criterion hospitalization). At the time of the report, MYOCARDITIS (Myocarditis) was resolving. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Age of the patient was reported as 34.4. The patient had past history of mitral valve prolapse. The patient took contraceptives and denied other medications used. The patient visited LMD and cardiac echo at Doctor's clinic revealed moderate MR, PR, LVE, LAE, EF 43% (cardiomegaly with reduced EF). On 19-Nov-2021, the patient sought medical attention at the cardiology outpatient of hospital, due to short of breath for 2 weeks, episodes of palpitation (arrhythmia), DOE and orthopnea were noted in recent three days. The patient denied recent TOCC history, fever chest pain/tightness or extremities edema. Therefore, the patient was referred to ER, due to possible heart failure and/or myocarditis. At ER, her initial vital sign was T 36.6, P 70, R 20, BP 116/78 and GCS was E4V5M6. PE	34 years old female with medical history of mitral valve prolapse and contraceptive use who 2 days after the 2nd dose of Spikevax experienced shortness of breath, palpitations, dyspnoea on exertion and orthopnea for about two weeks before going to the ER where and ECG showed diffuse Twave inversion and a suspected diagnosis of myocarditis was given. Cardiac enzymes were normal. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the EKG results; a causal relationship cannot be excluded.

Case ID	WW Identifier	Narrative	MAH Comment
		showed regular heart beat and no murmur was noted. Lab data was grossly normal. However EKG showed diffuse T wave inversion and LVH was noted, raising concern of myocarditis and heart failure. Heart echo was done and showed LVEF is 30.7%, DCM and regional wall motion abnormality, suspect coronary artery disease. Follow up cardiac enzyme was normal. On 20-Nov-2021, under the impression of heart failure, DCM and myocarditis she was admitted to the hospital for further evaluation. After admission, the patient was prescribed with entresto, carvedilol, spironolactone, lasix for her HF. CTA was also arranged and the patient was prescribed aspirin for suspect CAD. In ward, hypokalemia was noted so follow up lab data was kept. The patient was prescribed colchicine for myocarditis and her symptoms subsided after medications used. Three days later, the patient's symptom subside and electrolyte was corrected. CTA showed no evidence of CAD and Holter showed. Under, relatively stable condition, on 24-Nov-2021, the patient was discharged from the hospital and the patient was advised to keep OPD follow up. The patient was expected to come for a follow-up visit on 02-Dec-2021 Company Comment: This case concerns a 34-year-old female patient with no relevant medical history, who experienced the unexpected serious adverse event of special interest Myocarditis. The event, which caused hospitalization for the patient occurred 2 days after receiving the second dose of mRNA-1273 Vaccine. The rechallenge was not applicable since only information about the second dose was disclosed. The patient stayed at the hospital for 5 days and diagnostics	

Case ID	WW Identifier	Narrative	MAH Comment
		revealed abnormalities in the EKG and echocardiogram, there was also noted hypokalemia. She was discharged improved and given with home medications. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report.	
4.1(b)	4.1(b)	This case was received via an unknown source (no reference has been entered for a health authority or license partner) on 06-Dec-2021 and was forwarded to Moderna on 08-Dec-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCARDITIS (Myocarditis) in a 30-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 072F21A_1101212-CDC) for COVID-19 vaccination. No Medical History information was reported. On 22-Nov-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 25-Nov-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criterion medically significant). At the time of the report, MYOCARDITIS (Myocarditis) was resolving. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medication were reported No treatment medication were reported Patient received the second of moderna vaccine on 22-Nov-2021. After the vaccine patient experienced fever for 5 days, chest tightness (+) palpitation (+) dyspnea (+) N/V (-) abdominal pain (-) URI (-) dysuria (-).	30 years old male with unknown medical history who 3 days after the 2nd dose experienced pyrexia, chest tightness, palpitations, dyspnea, and was found to have elevated troponin, and NT-proBNP, 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 results; a causal relationship cannot be excluded.

Case ID	WW Identifier	Narrative	MAH Comment
		Patient stated consciousness E: 4 M: 6 V: 5. Laboratory data included Body temp 36.9°C, SpO2 100%, P: 95 (beats/min), R: 20 (breaths/min) BP 134/86 (mmHg), NT-proBNP 132.0 pg/m, hs-Troponin I: 71.1 pg/mL, Patient also stated Conscious clear, Chest: clear breathing sound. Abdomen: soft, no tenderness. Limb: no edema. NE: no specific finding, Myocarditis. Patient stated that due to body temperature maintained 40°C for two consecutive days since November 23. Patient went to the Emergency Department on November 25. The fever has subsided after treatment, and he returned to Cardiology Outpatient department on November 26. This case concerns a 30-year-old male patient with no medical history, who experienced the unexpected serious adverse event of special interest Myocarditis. The event occurred 4 days after receiving the second dose of mRNA-1273 Vaccine. The rechallenge was not applicable since only information about the second dose was disclosed. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report.	
4.1(b)	4.1(b)	This case was received via an unknown source (no reference has been entered for a health authority or license partner) on 06-Dec-2021 and was forwarded to Moderna on 08-Dec-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCARDITIS (Myocarditis) in a 26-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for an unknown indication. No Medical History information was reported. On 15-Nov-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine)	26 years old male with unknown medical history who 3 days after the 2nd dose of Spikevax experienced pyrexia, chest tightness and wheezing. Symptoms persisted for 7 days when the patient went to the hospital and was found to have elevated cardiac enzymes, and abnormal EKG, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated cardiac enzymes and EKG

Case ID	WW Identifier	Narrative	MAH Comment
		(unknown route) 1 dosage form. On 18-Nov-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criterion medically significant). At the time of the report, MYOCARDITIS (Myocarditis) was resolving. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Patient was reported to be given second dose of Moderna vaccine on 25-Nov-2021 and also had second dose of Moderna vaccine in afternoon on 15-Nov-2021. Patient started to have a fever of about 39 degrees, chills and general fatigue. The fever subsided the same night after the patient used antipyretics, and the symptoms of chills and general fatigue lasted for 1 day before recovery. On November 18, the patient suffered from chest tightness and wheezing after getting up in the morning and later the symptoms were improved. Patient also suffered from asthma and went to the clinic for X-ray and electrocardiographic examinations, where no abnormality was found. On November 20, 2021, the patient started to suffer from chest tightness in addition to wheezing. On November 25, 2021 patient went to hospital Abnormality was found in the electrocardiogram and a blood test was performed. Abnormal increase of myocardial enzymes were detected. The patient was diagnosed with vaccine-induced myocarditis and was hospitalized for treatment. On November 29, 2021, the patient was taken daily blood tests during hospitalization. The myocardial enzymes decreased slightly but the improvement was not obvious and	results; a causal relationship cannot be excluded.

Case ID	WW Identifier	Narrative	MAH Comment
		electrocardiogram was found to be normal, and the patient was discharged on the same day and arranged a return visit. Relevant concomitant medications were not provided. Treatment information was not provided. This case concerns a 26-year-old male patient with no medical history, who experienced the unexpected serious adverse event of special interest Myocarditis. The event occurred 4 days after receiving the second dose of mRNA-1273 Vaccine. The rechallenge was not applicable since only information about the second dose was disclosed. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report.	
4.1(b)	4.1(b)	This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCARDITIS (Myocarditis) in a 24-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for an unknown indication. No Medical History information was reported. On 21-Nov-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 24-Nov-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criterion hospitalization). At the time of the report, MYOCARDITIS (Myocarditis) was resolving. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medications reported. On 23-Sep-2021, the patient received the first dose of COVID-19 vaccine (AZ) and second shot of COVID-19	24 year old male with unknown medical history and who received AstraZeneca Covid-19 vaccine as first dose and 1 day after the second dose of Spikevax experienced chest tightness, fever and chest pain. 2 days later the patient went to the cardiology outpatient clinic due to dyspnea and chest pain and was found to have abnormal EKG and had elevated cardiac enzymes. The patient was diagnosed with myocarditis and referred to the emergency department. Bedside Echocardiogram showed good LV motion, no pericardial effusion, no pleural effusion, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated cardiac enzymes and EKG results; a causal relationship cannot be excluded.

Case ID	WW Identifier	Narrative	MAH Comment
		vaccine (Moderna) on 21-Nov-2021. At the night of 21-Nov-2021, and experienced chest tightness, chest pain and fever on 22-Nov-2021. The patient visited the outpatient clinic of the Dept of Cardiology for follow-up on 24-Nov-2021 as he experienced symptoms of chest pain and shortness of breath. It was found that the complete EKG showed II, III, AVF, V1-V6 STE and elevation cardio [sic: cardiac] enzyme. The patient was diagnosed with myocarditis and was transferred to the ED for treatment. Vital signs: body temperature: 36.7 degree Celsius; BP: 122/77 mmHg; pulse: 103 beats/min; respiratory rate: 16 breaths/min. The CXR was no obvious acute lesion. Bed side Echo: well LV motion, no pericardiac effusion, no pleural effusion, no ascites, no AAA, no intimal flap. The patient was directly admitted to the ICU for 2 days for treatment subsequently. Cardiac enzymes & gt; 15000-17000. Cardiac enzymes 3800. The patient was transferred to the general ward on 26-Nov-2021 after the symptoms improved and was discharged on 29-Nov-2021 after the condition stabilized. The patient has to take medication regularly now. The patient returned for visit on 06-Dec-2021. The patient has no symptoms of discomfort. The patient was instructed to avoid strenuous exercise at the moment and to seek medical attention as soon as possible in case of chest discomforts. Patient has no history of chronic illness. Company Comment: This case concerns a 24 year old male patient with no reported medical history who experienced the serious, expected AESI event of myocarditis 3 days after the second dose of Covid-19 vaccine (mRNA 1273). Patient received AstraZeneca Covid-19 vaccine as first dose in the Covid-19 vaccine series. One day after the mRNA 1273 vaccine patient	

Case ID	WW Identifier	Narrative	MAH Comment
		experienced chest tightness, then fever the following day. The patient went to the cardiology outpatient clinic 3 days after the mRNA 1273 vaccine due to dyspnea and chest pain. EKG showed II, III, AVF, V1-V6 STE and had elevated cardiac enzymes. The patient was diagnosed with myocarditis and referred to the emergency department. Bedside Echocardiogram showed good LV motion, no pericardial effusion, no pleural effusion, no ascites, no AAA, no intimal flap. Patient was admitted to the ICU for further management, two days after was transferred to general ward. Patient was discharged 6 days after admission. The benefit-risk relationship of mRNA 1273 vaccine is not affected by this report.	
4.1(b)	4.1(b)	This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCARDITIS (Myocarditis) in a 35-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. Concurrent medical conditions included Mitral valve prolapse. On 20-Nov-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 28-Nov-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criterion hospitalization prolonged). At the time of the report, MYOCARDITIS (Myocarditis) was resolving. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medication were reported. First dose of mrna1273 (AstraZeneca) on 05-AUG-2021. After second dose (Moderna) , she	35 years old female with medical history of mitral valve prolapse and Astrazeneca vaccine as her first dose who 8 days after the 2nd dose experienced chest tightness, loss of consciousness and was taken to the ED where she was found to have pyrexia, elevated blood pressure, elevated troponin, abnormal ECG, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and EKG results; a causal relationship cannot be excluded.

Case ID	WW Identifier	Narrative	MAH Comment
		felt unwell in her whole body, lost her appetite, and noticed her muscles were twisted. On 25-NOV-2021 experienced intermittent chest tightness. On 28-NOV-2021 Chest tightness suddenly occurred during jogging in morning. She lost consciousness for a few minutes and was sent to emergency room for medical treatment. In emergency room, the fever was 38.9 and HR: 135 BPM, and the blood samples showed an increase in myocardial enzymes. Electrocardiogram showed sinus tachycardia with T wave inversion. Bedside echocardiography was normal. After about 10 seconds later, the whole body twitch was noticed, but no change of consciousness level was found, so antiepileptic drugs were given. Subsequent blood samples showed an increase in myocardial enzymes. On 28-NOV-2021 12:31, Troponin I was 1.13. Suspected of acute myocarditis, she was admitted to intensive care unit. On 29-NOV-2021 She was transferred to general ward. On 30-nov-2021, patient complained of being unwell and suffering from asthma Company Comment: This regulatory case concerns a 35-year-old female patient, with no relevant medical history reported, who experienced the serious (hospitalization) expected AESI of MYOCARDITIS. The event occurred 8 days after receiving the second dose of mRNA-1273. According to source narrative, patient experienced chest discomfort five days after being vaccinated. On the eighth day after vaccination, patient went to the ER where increase in myocardial enzymes and an abnormal electrocardiogram with T wave inversion were obtained. Echocardiogram was normal. Patient also experienced an episode of muscle twitching in the emergency room and was treated with antiepileptic drugs. She was admitted to the ICU for suspected myocarditis and the day after she was transferred to the general ward. The benefit-risk	

Case ID	WW Identifier	Narrative	MAH Comment
		relationship of mRNA-1273 is not affected by this report	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 07-Dec-2021 and was forwarded to Moderna on 07-Dec-2021. This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Acute myocarditis) in a 15-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. Concurrent medical conditions included Overweight. On 13-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On an unknown date, the patient experienced MYOCARDITIS (Acute myocarditis) (seriousness criteria hospitalization prolonged and medically significant). At the time of the report, MYOCARDITIS (Acute myocarditis) had resolved with sequelae. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In September 2021, Magnetic resonance imaging: normal (normal) VI and VD with segmental and global contractility normal Signs of non-ischemic myocardial damage in relation to myocarditis. On 17-Sep-2021, Blood creatine phosphokinase: high (High) 496. On 17-Sep-2021, Electrocardiogram: abnormal (abnormal) RS at 110 bpm. On 17-Sep-2021, SARS-CoV-2 test negative: negative (Negative) Negative. On 17-Sep-2021, Troponin: abnormal (abnormal) 366. On 21-Sep-2021, Echocardiogram: abnormal (abnormal) Trivalva aortic valve, normal appearance and function. Transvalve flow with v of 1.15 m/s. Aorta ascending measures 27 mm in Valsalva sinuses and 21	15 years old male with medical history of overweight who 4 days after the 2nd dose was found to have elevated troponin, and CK-MB, and abnormal EKG, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and EKG results; a causal relationship cannot be excluded.

Case ID	WW Identifier	Narrative	MAH Comment
		mm at tubular level. Left auricula of normal size, measures 30 mm on long axis Normal-looking mitral valve Mitral flow E 77 cm/s, A 57 cm/s e lateral 6.3 cm/s e medial 7.1 cm/s E/e 11.6 Left ventricle with DTD 50 mm, septum 7.8 mm, pp 11.6 mm, VTD 125 ml (68 ml/m2) FE 51%, no contraction alterations would. Right ventricle of normal size and function with TAPSE 19 mm Normal tricuspid and pulmonary valves. Don't spill pericardial. Normal.Measures 15 mm Coronary sinus dilation is observed, suggesting the existence of a persistent left superior vena cava draining into the coronary sinus. We administer agitated physiological serum into vein of the left arm, observing its appearance in the coronary sinus Conclusions VI of normal size with 51% VCSI persistent FE drained to the coronary sinus. On 23-Sep-2021, Echocardiogram: normal (normal) Trivalva aortic valve, normal appearance and function. Transvalve flow with v 1.15 m/s ascending aorta measures 27 mm in sinuses of Valsalva and 21 mm at tubular level.Left auricula normal size, measures 30 mm on long axis Normal-looking mitral valve E 77 cm/s A 57 cm/s and lateral 6.3 cm/s e medial 7.1 cm/s E/E 11,6Left ventricle with DTD 50 mm, septum 7.8 mm, pp 11.6 mm, VTD 125 ml (68 ml/m2) FE 51%, without segmental contraction alterations. Right ventricle of normal size and function with TAPSE 19 mmNormal tricuspid and pulmonary valves. No pericardial effusion. Normal IV.Measures 15 mmCoronary sinus dilation is observed, suggesting the existence of a persistent left superior vena cava draining into the coronary sinus. We administer agitated physiological serum into vein of the left arm, observing its appearance in the coronary sinus Conclusions VI of normal size with 51% VCSI persistent FE drained to the coronary sinus. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.	

Case ID	WW Identifier	Narrative	MAH Comment
		Concomitant medications were not provided. Treatment medication was not provided. Company comment: This case concerns a 15-year-old male patient, with no relevant medical history, who experienced the serious expected event of MYOCARDITIS. The event occurred after an unknown time interval after the second dose of the mRNA-1273 vaccine. The rechallenge is not applicable since no information about further dosing has been disclosed. An electrocardiogram, a echocardiogram and a blood test with creatine phosphokinase and troponin dosage were performed with abnormal results. Magnetic resonance imaging was also performed with no signs of myocarditis. The benefit-risk relationship of the mRNA-1273 is not affected by this report.	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 09-Dec-2021 and was forwarded to Moderna on 09-Dec-2021. This regulatory authority case was reported by a physician and describes the occurrence of HYPOXIA (HYPOXIA), MYOCARDITIS (MYOPERICARDITIS), PALPITATIONS (PALPITATIONS), CHEST PAIN (CHEST PAIN) and CHEST DISCOMFORT (CHEST PRESSURE) in a 25-year-old male patient who received mRNA-1273 (Spikevax) (batch no. FE9174) for Vaccination. Previously administered products included for Vaccination: Comirnaty. Past adverse reactions to the above products included No adverse event with Comirnaty. Concurrent medical conditions included Asthma (Mild disease. The patient uses no medications for his asthma.).	35 years old female with medical history of asthma and Comirnaty vaccine as his first dose who 3 days after the 2nd dose with Spikevax experienced chest pain, palpitations, chest discomfort as chest pressure and was hospitalized where he was found to have elevated blood pressure, elevated troponin, abnormal ECG, and Echo and was diagnosed with myopericarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and EKG results; a causal relationship cannot be excluded.

Case ID	WW Identifier	Narrative	MAH Comment
		On 19-Nov-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On an unknown date, the patient experienced HYPOXIA (HYPOXIA) (seriousness criterion hospitalization), MYOCARDITIS (MYOPERICARDITIS) (seriousness criteria hospitalization and medically significant), PALPITATIONS (PALPITATIONS) (seriousness criterion hospitalization), CHEST PAIN (CHEST PAIN) (seriousness criterion hospitalization) and CHEST DISCOMFORT (CHEST PRESSURE) (seriousness criterion hospitalization). At the time of the report, HYPOXIA (HYPOXIA), MYOCARDITIS (MYOPERICARDITIS), PALPITATIONS (PALPITATIONS), CHEST PAIN (CHEST PAIN) and CHEST DISCOMFORT (CHEST PRESSURE) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In November 2021, Blood gases: 9.3 kpa 9.3 kPa (kilopascal). In November 2021, C-reactive protein: 13 mg/l 13 mg/L (milligram per litre) and 37 mg/l 37 mg/L (milligram per litre). In November 2021, Echocardiogram: decreased (Low) Diffuse decreased strain basal segments.. In November 2021, Electrocardiogram: increased (High) ECG shows global ST-elevation.. In November 2021, Fibrin D dimer: normal (normal) Normal. In November 2021, Liver function test: normal (normal) Normal. In November 2021, Physical examination: normal (normal) At examination the patient had nice vitalia and effortless respiration.. In November 2021, Renal function test: normal (normal) Normal. In November 2021, Troponin: 20 ng/l 20 ng/L (nanogram per litre) and 20 ng/l 20 ng/L (nanogram per litre). In November 2021, White blood cell count: normal (normal) Normal.	

Case ID	WW Identifier	Narrative	MAH Comment
		For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medication details was provided. No treatment medication details was provided. Company Comment: This is a case of Interchange of vaccine products for this 25-year-old, male subject with a medical history of prior vaccination with Comirnaty vaccine and mild asthma, who experienced the serious expected event of Myopericarditis (AESI) and the serious unexpected events of Hypoxia, Palpitations, Chest pain, and Chest discomfort. These events, which caused hospitalization, occurred 3 days after the second dose of mRNA 1273 Vaccine. Diagnostic tests were done on unknown dates: Troponin was elevated (20 ng/L), C-reactive protein was elevated (13 mg/L, 37 mg/L), ABG's showed mild hypoxemia(9.3kPa), Echocardiography showed diffuse decreased strain in basal segments, ECG showed global ST-elevation). No treatment medication given was mentioned. Rechallenge was not applicable as no information regarding an additional dose was given. At the time of the report, outcome of the events was unknown. The events were considered related to the product per the reporter's assessment. The patient's age and gender, which are predisposing factors for Myopericarditis, and medical history of prior vaccination with Comirnaty vaccine and mild asthma remain as confounders. The benefit-risk relationship of mRNA 1273 Vaccine is not affected by this report.	
4.1(b)	4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b) on 06-Dec-2021	25 years old male with unknown medical history who the next day after the 2nd dose experienced chest pain, and two days later was found to

Case ID	WW Identifier	Narrative	MAH Comment
		and was forwarded to Moderna on 13-Dec-2021. This case, initially reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref, 4.1(b) Myocarditis was assessed as serious by the MAH. On an unknown date, the patient received the 1st dose of this vaccine. On 26-Nov-2021, the patient received the 2nd dose of this vaccine. On 27-Nov-2021, around 20:00, the patient was aware of precordial pain and experienced myocarditis. On 28-Nov-2021, the precordial pain was relieved. Newly, the patient experienced a feeling of suffocation, as if the body had been submerged in water. On 29-Nov-2021, the patient visited a medical institution. The patient was referred to and visited the reporting hospital because of the suspected myocarditis. The blood test performed at the reporting hospital showed an abnormally high value of hsTnI 415.2. No abnormal finding was noted on the electrocardiogram and echocardiography. Family members were asked to follow up with the patient at home. The patient was prescribed a non-steroidal anti-inflammatory drug and returned home. On 03-Dec-2021, at an outpatient visit, the disappearance of symptoms was confirmed. The symptoms were observed to be resolved. The outcome of myocarditis was reported as resolved. Follow-up investigation will be made. Company Comment: The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. Company comment: This is a regulatory authority case concerning a 25-year-old, male patient with no reported medical history, who experienced the expected, serious, AESI event of myocarditis which resulted to hospital consultation. The event myocarditis occurred approximately 1 day after	have elevated troponin, and normal EKG and Echo, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin; a causal relationship cannot be excluded.

Case ID	WW Identifier	Narrative	MAH Comment
		the second dose of mRNA-1273 vaccine administration. Laboratories and Diagnostics were performed as follows, blood test hsTnI 415.2 ng/mL showed abnormally high value while the electrocardiogram and echocardiography showed no abnormal findings. The patient was prescribed a non-steroidal anti-inflammatory drug and returned home. Patient's follow up revealed symptoms resolved and the outcome of myocarditis was reported as resolved. The rechallenge was not applicable. The patient's age and gender remain confounders. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.	
4.1(b)	4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b) on 14-Dec-2021 and was forwarded to Moderna on 14-Dec-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of ARTHRALGIA (Arthralgia), ECHOCARDIOGRAM ABNORMAL (Echocardiogram abnormal), PAIN (Pain), DYSPNOEA (Dyspnoea), CHEST PAIN (Chest pain), PERICARDIAL EFFUSION (Pericardial effusion) and PERICARDITIS (Pericarditis) in a 40-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 026B21A and 044B21A) for an unknown indication. Concurrent medical conditions included Chronic kidney disease stage 5 (CKD Stage -V), High cholesterol, Hypertension, Gout and 4.1(b) On 09-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 09-Apr-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage	40 years old male with medical history of chronic kidney disease stage 5, hypertension, gout and 4.1(b) who 31 days after the 2nd dose experienced chest pain, dyspnea, and was found to have pericardial effusion on the echocardiogram and was diagnosed with pericarditis. No other information was provided. Important information is missing in the report including patient's full medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. Pericardial disease is common in patients with renal disease. Approximately 20% of uremic patients develop uremic pericarditis. In all forms of uremic pericarditis, cardiac tamponade is the main danger, and can be life-threatening, also is more common in dialyzed than in non-dialyzed patients with chronic renal failure. The medical history of the patient of CKD-stage V, hypertension and glomerulonephritis before the occurrence of the events are important risk factors that provide a more plausible explanation for the occurrence of the reported events. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and

Case ID	WW Identifier	Narrative	MAH Comment
		form. On 10-May-2021, the patient experienced ARTHRALGIA (Arthralgia) (seriousness criterion hospitalization), ECHOCARDIOGRAM ABNORMAL (Echocardiogram abnormal) (seriousness criterion hospitalization), PAIN (Pain) (seriousness criterion hospitalization), DYSPNOEA (Dyspnoea) (seriousness criterion hospitalization), CHEST PAIN (Chest pain) (seriousness criterion hospitalization), PERICARDIAL EFFUSION (Pericardial effusion) (seriousness criterion hospitalization) and PERICARDITIS (Pericarditis) (seriousness criterion hospitalization). At the time of the report, ARTHRALGIA (Arthralgia), ECHOCARDIOGRAM ABNORMAL (Echocardiogram abnormal), PAIN (Pain), DYSPNOEA (Dyspnoea), CHEST PAIN (Chest pain), PERICARDIAL EFFUSION (Pericardial effusion) and PERICARDITIS (Pericarditis) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Echocardiogram: abnormal (abnormal) small pericardial effusion. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medication was reported. No treatment information was reported. Other medications included furosemide 200 mg BID, verapamil 80, prednisone 10, lipitor 20, labetalol 300 BID and sodium and bicarb and flomax 4. Within 1-2 days after vaccine, the patient did have chest pain that radiated to the shoulder and also experienced some dyspnea. After a few weeks the chest pain moved to the center chest and progressed. The	the start of the events; a causal relationship cannot be excluded.

Case ID	WW Identifier	Narrative	MAH Comment
		patient went to ED 6/20/2021 and was diagnosed with pericarditis. Company comment: This regulatory authority case concerns a 40-year-old male patient with no relevant medical history of 4.1(b) [REDACTED], who experienced the expected serious (hospitalization) event of Pericarditis after mRNA- 1273 Moderna vaccine. The onset of the event occurred approximately 1 to 2 days after the second dose of mRNA- 1273 vaccine. Clinical manifestations included chest pain and dyspnoea. Pericarditis was diagnosed 2 months and 11 days after vaccination. Additionally, Pericardial effusion was also reported and could be in connection with Pericarditis. Very limited information is available regarding clinical course and treatment. At the time of the report, the events had resolved. Additionally, very limited information is available regarding history of glomerulonephritis, which might be a confounder. The benefit-risk relationship of mRNA- 1273 vaccine is not affected by this report.	
4.1(b) [REDACTED]	4.1(b) [REDACTED]	This case was received via 4.1(b) [REDACTED] (Reference number: 4.1(b) [REDACTED] on 14-Dec-2021 and was forwarded to Moderna on 14-Dec-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCARDITIS (Myocarditis), PERICARDITIS (Pericarditis), C-REACTIVE PROTEIN DECREASED (C-reactive protein decreased), CHEST PAIN (Chest pain) and DYSPNOEA (Dyspnoea) in a 21-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for an unknown indication. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Obesity.	21-year-old female patient with medical history of obesity, who next day after the 2nd dose of Spikevax fatigue, nausea, headache, chest pain, shortness of breath, vomiting. Found to have sinus tachycardia in the 130s-140s. She was admitted to rule out myocarditis. Diagnostic test included Echocardiogram and Electrocardiogram and both showed myopericarditis; Troponin was normal and CRP was decreased 1 day after vaccine on admission. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the Echo and EKG results;

Case ID	WW Identifier	Narrative	MAH Comment
		On 23-Nov-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 24-Nov-2021, the patient experienced MYOCARDITIS (Myocarditis), PERICARDITIS (Pericarditis), C-REACTIVE PROTEIN DECREASED (C-reactive protein decreased), CHEST PAIN (Chest pain), DYSPNOEA (Dyspnoea), ECHOCARDIOGRAM ABNORMAL (Echocardiogram abnormal), ELECTROCARDIOGRAM ABNORMAL (Electrocardiogram abnormal), SINUS TACHYCARDIA (Sinus tachycardia), TROPONIN NORMAL (Troponin normal), FATIGUE (Fatigue), HEADACHE (Headache), NAUSEA (Nausea), PYREXIA (Pyrexia) and VOMITING (Vomiting). At the time of the report, MYOCARDITIS (Myocarditis), PERICARDITIS (Pericarditis), C-REACTIVE PROTEIN DECREASED (C-reactive protein decreased), CHEST PAIN (Chest pain), DYSPNOEA (Dyspnoea), ECHOCARDIOGRAM ABNORMAL (Echocardiogram abnormal), ELECTROCARDIOGRAM ABNORMAL (Electrocardiogram abnormal), SINUS TACHYCARDIA (Sinus tachycardia), TROPONIN NORMAL (Troponin normal), FATIGUE (Fatigue), HEADACHE (Headache), NAUSEA (Nausea), PYREXIA (Pyrexia) and VOMITING (Vomiting) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, C-reactive protein: 2.85 and asymptomatic (abnormal) 1 day after vaccine on admission .7, the next day 2.85 and asymptomatic.. On an unknown date, Echocardiogram: showed to clear evidence of myocarditis/pericardit (abnormal) showed to clear evidence of myocarditis/pericarditis..	a causal relationship cannot be excluded.

Case ID	WW Identifier	Narrative	MAH Comment
		On an unknown date, Electrocardiogram: showed to clear evidence of myocarditis/pericarditis (abnormal) showed to clear evidence of myocarditis/pericarditis.. On an unknown date, Troponin: negative (Negative) Negative. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. No concomitant medications were reported. It was reported that patient went to ER with chest pain, shortness of breath, fatigue, nausea, vomiting and headache, was found to have sinus tachycardia in the 130s-140s and was admitted to rule out myocarditis. Patient developed fever later that day. Treatment medications were not reported. Company comment: This is a regulatory authority case concerning a 21-year-old female patient with no relevant medical history, who experienced myocarditis and pericarditis. The events occurred 1 day after the second dose of mRNA-1273 vaccine. Patient presented to ER with chest pain, shortness of breath, fatigue, nausea, vomiting and head ache. Found to have sinus tachycardia in the 130s-140s. She was admitted to rule out myocarditis. Later that day developed fever. Diagnostic test included Echocardiogram and Electrocardiogram: both showed to clear evidence of myocarditis/pericarditis; Troponin: negative; C-reactive protein: 1 day after vaccine on admission .7, the next day 2.85 Treatment details were not provided. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.	

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-Dec-2021 and was forwarded to Moderna on 14-Dec-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of ELECTROCARDIOGRAM ST SEGMENT ELEVATION (Electrocardiogram ST segment elevation), CHEST PAIN (Chest pain), DYSPNOEA EXERTIONAL (Dyspnoea exertional), ELECTROCARDIOGRAM ABNORMAL (Electrocardiogram abnormal), PYREXIA (Pyrexia), TROPONIN INCREASED (Troponin increased) and MYOCARDITIS (Myocarditis) in a 30-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for an unknown indication. No Medical History information was reported. On 27-Nov-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 28-Nov-2021, the patient experienced ELECTROCARDIOGRAM ST SEGMENT ELEVATION (Electrocardiogram ST segment elevation) (seriousness criterion hospitalization), CHEST PAIN (Chest pain) (seriousness criterion hospitalization), DYSPNOEA EXERTIONAL (Dyspnoea exertional) (seriousness criterion hospitalization), ELECTROCARDIOGRAM ABNORMAL (Electrocardiogram abnormal) (seriousness criterion hospitalization), PYREXIA (Pyrexia) (seriousness criterion hospitalization), TROPONIN INCREASED (Troponin increased) (seriousness criterion hospitalization) and MYOCARDITIS (Myocarditis) (seriousness criterion hospitalization). At the time of the report, ELECTROCARDIOGRAM ST SEGMENT ELEVATION (Electrocardiogram ST segment elevation), CHEST PAIN (Chest	30 years old male with unknown medical history who the next day after the 2nd dose experienced pyrexia, chest pain, dyspnea, and was found to have elevated troponin, and abnormal EKG, and was diagnosed with myopericarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and EKG results; a causal relationship cannot be excluded.

Case ID	WW Identifier	Narrative	MAH Comment
		pain), DYSPNOEA EXERTIONAL (Dyspnoea exertional), ELECTROCARDIOGRAM ABNORMAL (Electrocardiogram abnormal), PYREXIA (Pyrexia), TROPONIN INCREASED (Troponin increased) and MYOCARDITIS (Myocarditis) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Electrocardiogram: abnormal (abnormal) Electrocardiogram with diffuse STE. On an unknown date, Troponin: 440 (Inconclusive) 440, 447 (Inconclusive) 447 and 800 (Inconclusive) 800. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No concomitant product use was provided by the reporter. The patient was presented with subjective fevers, chest pain, and progressive DOE for 3 days before presenting to Emergency department on 30-Nov-2021. Electrocardiogram and troponin positive, likely perimyocarditis. Treatment medication included NSAIDs and colchicine and was improved with treatment. Company comment: This case concerns a 30-year-old male patient, with no medical history reported, who experienced the serious (due to hospitalization) expected AESI of myocarditis and the serious (due to hospitalization) unexpected events of chest pain, dyspnoea exertional, electrocardiogram ST segment elevation and troponin increased after second dose of mRNA-1273. The events could be in association with each other. The events occurred the	

Case ID	WW Identifier	Narrative	MAH Comment
		next day after second dose of mRNA-123. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 13-Dec-2021 and was forwarded to Moderna on 13-Dec-2021. This regulatory authority case was reported by a physician and describes the occurrence of ELECTROCARDIOGRAM ST SEGMENT ELEVATION (ST-LIFT ON THE ECG), ELECTROCARDIOGRAM CHANGE (ECG CHANGES AS WITH PERI/MYOCARDITIS, HOWEVER, NO TROPONIN RELEASE), MYOCARDITIS (PERI/MYOCARDITIS) and CHEST PAIN (CHEST PAIN) in a 17-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 3005238 and 3004493) for COVID-19 vaccination. No Medical History information was reported. On 16-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. In October 2021, the patient experienced ELECTROCARDIOGRAM ST SEGMENT ELEVATION (ST-LIFT ON THE ECG) (seriousness criterion disability), ELECTROCARDIOGRAM CHANGE (ECG CHANGES AS WITH PERI/MYOCARDITIS, HOWEVER, NO TROPONIN RELEASE) (seriousness criterion disability), MYOCARDITIS (PERI/MYOCARDITIS) (seriousness criterion disability) and CHEST PAIN (CHEST PAIN) (seriousness criterion disability). At the time of the report, ELECTROCARDIOGRAM ST SEGMENT ELEVATION (ST-LIFT ON THE ECG),	17 years old male with unknown medical history who at an unknown TTO after the 2nd dose of Spikevax experienced chest pain and was found to have abnormal ECG and Echo. Troponin information was not provided. Patient was diagnosed with myopericarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the EKG and Echo results; a causal relationship cannot be excluded.

Case ID	WW Identifier	Narrative	MAH Comment
		ELECTROCARDIOGRAM CHANGE (ECG CHANGES AS WITH PERI/MYOCARDITIS, HOWEVER, NO TROPONIN RELEASE), MYOCARDITIS (PERI/MYOCARDITIS) and CHEST PAIN (CHEST PAIN) had not resolved. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. No relevant concomitant medications was reported. Treatment information was not provided. Company comment: This is a regulatory case concerning a 17-year-old, male patient with no medical history reported, who experienced the serious expected, according CCDS, AESI of Myocarditis and the serious unexpected events of chest pain . Additionally, Electrocardiogram ST segment elevation and Electrocardiogram change were reported. The events occurred after second dose of mRNA-1273 vaccine. The rechallenge was not applicable since the events happened after the second dose and no information on additional dosing is available. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. The case was assessed as serious as per Regulatory Authority's report due to disability.	
4.1(b)	4.1(b)	This case was initially received via 4.1(b) (Reference number: 4.1(b)) on 05-Dec-2021. The most recent information was received on 15-Dec-2021 and was forwarded to Moderna on 15-Dec-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of FATIGUE (Fatigue), CHEST PAIN (Chest Pain), TACHYCARDIA (Tachycardia), DYSPNOEA (Dyspnoea),	18 years old male with unknown medical history who the 4 days after the 3rd dose experienced fatigue, chest pain, tachycardia, dyspnea, and was found to have elevated troponin, CRP, and abnormal EKG and Echo, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality

Case ID	WW Identifier	Narrative	MAH Comment
		HOSPITALISATION (Hospitalisation) and MYOCARDITIS (Myocarditis) in an 18-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) (batch no. 3004737) for COVID-19 vaccination. Previously administered products included for COVID-19 vaccination: SARS-COV-2 VIRUS and SARS-COV-2 VIRUS. Past adverse reactions to the above products included No adverse event with SARS-COV-2 VIRUS and SARS-COV-2 VIRUS. Concurrent medical conditions included Asthma (on inhalers.). Concomitant products included SALBUTAMOL for Asthma. On 27-Nov-2021, the patient received third dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 01-Dec-2021, the patient experienced FATIGUE (Fatigue) (seriousness criterion hospitalization), CHEST PAIN (Chest Pain) (seriousness criterion hospitalization), DYSPNOEA (Dyspnoea) (seriousness criterion hospitalization), HOSPITALISATION (Hospitalisation) (seriousness criterion hospitalization) and MYOCARDITIS (Myocarditis) (seriousness criterion hospitalization). On an unknown date, the patient experienced TACHYCARDIA (Tachycardia) (seriousness criterion hospitalization). On 08-Dec-2021, HOSPITALISATION (Hospitalisation) had resolved. At the time of the report, FATIGUE (Fatigue), CHEST PAIN (Chest Pain), TACHYCARDIA (Tachycardia) and DYSPNOEA (Dyspnoea) outcome was unknown and MYOCARDITIS (Myocarditis) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 01-Dec-2021, Blood creatine: 73 (abnormal) abnormal.	assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and EKG results; a causal relationship cannot be excluded.

Case ID	WW Identifier	Narrative	MAH Comment
		On 01-Dec-2021, Blood potassium: 4.6 (abnormal) abnormal. On 01-Dec-2021, Blood sodium: 136 (abnormal) abnormal. On 01-Dec-2021, Blood urea: 3.0 (abnormal) abnormal. On 01-Dec-2021, C-reactive protein: 17 (abnormal) abnormal. On 01-Dec-2021, Chest X-ray: normal (normal) Normal. On 01-Dec-2021, Echocardiogram: results not provided Results not provided. On 01-Dec-2021, Electrocardiogram: results not provided Results not provided. On 01-Dec-2021, Full blood count: hb 160, wc 10.3 (abnormal) Hb 160, WC 10.3. On 01-Dec-2021, SARS-CoV-2 test: negative (Negative) No - Negative COVID-19 test. On 01-Dec-2021, Troponin: 759 (abnormal) abnormal. On 03-Dec-2021, Troponin: 6023 (abnormal) abnormal. On 06-Dec-2021, C-reactive protein: 3 (abnormal) abnormal. On 07-Dec-2021, Magnetic resonance imaging heart: epicardial oedema (abnormal) Epicardial oedema. For mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Patient was admitted to hospital on the 1st of December with chest pain. Treated as myocarditis / peri-myocarditis likely secondary to covid vaccine. The patient was treated with prednisolone, colchicine, ibuprofen. On 1-DEC-2021, cardiac troponin was raised with peak troponin value of 759, and serial values of 672/759. ECG showed ST depression in V1-V2. Echocardiogram result was preserved left ventricular dysfunction. Patient has not tested positive for COVID-19 since having the vaccine. Patient is not enrolled in clinical trial.	

Case ID	WW Identifier	Narrative	MAH Comment
		Concomitant medication included INHALERS. Company comment: This regulatory authority case concerns an 18-year-old, male subject with a medical history of asthma and medication with inhalers, who experienced the serious expected event of Myopericarditis (AESI) and the serious unexpected events of fatigue, chest pain, tachycardia and hospitalization. The event occurred 4 days after the third dose of mRNA vaccine. 4 days after the vaccination, patient was admitted to hospital with chest pain and treated as myocarditis/peri-myocarditis likely secondary to mRNA-1273 vaccine. At the time of the report, event myocarditis was resolving while all the other events had unknown outcome. Rechallenge was not applicable as no additional dose is expected to be given. The patient's age and gender remain as confounders for the event myocarditis, while his medical history of asthma and medication with inhalers remain as confounders for events fatigue, chest pain, and tachycardia. The benefit-risk relationship of mRNA 1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 15-Dec-2021: Follow-up received included Events updated, Concomitant medication and Lab data updated.	
4.1(b)	4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b) on 08-Dec-2021 and was forwarded to Moderna on 14-Dec-2021. This case, initially reported to the 4.1(b)) by a physician, was received via the 4.1(b) (Ref, 4.1(b) On an unknown date, the patient received the 1st dose of this vaccine. On 07-Nov-2021, the patient received the 2nd dose of this vaccine. On 10-Nov-	28 years old male with unknown medical history who the 3 days after the 2nd dose experienced chest pain and was found to have elevated troponin, and CK-MB, and abnormal EKG, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible

Case ID	WW Identifier	Narrative	MAH Comment
		2021, at 14:12, the patient was aware of chest pain and visited a nearby hospital. Electrocardiogram showed a diffuse ST-segment elevation, and the patient was referred to the reporting hospital. Blood tests showed elevated troponin I, CK, and CK-MB, and the patient was hospitalized with a diagnosis of acute myocarditis. On an unknown date, monitor management and echo follow were performed, and symptoms tended to improve with analgesics. On 15-Nov-2021, the symptoms were resolving, and the patient was discharged from the hospital. The outcome of acute myocarditis was reported as resolving. Follow-up investigation will be made. Company Comment: The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and EKG results; a causal relationship cannot be excluded.
4.1(b)	4.1(b)	This case was initially received via 4.1(b) (Reference number: 4.1(b)) on 14-Dec-2021. The most recent information was received on 19-Dec-2021 and was forwarded to Moderna on 19-Dec-2021. This regulatory authority case was reported by a consumer and describes the occurrence of FATIGUE (Fatigue/unusual tiredness), CHEST PAIN (Chest pain), DYSPNOEA (Shortness of breath), PALPITATIONS (Heart palpitations), FLANK PAIN (side), PERIPHERAL SWELLING (hand), GASTRIC ULCER (Stomach ulcer) and PERICARDITIS (Pericarditis) in a 38-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) (batch no. 3004223) for an unknown indication. The patient's past medical history included 4.1(b) syndrome (Suffered with 4.1(b) Syndrome approx 8 weeks after first Moderna dose. Reported via 4.1(b) in 2021. Previously administered products included for Product used for	38 years old male with medical history of 4.1(b) syndrome who 71 days after the 2nd dose experienced fatigue, chest pain, dyspnea, palpitations, flank pain, peripheral swelling, and gastric ulcer and was found to have abnormal EKG, and was diagnosed with pericarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the EKG results; a causal relationship cannot be excluded.

Case ID	WW Identifier	Narrative	MAH Comment
		unknown indication: 152686.04.003 on 15-May-2021. Past adverse reactions to the above products included 4.1(b) syndrome with 152686.04.003. Concomitant products included ELASOMERAN (COVID-19 VACCINE MODERNA) for COVID-19 vaccination. On 21-Sep-2021, the patient received second dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 01-Dec-2021, after starting mRNA-1273 (Moderna CoviD-19 Vaccine), the patient experienced PERICARDITIS (Pericarditis) (seriousness criterion medically significant). On an unknown date, the patient experienced FATIGUE (Fatigue/unusual tiredness) (seriousness criterion medically significant), CHEST PAIN (Chest pain) (seriousness criterion medically significant), DYSPNOEA (Shortness of breath) (seriousness criterion medically significant), PALPITATIONS (Heart palpitations) (seriousness criterion medically significant), FLANK PAIN (side) (seriousness criterion medically significant), PERIPHERAL SWELLING (hand) (seriousness criterion medically significant) and GASTRIC ULCER (Stomach ulcer) (seriousness criterion medically significant). At the time of the report, FATIGUE (Fatigue/unusual tiredness), CHEST PAIN (Chest pain), DYSPNOEA (Shortness of breath), PALPITATIONS (Heart palpitations) and GASTRIC ULCER (Stomach ulcer) outcome was unknown, FLANK PAIN (side) and PERIPHERAL SWELLING (hand) was resolving and PERICARDITIS (Pericarditis) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):	

Case ID	WW Identifier	Narrative	MAH Comment
		On an unknown date, Electrocardiogram: result not reported No information. On an unknown date, X-ray: result not reported No information. Patient has not had symptoms associated with COVID-19 not had a COVID-19 test not tested positive for COVID-19 since vaccine. Patient had chest pain on left hand side, radiating across neck and behind collarbone and down left arm. Attended A&E - ECG and X Ray taken - acute pericarditis diagnosed. The symptoms did not lead to a hospital stay. Diagnosis was made by a medical professional. A&E Doctor - acute pericarditis. Treatment given for symptoms with following medication prescribed: 600mg Ibuprofen. One to be taken three times per day. Unspecified blood tests for certain proteins were done and Doctor advised all bloods were normal. Patient was received Moderna. 1st (3002332) was 15/05/21 and 2nd (3004223) was 21/09/21. He was reluctant to getting the booster as he was very unwell Company comment: This regulatory authority case concerns a 38-year-old male patient with relevant medical history of 4.1(b) syndrome after the first dose of mRNA-1273, who experienced serious unexpected events of fatigue, chest pain, shortness of breath, palpitations, flank pain, peripheral swelling and gastric ulcer and expected event of pericarditis. Additionally, time between the first and the second dose of mRNA-1273 was more than 35 days. The events occurred approximately 2 months and 10 days after the second dose of the mRNA-1273. Reportedly, the patient presented to the AE with chest pain on the left side that radiated across neck and behind the collarbone down to the left arm. ECG and X ray were performed and the patient was diagnosed with acute pericarditis. The patient was not hospitalized due	

Case ID	WW Identifier	Narrative	MAH Comment
		to the events and ibuprofen 600mg 3 times/day was prescribed as a corrective treatment for the event. The rechallenge was not applicable since the event/s occurred after the 2nd dose so, no rechallenge was done and recurrence was not applicable. The regulatory authority assessed the rechallenge as unknown. The benefit-risk relationship of mRNA-1273 is not affected by this report. Event seriousness assessed as per Regulatory Authority reporting. Most recent FOLLOW-UP information incorporated above includes: On 19-Dec-2021: significant follow up added includes Concomitant medication updated, Event added, I narrative updated	
4.1(b)	4.1(b)	This regulatory authority case was reported by a physician and describes the occurrence of DYSPNOEA (Intermittent dyspnoea), PYREXIA (Intermittent fever), MALAISE (Intermittent malaise), CHEST DISCOMFORT (Intermittent chest pressure sometimes located centrally), MYALGIA (Muscle pain) and MYOCARDITIS (Myocarditis) in a 28-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 immunisation. The patient's past medical history included Substance user (Previous monthly user of 4.1(b) but nothing since summer 2021) in 2021. Previously administered products included for COVID-19 immunisation: SPIKEVAX in 2021. Past adverse reactions to the above products included No adverse event with SPIKEVAX. Concurrent medical conditions included Cigarette smoker (Smokes 5 cigarettes per week). On 15-Nov-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 16-Nov-2021, the patient experienced PYREXIA (Intermittent	28-year-old male with medical history of substance Abuse 4.1(b) who next day after the 2nd dose of Spikevax experienced Dyspnoea, Pyrexia, Malaise, Chest discomfort, Myalgia and was found to have elevated troponin, CRP, and normal Echo, with ECG abnormal and investigation (not specify) showing myopericarditis without pericardial effusion. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and EKG results; a causal relationship cannot be excluded.

Case ID	WW Identifier	Narrative	MAH Comment
		fever) (seriousness criterion hospitalization), MYALGIA (Muscle pain) (seriousness criterion hospitalization) and MYOCARDITIS (Myocarditis) (seriousness criterion hospitalization). On 17-Nov-2021, the patient experienced DYSPNOEA (Intermittent dyspnoea) (seriousness criterion hospitalization) and CHEST DISCOMFORT (Intermittent chest pressure sometimes located centrally) (seriousness criterion hospitalization). On 18-Nov-2021, the patient experienced MALAISE (Intermittent malaise) (seriousness criterion hospitalization). At the time of the report, DYSPNOEA (Intermittent dyspnoea), PYREXIA (Intermittent fever), MALAISE (Intermittent malaise), CHEST DISCOMFORT (Intermittent chest pressure sometimes located centrally), MYALGIA (Muscle pain) and MYOCARDITIS (Myocarditis) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In November 2021, Cardiac telemetry: no arrhythmias No arrhythmias. In November 2021, Echocardiogram: nothing abnormal, no pericardial accumulation Nothing abnormal, no pericardial accumulation. In November 2021, Electrocardiogram: sinus rhythm, normal conduction Sinus rhythm, normal conduction, flattening of t-waves in v4 to v6 Flattening of T-waves in V4 to V6, normalised, nothing abnormal (At cardiology unit) Normalised, nothing abnormal, borderline significant q-waves in v4 to v6 Borderline significant q-waves in V4 to V6 and narrow complexes Narrow complexes. On 20-Nov-2021, C-reactive protein: 68 (At hospitalisation) 68 Unit not specified. On 20-Nov-2021, Troponin T: 139 (At hospitalisation) 139 Unit not specified.	

Case ID	WW Identifier	Narrative	MAH Comment
		On 21-Nov-2021, C-reactive protein: 31 (At discharge) 31 Unit not specified. On 21-Nov-2021, Investigation: perimyocarditis without pericardial effusion (abnormal) Perimyocarditis without pericardial effusion and slight enzyme emission Slight enzyme emission. On 21-Nov-2021, Physical examination: feeling well and without pain Feeling well and without pain. On 21-Nov-2021, Troponin T: 83 (At discharge) 83 Unit not specified. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medication were reported. No treatment medication were reported. This is a regulatory authority case concerning a 28-year-old, male patient with past medical history of substance Abuse (4.1(b)) who experienced the unexpected serious events of Dyspnoea, Pyrexia, Malaise, Chest discomfort, Myalgia and expected serious event of myocarditis. The events occurred approximately 1 day after the second dose of mRNA-1273 COVID 19 Vaccine. The events were reported as resolving. The rechallenge was unknown since no information about the first dose was disclosed. The medical history, of substance Abuse (4.1(b)) remains a confounder. The benefit-risk relationship of mRNA-1273 COVID 19 Vaccine, is not affected by this report.	
4.1(b)	4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b)) on 13-Dec-2021 and was forwarded to Moderna on 17-Dec-2021. This case, initially reported to the 4.1(b) by a physician, was received via the	35 years old female with unknown medical history who 3 days after the 2nd dose experienced not described events and was found to have abnormal Echo, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted,

Case ID	WW Identifier	Narrative	MAH Comment
		4.1(b) (Ref, 4.1(b)) Myocarditis was assessed as serious by the MAH. On 07-Sep-2021, at 11:00, the patient received the 1st dose of this vaccine. On 05-Oct-2021, at 11:00, the patient received the 2nd dose of this vaccine. On an unknown date, the patient experienced physical deconditioning. On 08-Oct-2021, myocarditis developed. The patient made the initial visit to the reporting hospital. Echocardiography was performed to show decreased left ventricular ejection fraction (EF) of 67.3%. On 25-Nov-2021, the patient revisited the hospital. Echocardiography was performed to show a recovery of EF of 80.2%. The symptoms were resolving. The outcome of myocarditis was reported as resolving. Follow-up investigation will be made. Company Comment: The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the Echo results; a causal relationship cannot be excluded.
4.1(b)	4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b)) on 14-Dec-2021 and was forwarded to Moderna on 17-Dec-2021. This case, initially reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref, 4.1(b)) On 17-Oct-2021, the patient received the 1st dose of the vaccine. On 14-Nov-2021, around noon, the patient received the 2nd dose of the vaccine. On 15-Nov-2021, at 08:00, the patient experienced chest pain with pyrexia, chest tightness, and dyspnea. Thereafter, the symptoms were relieved temporarily. Around 23:00, symptoms were aggravated. On 16-Nov-2021, at 03:00, the patient visited an emergency outpatient department.	16 years old male with unknown medical history who the next day after the 2nd dose experienced pyrexia, chest pain, chest tightness, and dyspnea and was found to have elevated troponin, and CK-MB, and abnormal EKG, myocardial biopsy showed no important findings and cMRIS showed acute myocarditis. Myocarditis was considered mild. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and other diagnostic results; a causal relationship cannot be excluded.

Case ID	WW Identifier	Narrative	MAH Comment
		Electrocardiogram showed ST elevations in chest leads with increased CPK, and the patient was referred to and admitted to the reporting hospital with suspected acute myocarditis. The emergency coronary angiography revealed no significant stenosis, and myocardial biopsy showed no appreciable findings. Cardiac MRI showed a finding of oedema in the left ventricular lateral wall which was suggestive of acute myocarditis. On an unknown date, the symptoms improved spontaneously with a follow up. Left ventricular asynergy, which was found by echocardiography, was relieved spontaneously. As CPK increased only to 700 U/L, the myocarditis was considered to be mild. On 25-Nov-2021, the patient was doing well. The symptoms resolved, and the patient was discharged from the hospital. The outcome of chest pain and suspected acute myocarditis was reported as resolved. Follow-up investigation will be made. Company Comment: The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. LP company comment: The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship Company comment: This case concerns a 16-year-old male patient with no relevant medical history, who experienced the serious expected event of Myocarditis (AESI), as well as serious unexpected event of Chest pain. AS per case description, one day after the administration of the second dose, the patient developed chest pain with pyrexia, chest tightness and dyspnea. Thereafter, the symptoms were relieved temporarily. However, in the evening, symptoms were aggravated and the patient visited an emergency outpatient department. ECG showed	

Case ID	WW Identifier	Narrative	MAH Comment
		ST elevations,CPK was increased, and the patient was admitted to the hospital with suspected acute myocarditis. The emergency coronary angiography revealed no significant stenosis, and myocardial biopsy showed no appreciable findings. Left ventricular asynergy was found by echocardiography. Cardiac MRI showed a finding of oedema in the left ventricular lateral wall which was suggestive of acute myocarditis. At the time of the report, the events had resolved and the patient was discharged from the hospital. The re-challenge is not applicable in line with source document, as it was stated that no rechallenge was done and recurrence is not applicable. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report.	
4.1(b)	4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b)) on 16-Dec-2021 and was forwarded to Moderna on 20-Dec-2021. This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Acute myocarditis) in an 18-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna Intramuscular Injection) for COVID-19 vaccination. No Medical History information was reported. On 30-Oct-2021, the patient received second dose of mRNA-1273 (COVID-19 Vaccine Moderna Intramuscular Injection) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna Intramuscular Injection) (Intramuscular) 1 dosage form. On 01-Nov-2021, after starting mRNA-1273 (COVID-19 Vaccine Moderna Intramuscular Injection), the patient experienced MYOCARDITIS (Acute myocarditis) (seriousness criteria hospitalization and medically	18 years old male with unknown medical history who the 2 days after the 2nd dose was found to have abnormal EKG and Echo suggestive of myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the EKG and echo results; a causal relationship cannot be excluded.

Case ID	WW Identifier	Narrative	MAH Comment
		significant). At the time of the report, MYOCARDITIS (Acute myocarditis) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 31-Oct-2021, Blood test: normal (normal) No abnormalities. On 31-Oct-2021, Electrocardiogram: normal (normal) No abnormalities. On 01-Nov-2021, Blood test: abnormal (abnormal) Diagnosed with acute myocarditis. On 01-Nov-2021, Echocardiogram: abnormal (abnormal) Diagnosed with acute myocarditis. On 01-Nov-2021, Electrocardiogram: abnormal (abnormal) Diagnosed with acute myocarditis. On an unknown date, Body temperature: 36.6 (normal) 36.6 degree Celsius. For mRNA-1273 (COVID-19 Vaccine Moderna Intramuscular Injection) (Intramuscular), the reporter considered MYOCARDITIS (Acute myocarditis) to be possibly related. Company comment: This case concerns an 18-year-old male patient, with no medical history reported in this case, who experienced the serious expected AESI of Myocarditis. The event occurred approximately 3 days after the administration of the second dose of the mRNA-1273 vaccine and the outcome was reported as Recovering/Resolving. The event was assessed with the seriousness criteria of Hospitalization and Medically Significant by the reporter. It was reported that, as diagnostic tests, a blood test, an electrocardiogram and an echocardiogram were performed. No further information on performed treatment was disclosed. The rechallenge is not applicable since the event occurred after the second dose of the of the mRNA-1273 vaccine. The benefit-risk relationship	

Case ID	WW Identifier	Narrative	MAH Comment
4.1(b)	4.1(b)	of mRNA-1273 vaccine is not affected by this report. This case was received via 4.1(b) (Reference number: 4.1(b)) on 17-Dec-2021 and was forwarded to Moderna on 17-Dec-2021. This regulatory authority case was reported by a physician and describes the occurrence of the first episode of CHEST PAIN (Chest pain), DYSPNOEA (Breath shortness), the second episode of CHEST PAIN (Chest pain), FATIGUE (Fatigue), CHEST PAIN (Chest Pain), DYSPNOEA (Dyspnoea), TACHYCARDIA (Tachycardia), PAIN (Generalised aching), DYSPNOEA (Shortness of breath), PERICARDIAL EFFUSION (Pericardial effusion), MYOCARDITIS (Myocarditis) and PERICARDITIS (Pericarditis) in a 39-year-old female patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for COVID-19 vaccination. Co-suspect product included non-company product COLCHICINE for an unknown indication. Concomitant products included COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (COVID-19 VACCINE ASTRAZENECA) from 04-Mar-2021 to an unknown date for COVID-19 vaccination. On 08-Dec-2021, the patient received third dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On an unknown date, the patient started COLCHICINE (unknown route) at an unspecified dose. On 08-Dec-2021, the patient experienced the first episode of CHEST PAIN (Chest pain) (seriousness criteria hospitalization, disability, medically significant and life threatening). On 09-Dec-2021, the patient experienced DYSPNOEA (Breath shortness) (seriousness criteria hospitalization, disability, medically significant and life threatening), the second episode of CHEST PAIN (Chest pain)	39 years old female with unknown medical history and the Astrazeneca vaccine as the primary series for Covid-19 vaccination, who the next day after the 3rd dose experienced chest pain, dyspnea, fatigue, tachycardia, generalized pain, and was found to have elevated troponin, CRP, and abnormal EKG, and echo with pericardial effusion and was diagnosed with myopericarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and EKG and echo results; a causal relationship cannot be excluded.

Case ID	WW Identifier	Narrative	MAH Comment
		(seriousness criteria hospitalization, disability, medically significant and life threatening), MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization, disability, medically significant and life threatening) and PERICARDITIS (Pericarditis) (seriousness criteria hospitalization, disability, medically significant and life threatening). On an unknown date, the patient experienced FATIGUE (Fatigue) (seriousness criteria hospitalization, disability, medically significant and life threatening), CHEST PAIN (Chest Pain) (seriousness criteria hospitalization, disability, medically significant and life threatening), DYSPNOEA (Dyspnoea) (seriousness criteria hospitalization, disability, medically significant and life threatening), TACHYCARDIA (Tachycardia) (seriousness criteria hospitalization, disability, medically significant and life threatening), PAIN (Generalised aching) (seriousness criteria hospitalization, disability, medically significant and life threatening), DYSPNOEA (Shortness of breath) (seriousness criteria hospitalization, disability, medically significant and life threatening) and PERICARDIAL EFFUSION (Pericardial effusion) (seriousness criteria hospitalization, disability, medically significant and life threatening). At the time of the report, DYSPNOEA (Breath shortness), the last episode of CHEST PAIN (Chest pain), MYOCARDITIS (Myocarditis) and PERICARDITIS (Pericarditis) had not resolved, FATIGUE (Fatigue), CHEST PAIN (Chest Pain), DYSPNOEA (Dyspnoea), TACHYCARDIA (Tachycardia) and PAIN (Generalised aching) outcome was unknown and DYSPNOEA (Shortness of breath) and PERICARDIAL EFFUSION (Pericardial effusion) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):	

Case ID	WW Identifier	Narrative	MAH Comment
		On 13-Dec-2021, Chest X-ray: abnormal (abnormal) Slightly enlarged heart. On 13-Dec-2021, Computerised tomogram thorax: abnormal (abnormal) Small pericardial effusion. On 13-Dec-2021, SARS-CoV-2 test: negative (Negative) No - Negative COVID-19 test. On 13-Dec-2021, Troponin: elevated (High) Elevated. On 14-Dec-2021, Echocardiogram: abnormal (abnormal) Pericardial effusion. On an unknown date, Blood test: result not provided (Inconclusive) Result not provided. On an unknown date, C-reactive protein: 345 345. On an unknown date, Ejection fraction: 40 40%. For mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. No medical history was provided by the reporter. It was reported that patient took the vaccine and 5 hours later she felt mild chest pain. On next day that chest pain became much more intense and severe, associated with shortness of breath, aching and tearing. Work up showed high inflammatory markers with raised C-reactive protein (CRP) 345, elevated Troponin, echocardiogram (ECHO) showed pericardial effusion, ejection fraction (EF) of 40%. She took treatment for myo-pericarditis. Patient not tested positive for COVID-19 since she had the vaccine and not had symptoms associated with COVID-19. It was reported that the event was relate to possible myocarditis or pericarditis	

Case ID	WW Identifier	Narrative	MAH Comment
		Patient did few tests like ECHO, Troponin, Basic blood test. Patient had Myocarditis and pericarditis. Patient was admitted to the hospital since 13-Dec-2021 and not discharged at the time of report. She consulted one cardiologist and diagnosed with Myo-pericarditis. Colchicine, ACE-I, B. Blocker was given as treatment drugs. Troponin, chest x-ray was checked on 13-Dec-2021. Troponin was raised and the chest x-ray result was slightly enlarged heart. On 14 Dec 2021 echocardiogram done and the results were overall impression of impaired left ventricle (LV) systolic function. Visually estimated left ventricle ejection fraction (LVEF) 40-45%. Regional wall abnormalities present. Small collection of pericardial fluid seen, measuring maximum in diastole 0.6cm. On 13-Dec-2021 chest computed tomography was carried out and the results were scan negative for pulmonary embolism (PE). Small pericardial effusion with some mediastinal fat stranding. The findings were non-specific and in the context of very raised CRP and mildly raised troponin include pericarditis or myocarditis. Most recent FOLLOW-UP information incorporated above includes: On 19-Dec-2021: Follow up document received contains, events and lab investigation were added, action taken was updated.	
4.1(b)	4.1(b)	This literature-non-study case was reported in a literature article and describes the occurrence of MYOCARDITIS (Acute myocarditis) in a 20-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. LITERATURE REFERENCE: Abellan C, Vivekanantham H, Mahmoudi A, Cook S, Doll S, Arroyo D. A case series of acute myocarditis	Literature report on a 20-yearold male who presented with on-going chest pain for the preceding 6 hours. The patient had no significant medical history and was a regular 4.1(b) consumer. Three days earlier, he received the second dose of the Moderna vaccine against SARS-CoV-2. The next day, he suffered from fever, chills, nausea and vomiting. The patient was afebrile, stable and in mild distress, with physical examination being unremarkable. Coronary angiography

Case ID	WW Identifier	Narrative	MAH Comment
		associated with SARS-CoV-2 mRNA vaccination. Cardiovasc Med. 2021;24:w10103 Concurrent medical conditions included 4.1(b) use (regular 4.1(b) consumer). On an unknown date, the patient received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (unknown route) 1 dosage form. On an unknown date, the patient experienced MYOCARDITIS (Acute myocarditis) (seriousness criteria hospitalization and medically significant). an unknown date, the patient experienced CHILLS (Chills), NAUSEA (Nausea) and VOMITING (Vomiting). The patient was hospitalized for 3 days due to MYOCARDITIS. The patient was treated with LISINAPRIL ongoing since an unknown date for Adverse event, at a dose of 10 milligram. At the time of the report, MYOCARDITIS (Acute myocarditis), CHILLS (Chills), NAUSEA (Nausea) and VOMITING (Vomiting) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Angiogram: normal (normal) Coronary angiography revealed normal coronary arteries. On an unknown date, Blood creatine phosphokinase: 529 u/l 529 U/l and 786 u/l (High) 786 U/l (on day 2). On an unknown date, C-reactive protein: 28 mg/l 28 mg/l. On an unknown date, Ejection fraction: 55 percent 55 percent with apical hypokinesia. On an unknown date, Electrocardiogram: abnormal (abnormal) Initial 12-lead ECG showing sinus rhythm at 66 bpm with an incomplete right bundle branch block pattern and significant ST-segment elevation in leads II, III, aVF and from V4 to V6. ST segment	revealed normal coronary arteries Relevant laboratory findings were: high-sensitive cardiac troponin T elevated, CK elevated, NTproBNP elevated, CRP elevated, PCR was negative for SARS-CoV-2. Echo and ECG abnormal. On day 3, cardiac magnetic resonance imaging (CMR) showed two areas of marked subepicardial late gadolinium enhancement (LGE), in basal to mid, and apical lateral walls, with signs of inflammation/oedema on dedicated sequences (short-tau inversion recovery [STIR]), and minimal pericardial effusion. Patient was discharged on day 4 on lisinopril 10 mg once daily (OD). According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the well document information provided by the authors; a causal relationship cannot be excluded.

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

Case ID	WW Identifier	Narrative	MAH Comment
		developed fever, chills, nausea and vomiting. The patient was hospitalized for 4 days, received treatment with Angiotensin-converting-enzyme inhibitors and was discharged on lisinopril. The outcome of the events was recovered. The rechallenge was not applicable, as the events were reported exclusively after the second dose and no information on additional dosing is available. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. This case was linked to 4.1(b) (Patient Link).	
4.1(b)	4.1(b)	This literature-non-study case was reported in a literature article and describes the occurrence of MYOCARDITIS (Acute myocarditis) in a 21-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. LITERATURE REFERENCE: Abellan C, Vivekanantham H, Mahmoudi A, Cook S, Doll S, Arroyo D. A case series of acute myocarditis associated with SARS-CoV-2 mRNA vaccination. Cardiovasc Med. 2021;24:w10103 No Medical History information was reported. On an unknown date, the patient received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (unknown route) 1 dosage form. On an unknown date, after starting mRNA-1273 (COVID-19 Vaccine Moderna), the patient experienced MYOCARDITIS (Acute myocarditis) (seriousness criteria hospitalization and medically significant) and INFLUENZA LIKE ILLNESS (flu-like symptoms). The patient was hospitalized for 2 days due to MYOCARDITIS. The patient was	Literature report for a 21-year-old healthy male presented with acute onset chest pain. Two days earlier, he had received the second of Spikevax and he developed flu-like symptoms and fever. The patient was afebrile and in no distress. Physical examination. was unremarkable. He was found to have elevated troponin, CK, NT-proBNP, negative RT-PCR for SARSCoV-2. CMR performed on the same day showed lateral wall subepicardial LGE. The patient was discharged on day 3 on lisinopril 5 mg OD. Patient was asymptomatic and doing well at 1-month clinical assessment. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the well document information provided by the authors; a causal relationship cannot be excluded.

Case ID	WW Identifier	Narrative	MAH Comment
		treated with LISINOPRIL ongoing since an unknown date for Adverse event, at a dose of 5 milligram once a day. At the time of the report, MYOCARDITIS (Acute myocarditis) and INFLUENZA LIKE ILLNESS (flu-like symptoms) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Blood creatine phosphokinase: 516 u/l 516 U/l and 652 u/l 652 U/l. On an unknown date, C-reactive protein: 94 mg/l 94 mg/l. On an unknown date, Culture throat: negative RT-PCR was negative for SARS-CoV-2. On an unknown date, Echocardiogram: normal normal LVEF. On an unknown date, Electrocardiogram: 91 bpm Initial 12-lead ECG showing a sinus rhythm at 91 bpm with diffuse concave ST-segment elevation, and PR segment depression.. On an unknown date, Magnetic resonance imaging: abnormal (abnormal) showed lateral wall subepicardial LGE. On an unknown date, N-terminal prohormone brain natriuretic peptide: 178 ng/l 178 ng/l. On an unknown date, SARS-CoV-2 test: negative (Negative) Negative. On an unknown date, Troponin T: 523 ng/l High-Sensitivity Cardiac Troponin T - 523 ng/l and 552 ng/l 552 ng/l. For mRNA-1273 (COVID-19 Vaccine Moderna) (Unknown), the reporter considered MYOCARDITIS (Acute myocarditis) and INFLUENZA LIKE ILLNESS (flu-like symptoms) to be related. The patient was afebrile and in no distress. Physical examination was unremarkable. The patient had chest pain and pyrexia.	

Case ID	WW Identifier	Narrative	MAH Comment
		The patient was admitted and started on an ACEi. CMR performed on the same day showed lateral wall subepicardial LGE No concomitant medications were not reported. Company comment: This literature report from 4.1(b) reported by other HCP concerns a 21 year-old, male patient with no reported medical history, who experienced the serious (due to hospitalization) expected, – according to 4.1(b) SmPC AESI of myocarditis and the non serious unexpected, – according to 4.1(b) SmPC event of Influenza like illness. The events occurred after the second dose of mRNA-1273 vaccine, exact dates not provided. The patient presented with chest pain two days after vaccination and developed Influenza like illness and pyrexia. The patient was hospitalized for 3 days, received treatment with Angiotensin-converting-enzyme inhibitors and was discharged on lisinopril. The outcome of the events was recovered. The rechallenge was not applicable, as the events were reported exclusively after the second dose and no information on additional dosing is available. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. This case was linked to 4.1(b) (Patient Link).	
4.1(b)	4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b) on 21-Dec-2021 and was forwarded to Moderna on 21-Dec-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of C-REACTIVE PROTEIN INCREASED (C-reactive protein increased), CHEST PAIN (Chest pain), MYOCARDITIS (Myocarditis) and TROPONIN (Troponin) in a 25-year-old male	25 years old male with unknown medical history who the next day after the third dose experienced chest pain and was found to have elevated troponin, and CRP, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal

Case ID	WW Identifier	Narrative	MAH Comment
		patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 045321A) for an unknown indication. No Medical History information was reported. On 03-Dec-2021, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 04-Dec-2021, the patient experienced C-REACTIVE PROTEIN INCREASED (C-reactive protein increased) (seriousness criterion hospitalization), CHEST PAIN (Chest pain) (seriousness criterion hospitalization), MYOCARDITIS (Myocarditis) (seriousness criterion hospitalization) and TROPONIN (Troponin) (seriousness criterion hospitalization). At the time of the report, C-REACTIVE PROTEIN INCREASED (C-reactive protein increased), CHEST PAIN (Chest pain), MYOCARDITIS (Myocarditis) and TROPONIN (Troponin) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, C-reactive protein: elevated (High) Elevated C-reactive protein. On an unknown date, Troponin: 12 (High) 12. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Symptom Text: Myocarditis Troponin = 12 Required hospital admission Sxs = severe, worsening chest pain beginning approximately 24hrs following booster dose. Company Comment: This case concerns a 25-year-old male subject, with no medical history reported, who experienced the unexpected and serious events of C-Reactive protein increased, Chest pain, and Troponin,	association between the use of the product and the start of the events, as well as the elevated troponin and EKG results; a causal relationship cannot be excluded.

Case ID	WW Identifier	Narrative	MAH Comment
		and the serious, expected, and AESI event of Myocarditis. The events occurred 1 day after the third dose of mRNA-1273 vaccine. The rechallenge is not applicable, as no additional dosing will be given. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.	
4.1(b)	4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b) on 21-Dec-2021 and was forwarded to Moderna on 21-Dec-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of C-REACTIVE PROTEIN INCREASED (C-reactive protein increased), CHEST X-RAY NORMAL (Chest X-ray normal), CHEST PAIN (Chest pain), COMPUTERISED TOMOGRAM THORAX NORMAL (Computerised tomogram thorax normal), ECHOCARDIOGRAM ABNORMAL (Echocardiogram abnormal), EFFUSION (Effusion), ELECTROCARDIOGRAM ABNORMAL (Electrocardiogram abnormal), FATIGUE (Fatigue), FIBRIN D DIMER INCREASED (Fibrin D dimer increased), MAGNETIC RESONANCE IMAGING ABNORMAL (Magnetic resonance imaging abnormal), MYOCARDITIS (Myocarditis), NAUSEA (Nausea), TACHYCARDIA (Tachycardia) and TROPONIN INCREASED (Troponin increased) in a 23-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for an unknown indication. Concurrent medical conditions included Schizophrenia. On 27-Nov-2021, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 01-Dec-2021, the patient experienced C-REACTIVE PROTEIN INCREASED (C-reactive protein increased) (seriousness	23 years old male with unknown medical history who 4 days after the 3rd dose experienced chest pain, nausea, tachycardia, and was found to have elevated troponin, fibrin d-dimer, CRP, abnormal ECG, cMRI, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the well documented diagnostic test results; a causal relationship cannot be excluded.

Case ID	WW Identifier	Narrative	MAH Comment
		criterion hospitalization), CHEST PAIN (Chest pain) (seriousness criterion hospitalization), ECHOCARDIOGRAM ABNORMAL (Echocardiogram abnormal) (seriousness criterion hospitalization), EFFUSION (Effusion) (seriousness criterion hospitalization), ELECTROCARDIOGRAM ABNORMAL (Electrocardiogram abnormal) (seriousness criterion hospitalization), FATIGUE (Fatigue) (seriousness criterion hospitalization), FIBRIN D DIMER INCREASED (Fibrin D dimer increased) (seriousness criterion hospitalization), MAGNETIC RESONANCE IMAGING ABNORMAL (Magnetic resonance imaging abnormal) (seriousness criterion hospitalization), MYOCARDITIS (Myocarditis) (seriousness criterion hospitalization), NAUSEA (Nausea) (seriousness criterion hospitalization), TACHYCARDIA (Tachycardia) (seriousness criterion hospitalization) and TROPONIN INCREASED (Troponin increased) (seriousness criterion hospitalization). 01-Dec-2021, the patient experienced CHEST X-RAY NORMAL (Chest X-ray normal) (seriousness criterion hospitalization) and COMPUTERISED TOMOGRAM THORAX NORMAL (Computerised tomogram thorax normal) (seriousness criterion hospitalization). At the time of the report, C-REACTIVE PROTEIN INCREASED (C-reactive protein increased), CHEST X-RAY NORMAL (Chest X-ray normal), CHEST PAIN (Chest pain), COMPUTERISED TOMOGRAM THORAX NORMAL (Computerised tomogram thorax normal), ECHOCARDIOGRAM ABNORMAL (Echocardiogram abnormal), EFFUSION (Effusion), ELECTROCARDIOGRAM ABNORMAL (Electrocardiogram abnormal), FATIGUE (Fatigue), FIBRIN D DIMER INCREASED (Fibrin D dimer increased), MAGNETIC RESONANCE IMAGING ABNORMAL (Magnetic resonance	

Case ID	WW Identifier	Narrative	MAH Comment
		imaging abnormal), MYOCARDITIS (Myocarditis), NAUSEA (Nausea), TACHYCARDIA (Tachycardia) and TROPONIN INCREASED (Troponin increased) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 01-Dec-2021, C-reactive protein: high (High) high. On 01-Dec-2021, Chest X-ray: normal (normal) normal. On 01-Dec-2021, Computerised tomogram: normal (normal) no pulmonary embolism. On 01-Dec-2021, Echocardiogram: abnormal (abnormal) myocarditis. On 01-Dec-2021, Electrocardiogram: abnormal (abnormal) abnormal. On 01-Dec-2021, Fibrin D dimer: elevated (High) elevated. On 01-Dec-2021, Magnetic resonance imaging: abnormal (abnormal) myocarditis. On 01-Dec-2021, Tachycardia: 120 (High) 120bp. On 01-Dec-2021, Troponin: 7.9 (High) Blood drawn troponin 7.9. On 01-Dec-2021, Ultrasound scan: abnormal (abnormal) mild effusion. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No treatment medications were provided Other Medication provided 300 mg, clozapine 20 mg, Lexapro 200 mg, Minocycline 750 mg, metformin 1000 mg, omega 3 Patient experienced myocarditis 4 days after vaccination Patient was experienced Exhaustion patient went to ER and admitted in hospital on 01 Dec 2021 to 02 Dec 2021 Company Comment: This case concerns a 23-year-old male subject, with no relevant medical history, who experienced the unexpected and	

Case ID	WW Identifier	Narrative	MAH Comment
		serious events of Troponin increased, Effusion, Tachycardia, Chest pain, among others, and the expected, serious, and AESI event of Myocarditis. Patient was hospitalized 2 days, and myocarditis was confirmed by imaging studies. The events occurred 4 days after the third dose of mRNA-1273 vaccine. The rechallenge is not applicable, as no additional dosing will be given. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.	
4.1(b)	4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b) on 21-Dec-2021 and was forwarded to Moderna on 21-Dec-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCARDITIS (Myocarditis), ELECTROCARDIOGRAM ST SEGMENT ELEVATION (Electrocardiogram ST segment elevation), C-REACTIVE PROTEIN INCREASED (C-reactive protein increased), ECHOCARDIOGRAM NORMAL (Echocardiogram normal) and TROPONIN INCREASED (Troponin increased) in a 24-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 065F21A) for an unknown indication. Concurrent medical conditions included 4.1(b), Scoliosis, Anxiety and Depression. On 19-Nov-2021, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 22-Nov-2021, the patient experienced MYOCARDITIS (Myocarditis), ELECTROCARDIOGRAM ST SEGMENT ELEVATION (Electrocardiogram ST segment elevation), C-REACTIVE PROTEIN INCREASED (C-reactive protein increased), ECHOCARDIOGRAM	24-year-old male patient with no relevant medical history who 3 days after the 3rd dose of Spikevax was found to have CRP elevated, Troponin elevated, EKG - with mild ST segment elevation, Echo showed normal LV size and systolic function, no pericardial effusion. The event was managed as outpatient with colchicine and ibuprofen. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and EKG results; a causal relationship cannot be excluded.

Case ID	WW Identifier	Narrative	MAH Comment
		NORMAL (Echocardiogram normal) and TROPONIN INCREASED (Troponin increased). At the time of the report, MYOCARDITIS (Myocarditis), ELECTROCARDIOGRAM ST SEGMENT ELEVATION (Electrocardiogram ST segment elevation), C-REACTIVE PROTEIN INCREASED (C-reactive protein increased), ECHOCARDIOGRAM NORMAL (Echocardiogram normal) and TROPONIN INCREASED (Troponin increased) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 22-Nov-2021, C-reactive protein: 5.0 (High) C Reactive protein - 5.0mg/dL (elevated). On 22-Nov-2021, Electrocardiogram ST segment: elevation (High) EKG - with mild ST segment elevation. On 22-Nov-2021, Troponin: 0.53 (High) Troponin serum - elevated (0.53ng/mL) with no increase over time and 0.46 (High) 0.46ng/mL - 3 hour repeat. On 29-Nov-2021, Echocardiogram: normal (normal) normal LV size and systolic function, no pericardial effusion. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Other medications include Duloxetine, Trazadone, hydroxyzine. Patient experienced myopericarditis (mild) managed as outpatient with colchicine, ibuprofen. Patient ongoing symptoms with slight improvement at follow up doctor's visit on 02-DEC-2021. Company comment: This is a regulatory authority case concerning a 24-year-old male patient with no relevant medical history who experienced expected event of	

Case ID	WW Identifier	Narrative	MAH Comment
		myocarditis (AESI). The event occurred 3 days after the third dose of mRNA-1273 vaccine. Diagnostic test results performed on 22-Nov-2021 showed C Reactive protein - 5.0mg/dL (elevated), Troponin serum - elevated (0.53ng/mL) with no increase over time (0.46ng/mL - 3 hour repeat) and EKG - with mild ST segment elevation. On 29-Nov-2021 Echocardiogram showed normal LV size and systolic function, no pericardial effusion. The event was managed as outpatient with colchicine and ibuprofen. It was reported a slight improvement of the symptoms at follow up doctor's visit on 02-DEC-2021. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.	
4.1(b)	4.1(b)	This literature-non-study case was reported in a literature article and describes the occurrence of MYOCARDITIS (recurrent myopericarditis) in a 20-year-old male patient who received mRNA-1273 (COVID 19 Vaccine Moderna) for COVID-19 vaccination. LITERATURE REFERENCE: Umei TC, Kishino. Recurrence of myopericarditis following mRNA COVID-19 vaccination in a male adolescent. CJC Open. 2021 The patient's past medical history included Myopericarditis (initial episode of influenza virus-induced myopericarditis.) in 2016. On an unknown date, the patient received second dose of mRNA-1273 (COVID 19 Vaccine Moderna) (unknown route) 1 dosage form. On an unknown date, the patient experienced MYOCARDITIS (recurrent myopericarditis) (seriousness criterion medically significant). At the time of the report, MYOCARDITIS (recurrent myopericarditis) outcome was unknown.	Literature report for a 20-year-old male adolescent with history of seasonal influenza virus-induced myopericarditis in 2016 who 2 days after the 2nd dose of Spikevax had fever and severe sharp chest pain in deep breathing improved by sitting up. The patient had been well and free from any flu-like illnesses a couple of months before admission. ECG showed global ST-T wave elevation. Echo showed regional hypokinesis of the anteroseptal wall, an ejection fraction 1 of 53.8%, and no pericardial effusion. cMRI showed suggestive findings for acute myocarditis. CK and troponin were elevated. SARS-CoV and Influenza test were negative as well as any other virus test conducted. His symptoms gradually resolved, and he was discharged on day 5. He remained stable and his left ventricular function improved one month after discharge. According to the WHO causality assessment this report is probable based on temporal association between the use of the product and the start of the events, as well as the well document information presented in this article; a causal relationship cannot be excluded. His previous medical history of myocarditis remains a confounder.

Case ID	WW Identifier	Narrative	MAH Comment
		For mRNA-1273 (COVID 19 Vaccine Moderna) (Unknown), the reporter considered MYOCARDITIS (recurrent myopericarditis) to be related. No relevant concomitant medications were reported. No treatment information was provided. Comapny comment: This is a literature case concerning a 20 year-old, male patient with a history of myocarditis (induced by influenza virus), who experienced the serious (due to medically important condition) expected, according CCDS, AESI of myocarditis. The event occurred on an unknown date after the second dose of the mRNA-1273 vaccine, date not provided. The rechallenge was not applicable, as the event was reported exclusively after the second dose and no information on additional dosing is available. The medical history, of myocarditis (induced by influenza virus) remains a confounder. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 20-Dec-2021 and was forwarded to Moderna on 20-Dec-2021. This regulatory authority case was reported by a physician and describes the occurrence of CHEST PAIN (Chest pain without radiation), MALAISE (Not feeling well and a sensation of something sharp), FEELING COLD (Had a feeling of very cold) and MYOCARDITIS (Myocarditis) in a 33-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3004954) for COVID-19 vaccination. Previously administered products included for COVID-19 immunisation: SPIKEVAX on 04-Sep-2021. Past adverse reactions to the above products included No adverse event with SPIKEVAX.	33-year-old male patient with unknown medical history, who the next day after his 2nd dose of Spikevac experienced chest pain, malaise and feeling cold and was found to have elevated troponin and normal ECG and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events. A causal relationship cannot be excluded due to the lack of information.

Case ID	WW Identifier	Narrative	MAH Comment
		On 02-Oct-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 03-Oct-2021, after starting mRNA-1273 (Spikevax), the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). In October 2021, the patient experienced CHEST PAIN (Chest pain without radiation) (seriousness criterion hospitalization), MALAISE (Not feeling well and a sensation of something sharp) (seriousness criterion hospitalization) and FEELING COLD (Had a feeling of very cold) (seriousness criterion hospitalization). At the time of the report, CHEST PAIN (Chest pain without radiation), MALAISE (Not feeling well and a sensation of something sharp) and FEELING COLD (Had a feeling of very cold) outcome was unknown and MYOCARDITIS (Myocarditis) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In October 2021, Electrocardiogram: normal (normal) Normal sinus rhythm. In October 2021, Troponin I: low (Low) Decreased from 210 to 40 in one day. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medications reported. Treatment details were not provided. This is a regulatory case concerning a 33-year-old male patient with no reported relevant medical history, who experienced the serious expected AESI event of myocarditis and serious unexpected events of chest pain, malaise and feeling cold.	

Case ID	WW Identifier	Narrative	MAH Comment
		The event of myocarditis occurred on the next day after the second dose of mRNA-1273 vaccine administration and the events of chest pain, malaise, feeling cold occurred on unknow day of the same month. The events were assessed as related, per temporal association with the product administration. The rechallenge was not applicable, since the events occurred after the second dose and no further dosing is expected. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.	
4.1(b)	4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b) on 21-Dec-2021 and was forwarded to Moderna on 21-Dec-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of ADENOVIRUS TEST (Adenovirus test), CARDIAC TELEMETRY NORMAL (Cardiac telemetry normal), CHEST PAIN (Chest pain), ECHOCARDIOGRAM (Echocardiogram), ELECTROCARDIOGRAM NORMAL (Electrocardiogram normal), HIV TEST NEGATIVE (HIV test negative), HUMAN METAPNEUMOVIRUS TEST (Human metapneumovirus test), HUMAN RHINOVIRUS TEST (Human rhinovirus test), INFLUENZA A VIRUS TEST NEGATIVE (Influenza A virus test negative), INFLUENZA B VIRUS TEST (Influenza B virus test), INFLUENZA VIRUS TEST NEGATIVE (Influenza virus test negative), MYOCARDITIS (Myocarditis), RESPIRATORY SYNCYTIAL VIRUS TEST NEGATIVE (Respiratory syncytial virus test negative), SARS-COV-2 TEST NEGATIVE (SARS-CoV-2 test negative) and TROPONIN INCREASED (Troponin increased) in a 25-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for an unknown indication.	25 years old male with unknown medical history who the next day after his 3rd dose of Spikevax presented with chest pain, he was found to have elevated troponin (EKG non-ischemic, no arrhythmia; BP and HR normal) and was diagnosed with myocarditis. Full viral test panel were conducted and all were negative. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events. A causal relationship cannot be excluded due to the lack of information.

Case ID	WW Identifier	Narrative	MAH Comment
		No Medical History information was reported. On 03-Dec-2021, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 04-Dec-2021, the patient experienced ADENOVIRUS TEST (Adenovirus test) (seriousness criterion hospitalization), CARDIAC TELEMETRY NORMAL (Cardiac telemetry normal) (seriousness criterion hospitalization), CHEST PAIN (Chest pain) (seriousness criterion hospitalization), ECHOCARDIOGRAM (Echocardiogram) (seriousness criterion hospitalization), ELECTROCARDIOGRAM NORMAL (Electrocardiogram normal) (seriousness criterion hospitalization), HIV TEST NEGATIVE (HIV test negative) (seriousness criterion hospitalization), HUMAN METAPNEUMOVIRUS TEST (Human metapneumovirus test) (seriousness criterion hospitalization), HUMAN RHINOVIRUS TEST (Human rhinovirus test) (seriousness criterion hospitalization), INFLUENZA A VIRUS TEST NEGATIVE (Influenza A virus test negative) (seriousness criterion hospitalization), INFLUENZA B VIRUS TEST (Influenza B virus test) (seriousness criterion hospitalization), INFLUENZA VIRUS TEST NEGATIVE (Influenza virus test negative) (seriousness criterion hospitalization), MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant), RESPIRATORY SYNCYTIAL VIRUS TEST NEGATIVE (Respiratory syncytial virus test negative) (seriousness criterion hospitalization), SARS-COV-2 TEST NEGATIVE (SARS-CoV-2 test negative) (seriousness criterion hospitalization) and TROPONIN INCREASED (Troponin increased) (seriousness criterion hospitalization). At the time of the report, ADENOVIRUS TEST (Adenovirus test), CARDIAC	

Case ID	WW Identifier	Narrative	MAH Comment
		TELEMETRY NORMAL (Cardiac telemetry normal), CHEST PAIN (Chest pain), ECHOCARDIOGRAM (Echocardiogram), ELECTROCARDIOGRAM NORMAL (Electrocardiogram normal), HIV TEST NEGATIVE (HIV test negative), HUMAN METAPNEUMOVIRUS TEST (Human metapneumovirus test), HUMAN RHINOVIRUS TEST (Human rhinovirus test), INFLUENZA A VIRUS TEST NEGATIVE (Influenza A virus test negative), INFLUENZA B VIRUS TEST (Influenza B virus test), INFLUENZA VIRUS TEST NEGATIVE (Influenza virus test negative), MYOCARDITIS (Myocarditis), RESPIRATORY SYNCYTIAL VIRUS TEST NEGATIVE (Respiratory syncytial virus test negative), SARS-COV-2 TEST NEGATIVE (SARS-CoV-2 test negative) and TROPONIN INCREASED (Troponin increased) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 06-Dec-2021, Adenovirus test: negative (Negative) Negative. On 06-Dec-2021, Influenza B virus test: negative (Negative) Negative. On 06-Dec-2021, Metapneumovirus infection: negative (Negative) Negative. On 06-Dec-2021, Parainfluenzae virus infection: negative (Negative) Negative. On 06-Dec-2021, Pneumonia influenzal: negative (Negative) Negative. On 06-Dec-2021, Polymerase chain reaction: negative (Negative) Negative. On 06-Dec-2021, Rhinovirus infection: negative (Negative) Negative. On 06-Dec-2021, Troponin: elevated troponin (High) elevated troponin. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter	

Case ID	WW Identifier	Narrative	MAH Comment
		did not provide any causality assessments. Diagonostics test included RNA PCR negative for Influenza A H3, Influenza B, RSV A, RSVB, Parainfluenza 1, Parainfluenza 2, Parainfluenza 3, and on 8th Dec 2021 Telemetry and TTE completed, results were pending. No concomitant medications provided. No treatment medications provided. Patient presented with chest pain that started the day after his Covid booster vaccine. He was found to have elevated troponin (EKG non-ischemic, no arrhythmia; BP and HR normal) and was diagnosed with myocarditis. No other possible cause of myocarditis was found. Specifically, he had no illness or sick contacts in the preceding weeks, a viral RNA PCR panel was negative (including Covid, Influenza A H1, Influenza A H3, Influenza B, RSV A, RSVB, Parainfluenza 1, Parainfluenza 2, Parainfluenza 3, Rhinovirus, Metapneumovirus, Adenovirus), HIV was negative, and he had no signs/symptoms/history of rheumatologic disease. His pain is improving without treatment. He has no s/sx of heart failure. A TTE was completed, result pending.	
4.1(b)	4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b) on 16-Dec-2021 and was forwarded to Moderna on 22-Dec-2021. This case was received via 4.1(b) (Reference number: 4.1(b) on 16-Dec-2021 and was forwarded to Moderna on 22-Dec-2021. This case, initially reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref, 4.1(b) On an unknown date, the patient received the 1st dose of this vaccine. On an unknown date, body temperature before the vaccination: 36.8 degrees	21 years old male with unknown medical history who 3 days after the 2nd dose experienced chest pain and was found to have elevated troponin, and normal EKG and echo, and was diagnosed with myocarditis. Patient was discharged 2 days later. No other information was provided. Important information is missing in the report including 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.

Case ID	WW Identifier	Narrative	MAH Comment
		Celsius. On 22-Nov-2021, at 16:00, the patient received the 2nd dose of this vaccine. Pyrexia developed. The patient took an antipyretic. On 23-Nov-2021, pyrexia improved. On 25-Nov-2021, at 07:30, the patient was urgently transported to the hospital as he was aware of left chest pain. Blood test showed elevated troponin I of 325 pg/mL. Acute myocarditis was suspected, so the patient was referred to the reporting hospital. Electrocardiogram and echocardiogram test showed no significant abnormalities, but troponin I was further elevated to 1,560.2 pg/mL; thus, the patient was hospitalized for follow-up. On 27-Nov-2021, the patient was discharged from the hospital as the symptoms were resolving. The outcome of pyrexia and suspected acute myocarditis was reported as resolving. Follow-up investigation will be made. Company Comment: The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	
4.1(b)	4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b) on 21-Dec-2021 and was forwarded to Moderna on 23-Dec-2021. This case, reported to the 4.1(b) by a corporation, was received via the 4.1(b) (Ref, 4.1(b) Myocarditis was assessed as serious by the MAH. On 16-Oct-2021, at 13:00, the patient received the 1st dose of the vaccine. On an unknown date, body temperature before the vaccination: 36.0 degrees Celsius. On 13-Nov-2021, at 13:00, the patient received the 2nd dose of the vaccine. On 14-Nov-2021, pyrexia and chest pain developed. On 16-Nov-2021, at 14:30, the patient visited a nearby hospital because the symptoms were not improved. Since elevated CPK was observed, the patient was referred to the reporting hospital. Cardiac ultrasonography showed	22 years old male with unknown medical history who 3 days after the 2nd dose experienced pyrexia, and chest pain and was found to have elevated CPK, and abnormal Echo, myocardial biopsy showed infiltration of inflammatory cells was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as document results including the myocardial biopsy; a causal relationship cannot be excluded.

Case ID	WW Identifier	Narrative	MAH Comment
		decreased cardiac function. A myocardial biopsy performed at the time of cardiac catheterization revealed infiltration of inflammatory cells intramyocardially, and the patient was diagnosed with myocarditis. On an unknown date, cardiac function improved to the normal range by follow-up. On 24-Nov-2021, the symptoms were resolving. The outcome of myocarditis was reported as resolving. Follow-up investigation will be made. Company Comment: The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	
4.1(b)	4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b) on 21-Dec-2021 and was forwarded to Moderna on 23-Dec-2021. This case, initially reported to the 4.1(b) by a (physician), was received via the 4.1(b) (Ref, 4.1(b) On an unknown date, the patient received the 1st dose of this vaccine. On 01-Oct-2021, at 17:00, the patient received the 2nd dose of this vaccine. On 02-Oct-2021, low-grade fever, queasy, and headache developed. On 03-Oct-2021, low-grade fever went down, and the symptoms were resolving. On 04-Oct-2021, at 07:00, myocarditis developed. The patient complained of chest pain and visited another hospital. No obvious abnormalities were found, and the patient returned home. In the afternoon, chest pain was exacerbated, and the patient visited another hospital again. The electrocardiogram showed ST elevation, and the patient was referred to a previous physician. Based on elevated troponin T, CK, and CK-MB in blood test and electrocardiogram, myocarditis was suspected, and the patient was raced the reporting hospital. The cardiac ultrasonography showed good cardiac function. The patient was	14 years old male with unknown medical history who 3 day after the 2nd dose experienced chest pain and was found to have elevated troponin, and CK-MB, and abnormal EKG, abnormal cMRI and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and EKG results; a causal relationship cannot be excluded.

Case ID	WW Identifier	Narrative	MAH Comment
		hospitalized for follow-up under management in the monitor. On 05-Oct-2021, chest pain tended to improve, but there was no change in the electrocardiogram. On 06-Oct-2021, cardiac MRI was performed. Delayed images showed enhancing effect of the lateral wall. On 12-Oct-2021, the symptoms were not exacerbated, and the patient was discharged from the hospital. On 10-Dec-2021, the symptoms were resolving. The outcome of myocarditis was reported as resolving. Follow-up investigation will be made. Company Comment: The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 23-Dec-2021 and was forwarded to Moderna on 23-Dec-2021. This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myocarditis) in a 20-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3004730) for COVID-19 vaccination. Previously administered products included for COVID-19 immunisation: SPIKEVAX on 31-Aug-2021. Past adverse reactions to the above products included No adverse event with SPIKEVAX. On 28-Nov-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On an unknown date, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criterion medically significant). At the time of the report, MYOCARDITIS (Myocarditis) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In 2021, C-reactive protein: high (High) Elevated.	20 years old male with unknown medical history who at an unknown TTO after the 2nd dose was found to have elevated troponin, and CRP, normal EKG, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and CRP results; a causal relationship cannot be excluded.

Case ID	WW Identifier	Narrative	MAH Comment
		In 2021, Cardiac telemetry: normal (normal) normal. In 2021, Echocardiogram: normal (normal) normal. In 2021, Troponin T: high (High) Elevated. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No concomitant product use was provided by the reporter. No treatment medications were reported.	
4.1(b)	4.1(b)	This case was received via Medison Pharma Ltd. (Reference number: 4.1(b) on 23-Dec-2021 and was forwarded to Moderna on 26-Dec-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of CHEST PAIN (stabbing pain in her chest) and MYOCARDITIS (Perimyocarditis) in a 33-year-old female patient who received mRNA-1273 (COVID 19 Vaccine Moderna) (batch no. 3001659) for COVID-19 vaccination. The patient's past medical history included COVID-19 in February 2021. Family history included IHD since an unknown date. On an unknown date, the patient received first dose of mRNA-1273 (COVID 19 Vaccine Moderna) (unknown route) 1 dosage form. On an unknown date, received second dose of mRNA-1273 (COVID 19 Vaccine Moderna) (unknown route) dosage was changed to 1 dosage form. On an unknown date, the patient experienced CHEST PAIN (stabbing pain in her chest) (seriousness criterion hospitalization) and MYOCARDITIS (Perimyocarditis) (seriousness criteria hospitalization and medically significant). The patient was hospitalized for 2 days due to CHEST PAIN and MYOCARDITIS. At the time of the report, CHEST PAIN (stabbing pain in her chest) and	Consumer report for a 33 years old female with medical history of COVID-19 who at an unknown day after the 2nd dose experienced chest pain and was found to have elevated troponin, CRP, elevated WBC, abnormal EKG and echo, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin, CRP, and EKG and echo results; a causal relationship cannot be excluded.

Case ID	WW Identifier	Narrative	MAH Comment
		MYOCARDITIS (Perimyocarditis) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Angiogram: normal (normal) normal. On an unknown date, C-reactive protein: 11 (High) 11. On an unknown date, Echocardiogram: abnormal (abnormal) a mild contractile disorder in the lower lateral wall. On an unknown date, Electrocardiogram: abnormal (abnormal) sinus tachycardia with no S-T-segment elevation. On an unknown date, Troponin: 3000 (High) 3000. On an unknown date, White blood cell count: 19000 (High) 19000. For mRNA-1273 (COVID 19 Vaccine Moderna) (Unknown Route), the reporter did not provide any causality assessments. patient was referred to an MRI No Concomitant medication were provided No Treatment medication were provided	
4.1(b)		This spontaneous prospective pregnancy case was reported by an other health care professional and describes the occurrence of MYOCARDITIS (Perimyocarditis) and DYSPNOEA (Pain when taking deep breaths) in a 30-year-old female patient (gravida 1) who received mRNA-1273 (COVID 19 Vaccine Moderna) (batch no. 3005889) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Hypothyroidism. Concomitant products included LEVOTHYROXINE for Hypothyroidism.	30 years old pregnant female with medical history of hypothyroidism who at an unknown TTO after the 2nd dose experienced dyspnea, chest discomfort, palpitations, cough, night sweats, and back pain, and was found to have elevated troponin, CRP, and abnormal EKG but normal echo, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's full medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and

Case ID	WW Identifier	Narrative	MAH Comment
		On an unknown date, the patient received second dose of mRNA-1273 (COVID 19 Vaccine Moderna) (unknown route) 1 dosage form. On an unknown date, received first dose of mRNA-1273 (COVID 19 Vaccine Moderna) (unknown route) dosage was changed to 1 dosage form. Last menstrual period and estimated date of delivery were not provided. On an unknown date, the patient experienced MYOCARDITIS (Perimyocarditis) (seriousness criteria hospitalization and medically significant), DYSPNOEA (Pain when taking deep breaths) (seriousness criterion medically significant), BACK PAIN (Back pain), CHEST DISCOMFORT (Pressure in the chest), PALPITATIONS (Palpitation), COUGH (Dry cough), NIGHT SWEATS (night sweats) and MATERNAL EXPOSURE DURING PREGNANCY (Maternal exposure during pregnancy). The patient was treated with PARACETAMOL (ACAMOL [PARACETAMOL]) (oral) for Back pain, at an unspecified dose and frequency and PREDNISONE for Dyspnoea, at an unspecified dose and frequency. At the time of the report, MYOCARDITIS (Perimyocarditis), DYSPNOEA (Pain when taking deep breaths), BACK PAIN (Back pain), CHEST DISCOMFORT (Pressure in the chest), PALPITATIONS (Palpitation), COUGH (Dry cough) and NIGHT SWEATS (night sweats) outcome was unknown and MATERNAL EXPOSURE DURING PREGNANCY (Maternal exposure during pregnancy) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, C-reactive protein: 90 90. On an unknown date, Chest X-ray: normal (normal) normal. On an unknown date, Echocardiogram: normal (normal) normal.	EKG results; a causal relationship cannot be excluded.

Case ID	WW Identifier	Narrative	MAH Comment
		On an unknown date, Electrocardiogram: abnormal (abnormal) abnormal. On an unknown date, Heart rate: 140 (High) 140. On an unknown date, Troponin: 122 122. For mRNA-1273 (COVID 19 Vaccine Moderna) (Unknown), the reporter did not provide any causality assessments.	
4.1(b)	4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b) on 17-Dec-2021 and was forwarded to Moderna on 23-Dec-2021. This regulatory authority case was reported by a pharmacist and describes the occurrence of PERICARDITIS (Pericarditis) in a 17-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna Intramuscular Injection) for COVID-19 vaccination. No Medical History information was reported. On 16-Oct-2021, the patient received second dose of mRNA-1273 (COVID-19 Vaccine Moderna Intramuscular Injection) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna Intramuscular Injection) (Intramuscular) 1 dosage form. On an unknown date, the patient experienced PERICARDITIS (Pericarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, PERICARDITIS (Pericarditis) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 17-Oct-2021, Body temperature: 38 Test Result: Above 38 Cel.	17 years old male with unknown medical history who 2 days after the 2nd dose experienced chest pain, palpitations, and was found to have elevated inflammatory markers, but normal EKG, and was diagnosed with pericarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated inflammatory markers; a causal relationship cannot be excluded.

Case ID	WW Identifier	Narrative	MAH Comment
		On 18-Oct-2021, Blood test: abnormal Elevated levels of inflammatory reaction. On 18-Oct-2021, Chest X-ray: no abnormal Test Result:No abnormal. On 20-Oct-2021, Electrocardiogram: no abnormal Test Result:No abnormal. For mRNA-1273 (COVID-19 Vaccine Moderna Intramuscular Injection) (Intramuscular), the reporter considered PERICARDITIS (Pericarditis) to be possibly related. This case, initially reported to the 4.1(b) [REDACTED] by a pharmacist, was received via the 4.1(b) (Ref, 4.1(b) [REDACTED]) On an unknown date, the patient received the 1st dose of the vaccine. On 16-Oct-2021, at 17:00, the patient received the 2nd dose of the vaccine. On 17-Oct-2021, the patient experienced generalized malaise, pyrexia above 38 degrees Celsius, and arthralgia from the neck to low back and from the arm to shoulder. On 18-Oct-2021, at 00:00, the patient noticed a pain in the middle of the chest. Palpitation also developed. The pain was intensified thereafter, and thus the patient visited the reporting hospital. Chest X-ray showed no abnormal findings. As the blood test confirmed elevated levels of inflammatory reaction, the patient was hospitalized for suspected pericarditis. On 20-Oct-2021, electrocardiogram was performed. No abnormalities were confirmed, and the patient was diagnosed with pericarditis after vaccination with the vaccine because there were no other underlying pathological conditions. On 21-Oct-2021, the patient recovered from the disease, with the chest pain resolving, and was discharged from the hospital. The outcome of pericarditis was reported as recovered. Follow-up investigation will be made. Company Comment: The event developed after the	

Case ID	WW Identifier	Narrative	MAH Comment
		administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. Company comment: This case concerns a 17-year-old male patient with no relevant medical history who experienced serious due to hospitalization and medical significance, expected event of pericarditis. The event occurred after the second dose of the mRNA-1273 with first symptom of chest pain and palpitations occurring 2 days after. Chest X ray and ECG were unremarkable whereas blood tests showed elevated inflammatory marker and the patient was subsequently diagnosed with pericarditis , 4 days after mRNA-1273. The rechallenge was not applicable since due to occurrence after the seco There have been several reports of pericarditis associated with the vaccine, and the patient background is known to be predominantly male in their teens and 20s. In this case, the patient complained of chest pain after the 2nd vaccination with the vaccine, which was consistent with the previous reports. Also, chest X-ray and electrocardiogram showed no abnormal findings, and the blood test confirmed elevated levels of inflammatory reaction, leading to the diagnosis of pericarditis.	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 27-Dec-2021 and was forwarded to Moderna on 27-Dec-2021. This regulatory authority case was reported by a physician and describes the occurrence of SINUS ARRHYTHMIA (Pericarditis (diagnosed by MRI) with sinus arrhythmia on ECG), DYSPNOEA (dyspnea for 10 days), CARDIOVASCULAR DISORDER (Cardiovascular problem), CHEST PAIN (vague thoracic pain with angina for 2 to 3 days), ANGINA	24 years old female with unknown medical history who after first vaccination had vague thoracic pain with angina for 2 to 3 days and then after an unknown TTO after second dose had severe thoracic pain with pronounced exercise intolerance, dyspnea for 10 days and was found to abnormal EKG, and abnormal cMRI suggestive of pericarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this

Case ID	WW Identifier	Narrative	MAH Comment
		PECTORIS (vague thoracic pain with angina for 2 to 3 days), EXERCISE TOLERANCE DECREASED (pronounced exercise intolerance) and PERICARDITIS (Pericarditis (diagnosed by MRI) with sinus arrhythmia on ECG) in a 24-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 4301081) for COVID-19 vaccination. Previously administered products included for Product used for unknown indication: Spikevax on 15-Jun-2021. Past adverse reactions to the above products included No adverse event with Spikevax. On 13-Jul-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On an unknown date, the patient experienced SINUS ARRHYTHMIA (Pericarditis (diagnosed by MRI) with sinus arrhythmia on ECG) (seriousness criterion medically significant), DYSPNOEA (dyspnea for 10 days) (seriousness criterion medically significant), CARDIOVASCULAR DISORDER (Cardiovascular problem) (seriousness criterion medically significant), CHEST PAIN (vague thoracic pain with angina for 2 to 3 days) (seriousness criterion medically significant), ANGINA PECTORIS (vague thoracic pain with angina for 2 to 3 days) (seriousness criterion medically significant), EXERCISE TOLERANCE DECREASED (pronounced exercise intolerance) (seriousness criterion medically significant) and PERICARDITIS (Pericarditis (diagnosed by MRI) with sinus arrhythmia on ECG) (seriousness criterion medically significant). At the time of the report, SINUS ARRHYTHMIA (Pericarditis (diagnosed by MRI) with sinus arrhythmia on ECG), DYSPNOEA (dyspnea for 10 days), CARDIOVASCULAR DISORDER	report is possible based on temporal association between the use of the product and the start of the events, as well as the EKG and cMRI results; a causal relationship cannot be excluded.

Case ID	WW Identifier	Narrative	MAH Comment
		(Cardiovascular problem), CHEST PAIN (vague thoracic pain with angina for 2 to 3 days), ANGINA PECTORIS (vague thoracic pain with angina for 2 to 3 days), EXERCISE TOLERANCE DECREASED (pronounced exercise intolerance) and PERICARDITIS (Pericarditis (diagnosed by MRI) with sinus arrhythmia on ECG) was resolving. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. No concomitant medication provided. No treatment information mentioned. The Medical imaging included MRI Cardiological review with ECG, bicycle test and lab ADR description - Pericarditis (diagnosed with MRI) with sinus arrhythmia on ECG More time relationship information (ADR) - After first vaccination, vague thoracic pain with angina for 2 to 3 days After second vaccination severe thoracic pain with pronounced exercise intolerance, dyspnea for 10 days Current during exercise thoracic pain/angina. Has stopped exercising to date. COVID-19 VACCINE MODERNA on 13 July 2021 on (2) (3003602) COVID-19 VACCINE MODERNA [15 June 2021] (1) (3002916) Dosage text reported as- Second dose administered After first vaccination vague thoracic pain with angina for 2 to 3 days After second vaccination severe thoracic pain with pronounced exercise intolerance, dyspnea for 10 days Current during exercise thoracic pain/angina. Has stopped exercising to date.	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 27-Dec-2021 and was forwarded to Moderna on 27-Dec-2021. This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myopericarditis) in a 34-year-old male patient who received mRNA-1273 (Spikevax)	34 years old female (conflicting information) with unknown medical history who 14 days after the 2nd dose of Spikevax experienced chest pain. Seven days later was admitted due to myopericarditis and was found to have suggestive ECG, characteristic MRI, elevated troponin. No concomitant drugs and no identification to date of another causative agent according to the reporter. No other information was

Case ID	WW Identifier	Narrative	MAH Comment
		(batch nos. 3005885 and 3005696) for COVID-19 vaccination. Concurrent medical conditions included Smoker. On 08-Sep-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 04-Oct-2021, received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to 1 dosage form. On 18-Nov-2021, the patient experienced MYOCARDITIS (Myopericarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Myopericarditis) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 25-Nov-2021, N-terminal prohormone brain natriuretic peptide: 130 pg/ml iu international unit(s) (High) 130 pg/ml lu international unit(s). On 25-Nov-2021, Troponin T: 461 ng/l iu international unit(s) (High) 461 ng/L lu international unit(s). For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Concomitant Elements: Healthy Concomitant product use was not provided by the reporter. No treatment information was provided.	provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and EKG results; a causal relationship cannot be excluded.
4.1(b)	4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b)) on 21-Dec-2021 and was forwarded to Moderna on 21-Dec-2021. This regulatory authority case was reported by a nurse and describes the occurrence of MYOCARDITIS (Myocarditis), CHEST PAIN (Chest Pain) and PYREXIA (Fever) in a 19-year-old female patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for an unknown indication.	19 years old female with unknown medical history who 3 day after the 2nd dose experienced pyrexia, and chest pain and was found to have elevated troponin, was diagnosed with myocarditis. Results for the ECG and Echo were not provided. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal

Case ID	WW Identifier	Narrative	MAH Comment
		Concomitant products included COLCHICINE, DOXYCYCLINE from 28-Oct-2021 to 04-Nov-2021, MEBEVERINE and SUMATRIPTAN for an unknown indication. On 15-Dec-2021, the patient received second dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 18-Dec-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant) and CHEST PAIN (Chest Pain) (seriousness criteria hospitalization and medically significant). On an unknown date, the patient experienced PYREXIA (Fever) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Myocarditis) had not resolved and CHEST PAIN (Chest Pain) and PYREXIA (Fever) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 19-Dec-2021, Troponin: 15,197 (High) 15,197. On an unknown date, Echocardiogram: result was not reported (Inconclusive) Result was not reported. On an unknown date, Electrocardiogram: result was not reported (Inconclusive) Result was not reported. For mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Myocarditis and pericarditis were reported. The patient was still hospitalized. Patient visited cardiologist. Treatment was provided to the patient which includes NSAIDS and colchicine.	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.

Case ID	WW Identifier	Narrative	MAH Comment
		Company Comment: This case concerns a 19 year-old female patient with no reported medical history who experienced the unexpected serious adverse events of special interest of myocarditis and the unexpected serious events of chest pain which occurred 4 days after the second dose of mRNA-1273 vaccine and the unexpected serious event of pyrexia which occurred on an unknown date relative to vaccination with mRNA-1273. The benefit-risk relationship of mRNA-1273 is not affected by this report. Events' seriousness assessed as per Regulatory Authority reporting. Most recent FOLLOW-UP information incorporated above includes: On 23-Dec-2021: Follow-up document received on 23-Dec-2021 contains significant information lab data updated and event coding updated.	
4.1(b)	4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b)) on 23-Dec-2021 and was forwarded to Moderna on 23-Dec-2021. This regulatory authority case was reported by a consumer and describes the occurrence of FATIGUE (Fatigue/unusual tiredness), CHEST PAIN (Chest pain) and PERICARDITIS (Pericarditis) in a 22-year-old male patient who received mRNA-1273 (COVID 19 Vaccine Moderna) (batch no. 000014A) for an unknown indication. Concomitant products included ELASOMERAN (COVID-19 VACCINE MODERNA) and ELASOMERAN (COVID-19 VACCINE MODERNA) for an unknown indication. On 20-Dec-2021, the patient received third dose of mRNA-1273 (COVID 19 Vaccine Moderna) (unknown route) 1 dosage form. On 21-Dec-2021, the patient experienced CHEST PAIN (Chest pain) (seriousness criterion medically significant) and	22 years old female with unknown medical history who next day after the 3rd dose experienced chest pain, and fatigue, and was found to have elevated troponin, and abnormal ECG, and was diagnosed with pericarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and ECG; a causal relationship cannot be excluded.

Case ID	WW Identifier	Narrative	MAH Comment
		PERICARDITIS (Pericarditis) (seriousness criterion medically significant). On an unknown date, the patient experienced FATIGUE (Fatigue/unusual tiredness) (seriousness criterion medically significant). At the time of the report, FATIGUE (Fatigue/unusual tiredness) and CHEST PAIN (Chest pain) outcome was unknown and PERICARDITIS (Pericarditis) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Blood test: crp 11 CRP 11. On an unknown date, Electrocardiogram: indicated pericarditis indicated pericarditis. On an unknown date, Troponin: raised 11 raised 11. other treatment medications- Ibuprofen and omeprazole Patient has not had symptoms associated with COVID-19 Not had a COVID-19 test Patient has not tested positive for COVID-19 since having the vaccine Patient is not enrolled in clinical trial Most recent FOLLOW-UP information incorporated above includes: On 23-Dec-2021: Initial and Follow-up processed together. Concomitant medications, Lot number and results for lab data were updated.	
4.1(b)	4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b)) on 27-Dec-2021 and was forwarded to Moderna on 27-Dec-2021. This regulatory authority case was reported by a consumer and describes the occurrence of CHEST PAIN (Chest pain), DYSPNOEA (Shortness of breath), PALPITATIONS (Heart palpitations), FATIGUE (Fatigue/unusual tiredness) and MYOCARDITIS (Myocarditis) in a 34-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) (batch no. 00014A) for an unknown indication.	Consumer report for a 34 years old male with unknown medical history who 2 days after the 3rd dose experienced chest pain, dyspnea, palpitations, and fatigue and was found to have elevated troponin, was diagnosed with myocarditis. Results for the ECG and Echo were not provided. SARS-CoV-2 test negative. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted. According to the WHO causality assessment this report is possible based on temporal association between the

Case ID	WW Identifier	Narrative	MAH Comment
		The patient's past medical history included ECG. On 22-Dec-2021, the patient received third dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 24-Dec-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). On an unknown date, the patient experienced CHEST PAIN (Chest pain) (seriousness criteria hospitalization and medically significant), DYSPNOEA (Shortness of breath) (seriousness criteria hospitalization and medically significant), PALPITATIONS (Heart palpitations) (seriousness criteria hospitalization and medically significant) and FATIGUE (Fatigue/unusual tiredness) (seriousness criteria hospitalization and medically significant). At the time of the report, CHEST PAIN (Chest pain), DYSPNOEA (Shortness of breath), PALPITATIONS (Heart palpitations) and FATIGUE (Fatigue/unusual tiredness) outcome was unknown and MYOCARDITIS (Myocarditis) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 25-Dec-2021, SARS-CoV-2 test: no - negative covid-19 test (Negative) No - Negative COVID-19 test. The action taken with mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown) was unknown. Concomitant product use was not provided by the reporter. Patient did not had symptoms associated with COVID-19. Post vaccine, patient had heart palpitation, sore chest, high blood pressure, raised troponin levels. The laboratory exam was done that included ECG and the result was found to be not provided, blood Pressure was 178/110. There was no history of high blood pressure. The	use of the product and the start of the events, as well as the elevated troponin; a causal relationship cannot be excluded.

Case ID	WW Identifier	Narrative	MAH Comment
		x-ray was also done but the result were not provided, all bloods tests were completed and lab confirmed troponin levels. The blood tests which had certain proteins (called troponin) that signal heart muscle damage taken and it was found that his blood troponin levels were raised. Since the patient had received the vaccine, she had not tested positive for COVID-19. Patient was prescribed amlodipine as a treatment medication.	
4.1(b)	4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b)) on 28-Dec-2021 and was forwarded to Moderna on 28-Dec-2021. This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myocarditis) in a 35-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) (batch no. 000040A) for an unknown indication. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Kidney polycystic (adult polycystic kidney disease). Concomitant products included COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (COVID-19 VACCINE ASTRAZENECA) from 01-Apr-2021 to an unknown date for Immunisation. On 20-Dec-2021, the patient received third dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 24-Dec-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criterion medically significant). On an unknown date, the patient experienced CHEST PAIN (Chest Pain). At the time of the report, MYOCARDITIS (Myocarditis) had not resolved and CHEST PAIN (Chest Pain) outcome was unknown.	35 years old male with medical history of kidney polycystic and receiving the Astrazeneca vaccine who 4 days after the 3rd dose experienced chest pain and was found to have elevated troponin, and abnormal ECG. Echo showed not pericardial effusion and chest x-ray was normal. SARS-CoV-2 test was negative. Patient was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted. According to the WHO causality assessment this report is 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.

Case ID	WW Identifier	Narrative	MAH Comment
		DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 24-Dec-2021, SARS-CoV-2 test: no - negative covid-19 test (Negative) No - Negative COVID-19 test. On an unknown date, Angiocardiogram: results not reported Results not reported. On an unknown date, Chest X-ray: results not reported Results not reported. On an unknown date, Electrocardiogram: results not reported Results not reported. On an unknown date, Magnetic resonance imaging heart: results not reported Results not reported. The action taken with mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown) was unknown. For mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Patient admitted on 24-DEC-2021 with chest tightness ECH changes indicative of pericarditis, cardiac troponin raised on admission shows 3000, on 24-12-2021 at 07:30 shows 2944, peak troponin value shows 4915. Lab data investigations shows ECG-ST elevation in all leads, worse inferiorly, Chest X-ray is clear and nil acute, Echocardiogram shows no effusion. Patient took Treatment for myo-pericarditis with analgesia at present. Patient well otherwise.	
4.1(b)	4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b)) on 23-Dec-2021 and was forwarded to Moderna on 23-Dec-2021. This regulatory authority case was reported by a physician and describes the occurrence of CHILLS (rigors), MYALGIA (generalised	29 years old male with unknown medical history who next day after the 3rd dose experienced chest pain, chills, myalgia, fatigue, pyrexia, and was found to have elevated troponin, and CRP. ECG results not provided. SARS-CoV-2 test was negative. Patient was diagnosed with myocarditis. No other information was

Case ID	WW Identifier	Narrative	MAH Comment
		muscle ache), FATIGUE (Fatigue), CHEST PAIN (Chest Pain), PYREXIA (Fever), DYSPNOEA (Dyspnoea), PALPITATIONS (Palpitations), SYNCOPES (Syncope) and MYOCARDITIS (Myocarditis) in a 29-year-old male patient who received mRNA-1273 (Moderna Covid-19 Vaccine) for COVID-19 vaccination. No past medical history Patient has not had symptoms associated with COVID-19. On 19-Dec-2021, the patient received third dose of mRNA-1273 (Moderna Covid-19 Vaccine) (unknown route) 1 dosage form. On 19-Dec-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criterion medically significant). On an unknown date, the patient experienced CHILLS (rigors) (seriousness criterion medically significant), MYALGIA (generalised muscle ache) (seriousness criterion medically significant), FATIGUE (Fatigue) (seriousness criterion medically significant), CHEST PAIN (Chest Pain) (seriousness criterion medically significant), PYREXIA (Fever) (seriousness criterion medically significant), DYSPNOEA (Dyspnoea) (seriousness criterion medically significant), PALPITATIONS (Palpitations) (seriousness criterion medically significant) and SYNCOPES (Syncope) (seriousness criterion medically significant). At the time of the report, CHILLS (rigors), MYALGIA (generalised muscle ache) and MYOCARDITIS (Myocarditis) had not resolved and FATIGUE (Fatigue), CHEST PAIN (Chest Pain), PYREXIA (Fever), DYSPNOEA (Dyspnoea), PALPITATIONS (Palpitations) and SYNCOPES (Syncope) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):	provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin; a causal relationship cannot be excluded.

Case ID	WW Identifier	Narrative	MAH Comment
		On 20-Dec-2021, SARS-CoV-2 test: negative (Negative) No - Negative COVID-19 test. On 22-Dec-2021, Troponin I (0-50): 3379 (Inconclusive) 3379. On an unknown date, C-reactive protein: 31 (Inconclusive) 31. On an unknown date, Chest X-ray: normal (normal) normal. On an unknown date, Electrocardiogram: results not reported Results not reported. The action taken with mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown) was unknown. For mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. No concomitant medication was provided by reporter. In the source document patient stated Generalised muscle ache, left sided sharp chest pain, fever/rigors, SOB, palpitations. Patient has not tested positive for COVID-19 since having the vaccine. Does your report relate to possible myocarditis or pericarditis? If yes, we will ask you additional questions at the end of this report: "Yes" Suspect Reactions Please provide details of any relevant investigations or tests conducted: "Trop I 3379, CRP 31" Myocarditis and pericarditis What treatment was provided to the patient? For example, NSAIDs, steroids or other anti inflammatory agents "Ibuprofen " If the troponin was measured, please provide the date this was taken: "22/12/21" Was the cardiac troponin normal or raised? : "raised: 3379" What was the peak troponin: "3379" What was the troponin reference range?: "0-50 ng/L" If a Chest Xray was performed, please provide the date and results: "Normal" Was an Echocardiogram carried out?: "Unknown"	

Case ID	WW Identifier	Narrative	MAH Comment
		Most recent FOLLOW-UP information incorporated above includes: On 24-Dec-2021: follow up received on 24Dec 2021 , added lab test :Troponin I , C-reactive protein.	
4.1(b)	4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b) on 27-Dec-2021 and was forwarded to Moderna on 29-Dec-2021. This case, initially reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref, 4.1(b) On an unknown date, the patient received the 1st dose of this vaccine. On 22-Oct-2021, the patient received the 2nd dose of this vaccine. On 23-Oct-2021, the patient was observed with pyrexia of 39 degrees Celsius, but it was decided to wait and see. On 24-Oct-2021, at 18:30, acute myocarditis developed. The patient was aware of chest pressure sensation at night. On 25-Oct-2021, chest pressure sensation was aggravated and the patient visited a previous physician. On 26-Oct-2021, although the patient was scheduled to be referred to the initial visit outpatient of the reporting hospital in the morning, the patient visited the emergency department due to a flare-up of chest pain. The patient was diagnosed with findings that are no different myocarditis based on electrocardiogram changes and elevated cardiac enzymes and was hospitalized. On 27-Oct-2021, coronary angiography, right heart catheterization, and myocardial biopsy were performed to confirm the absence of coronary artery disease. Then resolving was done by symptomatic therapy with antipyretic analgesics. On 01-Nov-2021. the patient was discharged from the hospital because	16 years old male with unknown medical history who next day after the 2nd dose experienced chest pressure and was found to have elevated cardiac enzymes, abnormal ECG and myocardial biopsy showing inflammatory changes suggestive of myocarditis. Patient was diagnosed with myocarditis. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated cardiac enzymes and ECG and biopsy results; a causal relationship cannot be excluded.

Case ID	WW Identifier	Narrative	MAH Comment
		of resolving symptoms. The results of the myocardial biopsy showed obvious diagnostic criteria for inflammatory cells, but edematous changes were observed. Considering his age, it was diagnosed as possible inflammation. Virus tests were also performed, but there was no obvious suspicion. The outcome of acute myocarditis was reported as resolving. Follow-up investigation will be made. Company Comment: The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	
4.1(b)	4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b) on 28-Dec-2021 and was forwarded to Moderna on 28-Dec-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of ELECTROCARDIOGRAM T WAVE INVERSION (Electrocardiogram T wave inversion), PERICARDIAL EFFUSION (Pericardial effusion) and MYOCARDITIS (Myocarditis) in a 35-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for an unknown indication. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Renal cell carcinoma (Resected Renal Cell Carcinoma in remission without active treatment.). Concurrent medical conditions included Drug allergy (Vancomycin - Itching) and Drug allergy (Morphine - Itching). On 11-Dec-2021, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 13-Dec-2021, the patient experienced ELECTROCARDIOGRAM T WAVE INVERSION (Electrocardiogram T wave inversion) (seriousness criterion	35 years old male with medical history of renal cell carcinoma in remission who 2 days after the 3rd dose experienced chest pain, hyperhidrosis, and vomiting and was found to have abnormal ECG, Echo showed pericardial effusion, but troponin negative twice. Patient was diagnosed with presumptive myopericarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated ECG and echo results; a causal relationship cannot be excluded.

Case ID	WW Identifier	Narrative	MAH Comment
		medically significant), PERICARDIAL EFFUSION (Pericardial effusion) (seriousness criterion medically significant), MYOCARDITIS (Myocarditis) (seriousness criterion medically significant), CHEST PAIN (Chest pain), ECHOCARDIOGRAM (Echocardiogram), ELECTROCARDIOGRAM (Electrocardiogram), FLANK PAIN (Flank pain), HYPERHIDROSIS (Hyperhidrosis), PAIN (Pain), TROPONIN (Troponin) and VOMITING (Vomiting). At the time of the report, ELECTROCARDIOGRAM T WAVE INVERSION (Electrocardiogram T wave inversion), PERICARDIAL EFFUSION (Pericardial effusion), MYOCARDITIS (Myocarditis), CHEST PAIN (Chest pain), ECHOCARDIOGRAM (Echocardiogram), ELECTROCARDIOGRAM (Electrocardiogram), FLANK PAIN (Flank pain), HYPERHIDROSIS (Hyperhidrosis), PAIN (Pain), TROPONIN (Troponin) and VOMITING (Vomiting) outcome was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Other medications included Testosterone and Adderall. At 48 hours on 13-Dec-2021, the patient developed left sided flank pain. Progressed to severe sub-sternal chest pain on 15-Dec-2021 prompting emergency department visit. Chest pain radiated to neck, worse with deep inspiration, relieved with sitting forward. Chest pain associated with diaphoresis and vomiting secondary to pain. Electrocardiogram changes new T wave inversions V4-V6, and I and II Bedside echo without clinically significant effusion. Troponin negative twice 2 and discharged home with presumptive diagnosis of pericarditis or myocarditis.	

Case ID	WW Identifier	Narrative	MAH Comment
4.1(b)		No treatment medication was provided. This case was received via Zuellig Pharma (Reference number: 4.1(b)) on 28-Dec-2021 and was forwarded to Moderna on 29-Dec-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCARDITIS (myopericarditis) in a 39-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) (batch no. 3005841) for an unknown indication. No Medical History information was reported. On 09-Nov-2021, the patient received third dose of mRNA-1273 (COVID-19 Vaccine Moderna) (unknown route) 1 dosage form. On an unknown date, the patient experienced MYOCARDITIS (myopericarditis) (seriousness criterion medically significant). At the time of the report, MYOCARDITIS (myopericarditis) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Troponin: 482-79 482-79. The action taken with mRNA-1273 (COVID-19 Vaccine Moderna) (Unknown) was unknown. For mRNA-1273 (COVID-19 Vaccine Moderna) (Unknown), the reporter did not provide any causality assessments. EKG :SR,ER was the same as previous baseline CRP 15.9 -> 4 CMR : increase T2 and T1 at apical segment of LV small area of pachy myocardial involvement in LGE	39 years old male with unknown medical history who at an unknown TTO after the 3rd dose was found to have elevated troponin, elevated CRP and abnormal ECG. Patient was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted. According to the WHO causality assessment this report is possible based on temporal association 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.

Case ID	WW Identifier	Narrative	MAH Comment
		No concomitant medications were reported. Treatment information was not provided.	
4.1(b)	4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b)) on 26-Dec-2021 and was forwarded to Moderna on 26-Dec-2021. This regulatory authority case was reported by a physician and describes the occurrence of PERICARDITIS (Pericarditis), SYNCOPE (Syncope), INFLUENZA LIKE ILLNESS (flu like symptoms), CHEST PAIN (Chest Pain), DYSPNOEA (Dyspnoea), HYPOAESTHESIA (Numbness of limbs) and PYREXIA (Fever) in a 29-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for COVID-19 vaccination. The patient's past medical history included TMJ syndrome (TMJ dysfunction) and TB (TB when younger). Concomitant products included TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) and TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) for COVID-19 vaccination. On 19-Dec-2021, the patient received third dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 19-Dec-2021, after starting mRNA-1273 (Moderna CoviD-19 Vaccine), the patient experienced PERICARDITIS (Pericarditis) (seriousness criteria hospitalization, disability and medically significant). On an unknown date, the patient experienced SYNCOPE (Syncope) (seriousness criteria hospitalization, disability and medically significant), INFLUENZA LIKE ILLNESS (flu like symptoms) (seriousness criteria hospitalization and disability), CHEST PAIN (Chest Pain) (seriousness criteria hospitalization and disability), DYSPNOEA (Dyspnoea)	29 years old male with unknown medical history and having the Pfizer vaccine as the primary series who 2 days after the 3rd dose of Spikevax experienced chest pain, left arm numbness, flu like symptoms, dyspnea, pyrexia, and was found to have elevated troponin, normal EKG, negative SARS-CoV-2 test and was diagnosed with myopericarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin; a causal relationship cannot be excluded.

Case ID	WW Identifier	Narrative	MAH Comment
		(seriousness criteria hospitalization and disability), HYPOAESTHESIA (Numbness of limbs) (seriousness criteria hospitalization and disability) and PYREXIA (Fever) (seriousness criteria hospitalization and disability). At the time of the report, PERICARDITIS (Pericarditis) was resolving, SYNCOPE (Syncope), CHEST PAIN (Chest Pain), DYSPNOEA (Dyspnoea), HYPOAESTHESIA (Numbness of limbs) and PYREXIA (Fever) outcome was unknown and INFLUENZA LIKE ILLNESS (flu like symptoms) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 22-Dec-2021, Electrocardiogram: normal (normal) Normal. On 22-Dec-2021, SARS-CoV-2 test: negative (Negative) No - Negative COVID-19 test. On 22-Dec-2021, Troponin: 3000 3000. For mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Patient has not had symptoms associated with COVID-19. The patient experienced Chest pain/left arm numbness, Flu like symptoms. Some subjective shortness of breath (SOB). Rise in troponin to 3000. Settling with NSAIDs. Patient has not tested positive for COVID-19 since having the vaccine. Unsure if patient was enrolled in clinical trial. The patient's report was related to possible myocarditis or pericarditis. The patient was hospitalized for 2 days. The patient seen by a cardiologist and diagnosed with Myopericarditis. The patient received treatment Aspirin/Colchicine/PPI.	

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-Dec-2021 and was forwarded to Moderna on 26-Dec-2021. This regulatory authority case was reported by a physician and describes the occurrence of CHEST PAIN (Chest Pain), PALPITATIONS (Palpitations), TACHYCARDIA (Tachycardia), LEFT VENTRICULAR DYSFUNCTION (Left ventricular dysfunction) and MYOCARDITIS (Myocarditis) in a 21-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for COVID-19 immunisation. Concomitant products included TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) from 25-Jun-2021 to an unknown date and TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) from 25-Jun-2021 to 03-Sep-2021 for COVID-19 immunisation. On 20-Dec-2021, the patient received third dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 22-Dec-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criterion medically significant). On an unknown date, the patient experienced CHEST PAIN (Chest Pain) (seriousness criterion medically significant), PALPITATIONS (Palpitations) (seriousness criterion medically significant), TACHYCARDIA (Tachycardia) (seriousness criterion medically significant) and LEFT VENTRICULAR DYSFUNCTION (Left ventricular dysfunction) (seriousness criterion medically significant). At the time of the report, CHEST PAIN (Chest Pain), PALPITATIONS (Palpitations), TACHYCARDIA (Tachycardia) and LEFT VENTRICULAR DYSFUNCTION (Left ventricular dysfunction) outcome was unknown	21 years old male with unknown medical history and who had the Pfizer vaccine as the primary series who 2 days after the 3rd dose experienced chest pain, palpitations, tachycardia, and was found to have elevated troponin, and abnormal EKG, cMRI, and negative SARS-CoV-2 test, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and EKG and cMRI results; a causal relationship cannot be excluded.

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

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

Case ID	WW Identifier	Narrative	MAH Comment
		On 10-Dec-2021, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 12-Dec-2021, the patient experienced BLOOD POTASSIUM DECREASED (Blood potassium decreased) (seriousness criterion hospitalization), CARDIAC TELEMETRY (Cardiac telemetry) (seriousness criterion hospitalization), CHEST DISCOMFORT (Chest discomfort) (seriousness criterion hospitalization), CHEST PAIN (Chest pain) (seriousness criterion hospitalization), DIFFERENTIAL WHITE BLOOD CELL COUNT (Differential white blood cell count) (seriousness criterion hospitalization), ECHOCARDIOGRAM (Echocardiogram) (seriousness criterion hospitalization), ELECTROCARDIOGRAM NORMAL (Electrocardiogram normal) (seriousness criterion hospitalization), FIBRIN D DIMER NORMAL (Fibrin D dimer normal) (seriousness criterion hospitalization), FULL BLOOD COUNT (Full blood count) (seriousness criterion hospitalization), HYPOKALAEMIA (Hypokalaemia) (seriousness criterion hospitalization), LABORATORY TEST ABNORMAL (Laboratory test abnormal) (seriousness criterion hospitalization), NAUSEA (Nausea) (seriousness criterion hospitalization), SLEEP DISORDER (Sleep disorder) (seriousness criterion hospitalization), TROPONIN INCREASED (Troponin increased) (seriousness criterion hospitalization) and MYOCARDITIS (Myocarditis) (seriousness criterion hospitalization). At the time of the report, BLOOD POTASSIUM DECREASED (Blood potassium decreased), CARDIAC TELEMETRY (Cardiac telemetry), CHEST DISCOMFORT (Chest discomfort), CHEST PAIN (Chest pain), DIFFERENTIAL WHITE BLOOD CELL COUNT (Differential white blood cell count), ECHOCARDIOGRAM (Echocardiogram),	

Case ID	WW Identifier	Narrative	MAH Comment
		ELECTROCARDIOGRAM NORMAL (Electrocardiogram normal), FIBRIN D DIMER NORMAL (Fibrin D dimer normal), FULL BLOOD COUNT (Full blood count), HYPOKALAEMIA (Hypokalaemia), LABORATORY TEST ABNORMAL (Laboratory test abnormal), NAUSEA (Nausea), SLEEP DISORDER (Sleep disorder), TROPONIN INCREASED (Troponin increased) and MYOCARDITIS (Myocarditis) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 13-Dec-2021, Blood potassium: 3.4 (Low) Chem panel - K = 3.4 (low). On 13-Dec-2021, Cardiac telemetry: 60-65% (Low) 60-65%. On 13-Dec-2021, Ejection fraction: 60-65 ECHO -LVEF 60-65%. On 13-Dec-2021, Electrocardiogram: normal (normal) normal. On 13-Dec-2021, Fibrin D dimer: 0.33 0.33. On 13-Dec-2021, Full blood count: results not reported CBC w/ diff. On 13-Dec-2021, Troponin: 4396 (High) 4396 pg/mL and 3377.4 1 3377.4 1. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Patient had hives. Other medications included creatine powder, occasional ibuprofen use. No treatment drug reported. 4.1(b) received Moderna booster on 12/10/21. He had got his 2 dose series with Pfizer initially. He flew on the 12/11 or 12/12. He began experiencing mild diffuse anterior chest discomfort on 12/12 3PM. At 3:30AM on 12/13, he was awakened from sleep with severe diffuse anterior chest pain, non-radiating. He had associated nausea without vomiting. He sought care in the ER where he was given morphine and ondansetron that improved his	

Case ID	WW Identifier	Narrative	MAH Comment
		symptoms. He was admitted for myocarditis and mild hypokalemia. This is a regulatory case concerning a 21-year-old male patient with relevant medical history of drug hypersensitivity, who experienced the serious expected AESI event of myocarditis and serious unexpected events of blood potassium decreased, cardiac telemetry, chest discomfort, chest pain, differential white blood cell count, echocardiogram, electrocardiogram normal, fibrin D dimer normal, full blood count, hypokalaemia, laboratory test abnormal, nausea, sleep disorder, troponin increased. The events occurred 3 days after the third dose of mRNA-1273 vaccine administration. The events were assessed as related to the product administration. The rechallenge was not applicable since the events occurred after the third dose and no further dosing is expected. The medical history of drug hypersensitivity considered as a confounder. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.	
4.1(b)	4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b) on 28-Dec-2021 and was forwarded to Moderna on 28-Dec-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of CARDIOMYOPATHY (Cardiomyopathy), CATHETERISATION CARDIAC ABNORMAL (Catheterisation cardiac abnormal), CHEST PAIN (Chest pain), ECHOCARDIOGRAM (Echocardiogram), EJECTION FRACTION (Ejection fraction), ELECTROCARDIOGRAM ST SEGMENT ELEVATION (Electrocardiogram ST segment elevation), TROPONIN INCREASED (Troponin increased), VACCINATION COMPLICATION (Vaccination complication) and MYOCARDITIS (Myocarditis) in a 23-year-old male	23 years old male with unknown medical history and who at an unknown TTO after the 3rd dose experienced chest pain, and was found to have elevated troponin, and abnormal EKG, Echo, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and EKG results; a causal relationship cannot be excluded.

Case ID	WW Identifier	Narrative	MAH Comment
		patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for an unknown indication. No Medical History information was reported. On 10-Dec-2021, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 10-Dec-2021, the patient experienced CARDIOMYOPATHY (Cardiomyopathy) (seriousness criteria hospitalization, medically significant and life threatening), CATHETERISATION CARDIAC ABNORMAL (Catheterisation cardiac abnormal) (seriousness criteria hospitalization and life threatening), CHEST PAIN (Chest pain) (seriousness criteria hospitalization and life threatening), ECHOCARDIOGRAM (Echocardiogram) (seriousness criteria hospitalization and life threatening), EJECTION FRACTION (Ejection fraction) (seriousness criteria hospitalization and life threatening), ELECTROCARDIOGRAM ST SEGMENT ELEVATION (Electrocardiogram ST segment elevation) (seriousness criteria hospitalization, medically significant and life threatening), TROPONIN INCREASED (Troponin increased) (seriousness criteria hospitalization and life threatening), VACCINATION COMPLICATION (Vaccination complication) (seriousness criteria hospitalization and life threatening) and MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization, medically significant and life threatening). At the time of the report, CARDIOMYOPATHY (Cardiomyopathy), CATHETERISATION CARDIAC ABNORMAL (Catheterisation cardiac abnormal), CHEST PAIN (Chest pain), ECHOCARDIOGRAM (Echocardiogram), EJECTION FRACTION (Ejection fraction), ELECTROCARDIOGRAM ST	

Case ID	WW Identifier	Narrative	MAH Comment
		SEGMENT ELEVATION (Electrocardiogram ST segment elevation), TROPONIN INCREASED (Troponin increased), VACCINATION COMPLICATION (Vaccination complication) and MYOCARDITIS (Myocarditis) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Catheterisation cardiac: negative for obstruction (Negative) negative for obstruction. On an unknown date, Echocardiogram: 45% Echocardiogram with EF of 45%. On an unknown date, Troponin: 18 Peaked. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medications were reported. No treatment medications were reported. Soon after receiving vaccine, patient developed severe chest pain. Sought care at the hospital, noted ST elevation. Urgent cardiac catheterization and echocardiogram showed Myopericarditis with cardiomyopathy due to Moderna booster vaccine and was hospitalized for 3 days.	
4.1(b)	4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b) on 28-Dec-2021 and was forwarded to Moderna on 28-Dec-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of CHEST PAIN (Chest pain), ANTICOAGULANT THERAPY (Anticoagulant therapy), BLOOD CREATINE PHOSPHOKINASE MB (Blood creatine phosphokinase MB), BLOOD CREATINE PHOSPHOKINASE ABNORMAL (Blood creatine phosphokinase	31 years old male with unknown medical history and who 5 days after the 3rd dose experienced chest pain, and was found to have elevated troponin, elevated fibrin d-dimer, elevated CRP, elevated NT-proBNP and abnormal EKG, Echo, and was diagnosed with myocarditis. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the well document information provided in the report; a causal relationship cannot be excluded.

Case ID	WW Identifier	Narrative	MAH Comment
		abnormal), C-REACTIVE PROTEIN ABNORMAL (C-reactive protein abnormal), CHEST X-RAY (Chest X-ray), DIFFERENTIAL WHITE BLOOD CELL COUNT ABNORMAL (Differential white blood cell count abnormal), ECHOCARDIOGRAM (Echocardiogram), ELECTROCARDIOGRAM (Electrocardiogram), FIBRIN D DIMER INCREASED (Fibrin D dimer increased), FULL BLOOD COUNT ABNORMAL (Full blood count abnormal), INFLUENZA A VIRUS TEST (Influenza A virus test), INFLUENZA B VIRUS TEST (Influenza B virus test), LABORATORY TEST ABNORMAL (Laboratory test abnormal), N-TERMINAL PROHORMONE BRAIN NATRIURETIC PEPTIDE ABNORMAL (N-terminal prohormone brain natriuretic peptide abnormal), SARS-COV-2 TEST (SARS-CoV-2 test), TROPONIN I ABNORMAL (Troponin I abnormal) and MYOCARDITIS (Myocarditis) in a 31-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 069H21A) for an unknown indication. No Medical History information was reported. On 04-Dec-2021, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 09-Dec-2021, the patient experienced CHEST PAIN (Chest pain) (seriousness criterion hospitalization), ANTICOAGULANT THERAPY (Anticoagulant therapy) (seriousness criterion hospitalization), BLOOD CREATINE PHOSPHOKINASE MB (Blood creatine phosphokinase MB) (seriousness criterion hospitalization), BLOOD CREATINE PHOSPHOKINASE ABNORMAL (Blood creatine phosphokinase abnormal) (seriousness criterion hospitalization), C-REACTIVE PROTEIN ABNORMAL (C-reactive	

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

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

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

Case ID	WW Identifier	Narrative	MAH Comment
		experiencing shortness of breath) and PYREXIA (Fever (39°C)) in a 30-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. No Medical History information was reported. On 13-Aug-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. In August 2021, the patient experienced CHEST PAIN (I'm still experiencing strong chest pain) (seriousness criterion hospitalization), BACK PAIN (I'm still experiencing back pain) (seriousness criterion hospitalization), ABDOMINAL PAIN UPPER (I'm still experiencing stomach pain) (seriousness criterion hospitalization), PALPITATIONS (I'm still experiencing fast beating/I'm still experiencing pounding heart) (seriousness criterion hospitalization), DYSPNOEA (I'm still experiencing shortness of breath) (seriousness criterion hospitalization) and PYREXIA (Fever (39°C)) (seriousness criterion hospitalization). On 16-Aug-2021, the patient experienced MYOCARDITIS (I'm one of the few unfortunate persons that experienced after the second dose of the Moderna vaccine) (seriousness criteria hospitalization and medically significant). The patient was hospitalized from 07-Sep-2021 to 09-Sep-2021 due to ABDOMINAL PAIN UPPER, BACK PAIN, CHEST PAIN, DYSPNOEA, MYOCARDITIS, PALPITATIONS and PYREXIA. The patient was treated with IBUPROFEN in October 2021 for Adverse event, at an unspecified dose and frequency and PREDNISOLONE in September 2021 for Adverse event, at an unspecified dose and frequency. At the time of the report, MYOCARDITIS (I'm one of the few unfortunate persons that experienced after the second dose of the Moderna vaccine), CHEST PAIN (I'm still experiencing strong chest pain),	this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and MRI results; a causal relationship cannot be excluded.

Case ID	WW Identifier	Narrative	MAH Comment
		BACK PAIN (I'm still experiencing back pain), ABDOMINAL PAIN UPPER (I'm still experiencing stomach pain), PALPITATIONS (I'm still experiencing fast beating/I'm still experiencing pounding heart), DYSPNOEA (I'm still experiencing shortness of breath) and PYREXIA (Fever (39°C)) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In August 2021, Body temperature: high (High) 39 degree celsius. In August 2021, Troponin I: abnormal (abnormal) Abnormal. In October 2021, Troponin I: normal (normal) Normal. For mRNA-1273 (Spikevax) (Unknown), the reporter considered MYOCARDITIS (I'm one of the few unfortunate persons that experienced after the second dose of the Moderna vaccine) to be related. No further causality assessments were provided for CHEST PAIN (I'm still experiencing strong chest pain), BACK PAIN (I'm still experiencing back pain), ABDOMINAL PAIN UPPER (I'm still experiencing stomach pain), PALPITATIONS (I'm still experiencing fast beating/I'm still experiencing pounding heart), DYSPNOEA (I'm still experiencing shortness of breath) and PYREXIA (Fever (39°C)). The NFD test showed that the patient had myocarditis. The myocarditis was confirmed 3 days later by altered levels of "troponin I" and an MRT. The heart functionality got back to normal around the end of October No concomitant medications were reported.	
4.1(b)	4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b) on 28-Dec-2021	26-year-old male with medical history of supraventricular tachycardia, obesity, congenital diaphragmatic

Case ID	WW Identifier	Narrative	MAH Comment
	4.1(b)	and was forwarded to Moderna on 28-Dec-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of CARDIAC FAILURE (Cardiac failure), CHEST X-RAY (Chest X-ray), CHEST PAIN (Chest pain), COMPUTERISED TOMOGRAM THORAX ABNORMAL (Computerised tomogram thorax abnormal), ELECTROCARDIOGRAM (Electrocardiogram), HAEMATOLOGY TEST (Haematology test), HILAR LYMPHADENOPATHY (Hilar lymphadenopathy), LEFT ATRIAL ENLARGEMENT (Left atrial enlargement), LUNG DISORDER (Lung disorder), MEDIASTINITIS (Mediastinitis), PAIN (Pain), PAIN IN EXTREMITY (Pain in extremity), PLEURAL EFFUSION (Pleural effusion), PULMONARY OEDEMA (Pulmonary oedema), TISSUE INFILTRATION (Tissue infiltration), TROPONIN INCREASED (Troponin increased) and MYOCARDITIS (Myocarditis) in a 26-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for an unknown indication. The patient's past medical history included Asthma, Supraventricular tachycardia (SVT), Myopia, Obesity, Vitamin D deficiency and Congenital diaphragmatic hernia. Concurrent medical conditions included House dust mite allergy. On 06-Dec-2021, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 13-Dec-2021, the patient experienced CARDIAC FAILURE (Cardiac failure) (seriousness criteria hospitalization and medically significant), CHEST X-RAY (Chest X-ray) (seriousness criterion hospitalization), CHEST PAIN (Chest pain) (seriousness criterion hospitalization), COMPUTERISED TOMOGRAM	hernia and allergy, who 7 days after the 3rd dose of Spikevax experienced chest pain, pain, pain in extremity and was found to have pleural effusion that was consistent with pulmonary edema due to heart failure or associated viral mediastinitis, and troponin was also increased. This report is heavily confounded due to the patient's medical history of supraventricular tachycardia, obesity, and congenital diaphragmatic hernia. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and EKG results; a causal relationship cannot be excluded.

Case ID	WW Identifier	Narrative	MAH Comment
		THORAX ABNORMAL (Computerised tomogram thorax abnormal) (seriousness criterion hospitalization), ELECTROCARDIOGRAM (Electrocardiogram) (seriousness criterion hospitalization), HAEMATOLOGY TEST (Haematology test) (seriousness criterion hospitalization), HILAR LYMPHADENOPATHY (Hilar lymphadenopathy) (seriousness criterion hospitalization), LEFT ATRIAL ENLARGEMENT (Left atrial enlargement) (seriousness criterion hospitalization), LUNG DISORDER (Lung disorder) (seriousness criterion hospitalization), MEDIASTINITIS (Mediastinitis) (seriousness criteria hospitalization and medically significant), PAIN (Pain) (seriousness criterion hospitalization), PAIN IN EXTREMITY (Pain in extremity) (seriousness criterion hospitalization), PLEURAL EFFUSION (Pleural effusion) (seriousness criterion hospitalization), PULMONARY OEDEMA (Pulmonary oedema) (seriousness criteria hospitalization and medically significant), TISSUE INFILTRATION (Tissue infiltration) (seriousness criterion hospitalization), TROPONIN INCREASED (Troponin increased) (seriousness criterion hospitalization) and MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, CARDIAC FAILURE (Cardiac failure), CHEST X-RAY (Chest X-ray), CHEST PAIN (Chest pain), COMPUTERISED TOMOGRAM THORAX ABNORMAL (Computerised tomogram thorax abnormal), ELECTROCARDIOGRAM (Electrocardiogram), HAEMATOLOGY TEST (Haematology test), HILAR LYMPHADENOPATHY (Hilar lymphadenopathy), LEFT ATRIAL ENLARGEMENT (Left atrial enlargement), LUNG DISORDER (Lung disorder), MEDIASTINITIS (Mediastinitis), PAIN (Pain), PAIN IN EXTREMITY (Pain in extremity),	

Case ID	WW Identifier	Narrative	MAH Comment
		PLEURAL EFFUSION (Pleural effusion), PULMONARY OEDEMA (Pulmonary oedema), TISSUE INFILTRATION (Tissue infiltration), TROPONIN INCREASED (Troponin increased) and MYOCARDITIS (Myocarditis) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 14-Dec-2021, Chest X-ray: result not reported Result not reported. On 14-Dec-2021, Haematology test: result not reported Result not reported. On 15-Dec-2021, Computerised tomogram thorax: abnormal The result showed combination of airspace disease, interlobular septal thickening, and bilateral simple attenuating pleural effusions that were most consistent with pulmonary edema due to heart failure. The left atrium was borderline enlarged. The findings were most consistent with the clinical diagnosis of myo-pericarditis. There was a mildly enlarged bilateral hilar lymph nodes, likely related to pulmonary edema. Mediastinal soft tissue infiltration was likely related to patient's pulmonary edema or associated viral mediastinitis.. On 15-Dec-2021, Electrocardiogram: result not reported Result not reported. On 15-Dec-2021, Troponin: 22 22. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Concomitant medications were not reported. Treatment medications were not reported. The patient had burning chest pain radiating to arms. This is a regulatory case concerning a 26-year-old male patient with relevant medical history of supraventricular tachycardia,	

Case ID	WW Identifier	Narrative	MAH Comment
		obesity, congenital diaphragmatic hernia and allergy, who experienced the serious expected AESI event of myocarditis, serious unexpected AESI events of cardiac failure, mediastinitis, pulmonary oedema, and serious unexpected events of chest X-ray, chest pain, computerised tomogram thorax abnormal, electrocardiogram, haematology test, hilar lymphadenopathy, left atrial enlargement, lung disorder, pain, pain in extremity, pleural effusion, tissue infiltration and troponin increased. The events occurred 8 days after the third dose of mRNA-1273 vaccine administration. The events were assessed as related to the product administration. The rechallenge was not applicable since the events occurred after the third dose and no further dosing is expected. The medical history of supraventricular tachycardia, obesity, congenital diaphragmatic hernia and allergy considered as confounders. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.	
4.1(b)	4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b) on 28-Dec-2021 and was forwarded to Moderna on 28-Dec-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of ELECTROCARDIOGRAM ST SEGMENT ELEVATION (Electrocardiogram ST segment elevation), MYOCARDITIS (Myocarditis), PERICARDITIS (Pericarditis), CHEST PAIN (Chest pain), BLOOD CREATINE PHOSPHOKINASE MB INCREASED (Blood creatine phosphokinase MB increased), BLOOD CREATINE PHOSPHOKINASE NORMAL (Blood creatine phosphokinase normal), CHEST X-RAY NORMAL (Chest X-ray normal), COMPUTERISED TOMOGRAM THORAX NORMAL (Computerised tomogram thorax normal), ECHOCARDIOGRAM	19 years old male with unknown medical history who the next day after the 2nd dose experienced chest pain and was found to have elevated troponin, and abnormal EKG, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and EKG results; a causal relationship cannot be excluded.

Case ID	WW Identifier	Narrative	MAH Comment
		NORMAL (Echocardiogram normal), FULL BLOOD COUNT NORMAL (Full blood count normal), SARS-COV-2 TEST NEGATIVE (SARS-CoV-2 test negative) and TROPONIN INCREASED (Troponin increased) in a 19-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for an unknown indication. Concurrent medical conditions included Allergy to nuts and Oil allergy. On 27-Apr-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 27-Apr-2021, the patient experienced ELECTROCARDIOGRAM ST SEGMENT ELEVATION (Electrocardiogram ST segment elevation) (seriousness criteria hospitalization and medically significant), MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant), PERICARDITIS (Pericarditis) (seriousness criteria hospitalization and medically significant), CHEST PAIN (Chest pain) (seriousness criterion hospitalization), BLOOD CREATINE PHOSPHOKINASE MB INCREASED (Blood creatine phosphokinase MB increased) (seriousness criterion hospitalization), BLOOD CREATINE PHOSPHOKINASE NORMAL (Blood creatine phosphokinase normal) (seriousness criterion hospitalization), CHEST X-RAY NORMAL (Chest X-ray normal) (seriousness criterion hospitalization), COMPUTERISED TOMOGRAPH THORAX NORMAL (Computerised tomogram thorax normal) (seriousness criterion hospitalization), ECHOCARDIOGRAM NORMAL (Echocardiogram normal) (seriousness criterion hospitalization), FULL BLOOD COUNT NORMAL (Full blood count normal) (seriousness criterion hospitalization),	

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

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

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

Case ID	WW Identifier	Narrative	MAH Comment
		On 10-Oct-2021, the patient received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form once a day. On 15-Oct-2021, after starting mRNA-1273 (COVID-19 Vaccine Moderna), the patient experienced MYOCARDITIS (Post-vaccine myopericarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Post-vaccine myopericarditis) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 17-Oct-2021, Electrocardiogram: normal (normal) Regular sinus rhythm at 82 bpm, normal axis at 64. On 18-Oct-2021, Echocardiogram: normal (normal) Left ventricle not dilated, not hypertrophied. On 20-Oct-2021, Echocardiogram: normal (normal) Sinus rhythm 85/min, normal axis, no hypertension. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered MYOCARDITIS (Post-vaccine myopericarditis) to be possibly related. Concomitant product use was not provided by the reporter. The patient was in usual good health. On 17-Oct-2021 patient was hospitalized for finding of perimyocarditis and admitted to intensive care on due to post-vaccination myopericarditis. Patient was subsequently developed a slight flu-like syndrome at 3.10 pm as well as transfixing chest pains with regard to the xyphoid appendix, of varying intensity, associated with nausea. The electrocardiogram and the cardiac enzyme assessment are compatible with myopericarditis. Simple pain relief was introduced. The transthoracic echocardiography	for myocarditis confirming the diagnosis of myocarditis. According to the WHO causality assessment this report is probable based on temporal association between the use of the product and the start of the events, a causal relationship cannot be excluded.

Case ID	WW Identifier	Narrative	MAH Comment
		showed a contractile segmentation and global normal function of the left ventricle and an absence of pericardial panicum. A beta-blocker treatment was introduced in small doses. A ban from moderate to intensive sport for 3 to 6 months was recommended. The patient was transferred from intensive care to pediatrics at 19-Oct-2021 and then following a cardiological consultation in the hospital at 20-Oct-2021. Pediatric cardiologist on 20-Oct-2021 stated that the patient showed a practically normal echocardiography, just with the most sensitive measurements (strain) there was the suspicion of a slight decrease in systolic function in the posterolateral regions of the left ventricle. With the elevation of troponin (672 ng/L), CK (632 U/L) and CK-MB (67 U/L) cardiac MRI was recommended. On 03-Dec-2021 the referring physician also reported again, confirmation from the doctor who on MRI stated that this examination showed small sequelae of the myocardium typical for myocarditis. The diagnosis of vaccine myocarditis therefore be confirmed. Patient took beta-blocker as a treatment medication. Most recent FOLLOW-UP information incorporated above includes: On 30-Dec-2021: Translation received on 04-Jan-2022 that contains patient laboratory data and inarrative updated.	
4.1(b)	4.1(b)	This case was received via an unknown source (no reference has been entered for a health authority or license partner) on 30-Dec-2021 and was forwarded to Moderna on 30-Dec-2021. This regulatory authority case was reported by a consumer and describes the occurrence of DYSPNOEA (I missed my breath), CHEST DISCOMFORT (weight on the sternum), FATIGUE (weariness) and PERICARDITIS (pericarditis) in a	Consumer report for a 38 year-old female with medical history of two episodes of deep vein thrombosis, who 17 days after the 2nd dose of Spikevax experienced dyspnoea, chest discomfort and fatigue and was found to have an abnormal ECG. No other information was provided. Important information is missing in the report including patient's full medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to

Case ID	WW Identifier	Narrative	MAH Comment
		38-year-old female patient who received mRNA-1273 (COVID-19 Vaccine Moderna) (batch nos. 3003660 and 3003660) for COVID-19 vaccination. The patient's past medical history included Thrombosis (deep vein thrombosis in 2017 and 2020 in the lower limbs). Concurrent medical conditions included Lactose intolerance. On 09-Jun-2021, the patient received dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form once a day. On 20-Jul-2021, received dose of mRNA-1273 (COVID-19 Vaccine Moderna) (unknown route) dosage was changed to 1 dosage form. On 06-Aug-2021, the patient experienced DYSPNOEA (I missed my breath) (seriousness criterion medically significant), CHEST DISCOMFORT (weight on the sternum) (seriousness criterion medically significant), FATIGUE (weariness) (seriousness criterion medically significant) and PERICARDITIS (pericarditis) (seriousness criterion medically significant). At the time of the report, DYSPNOEA (I missed my breath), CHEST DISCOMFORT (weight on the sternum), FATIGUE (weariness) and PERICARDITIS (pericarditis) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 20-Aug-2021, Electrocardiogram: pericardite (abnormal) pericardite. No concomitant medication was provided by reporter. Patient was without allergy (slight lactose intolerance), with a history of deep vein thrombosis (anticoagulants taken until October 2020). No therapy was currently underway. Not a smoker and alcohol consumer rarely. About 10 days after the second dose, walking in the mountains she missed	the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events. A causal relationship cannot be excluded due to the lack of information.

Case ID	WW Identifier	Narrative	MAH Comment
		her breath and felt a burden on the sternum. The patient thought it was simply due to post-vaccine tiredness, but the feeling comes up even if only by stairs. On 20-Aug-2021 she went to the doctor as the symptomatology persists and with an ECG the doctor diagnoses a pericarditis in the healing phase and treats it with 10 days of ibuprofen 600 mg 2 times a day. The patient was said to be active and often goes to the mountains and specifies that in 4.1(b) 2020 he had done an exertion of the heart that showed no pathologies. The symptomatology was getting better. Company comment: This is a regulatory case concerning a 38 year-old, female patient with a history of two episodes of deep vein thrombosis, who experienced the serious (due to medically important condition) expected, according CCDS, AESI of pericarditis and the serious (due to medically important condition) unexpected, according CCDS, events of dyspnoea, chest discomfort and fatigue. The events occurred approximately 17 days after the second dose of mRNA-1273 vaccine. The outcome of the events was reported as recovering. An electrocardiogram was performed and a diagnosis of pericarditis was made, patient received treatment with ibuprofen. The rechallenge was not applicable, as the events were reported exclusively after the second dose and no information on additional dosing is available. The medical history, of two episodes of deep vein thrombosis remains a confounder. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.	
4.1(b)	4.1(b)	This regulatory authority case was reported by a physician and describes the occurrence of PERICARDITIS (pericarditis) in a 31-year-old patient of an unknown gender who received mRNA-1273 (Moderna CoviD-19 Vaccine) for COVID-19 vaccination.	31 years old of unknown gender and unknown medical history who 54 days after the 2nd dose of Spikevax was found to have pericardial friction with mitral focus, ECG abnormal, CRP elevated, troponin elevated and fibrin d-dimmer elevated and was diagnosed with pericarditis. According to the WHO causality

Case ID	WW Identifier	Narrative	MAH Comment
		No Medical History information was reported. In August 2021, the patient received first dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (Intramuscular) 1 dosage form once a day. On 01-Sep-2021, received second dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 24-Oct-2021, the patient experienced PERICARDITIS (pericarditis) (seriousness criterion medically significant). At the time of the report, PERICARDITIS (pericarditis) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Blood test: gb = 7320 including 54% pnn, crp <5 rets bs normal GB = 7320 including 54% PNN, CRP <5 rets BS normal. On an unknown date, Electrocardiogram: sinus, regular. discrete sus st (<2mm) sinus, regular. discrete sus ST (<2mm). For mRNA-1273 (Moderna CoviD-19 Vaccine) (Intramuscular), the reporter considered PERICARDITIS (pericarditis) to be related. Concomitant product use was not provided by the reporter. Patient is 31 years old, unknown sex, weight 75 kg, height 185 cm. Performed the second dose of Spikevax on 01-Sep-2021. First dose presumably performed in August 2021 (date not indicated). On 24-Oct-2021 the patient experienced pericarditis. The doctor's examination reports: patient was conscious, oriented. No sensitivomotor deficit. Glasgow Score 4Y + 5V + 6M = 15. Symmetrical and reactive pupils. Headache. Examine cardios: Regular heart sounds, no murmur, pericardial friction with mitral focus +++ Distal pulses present and symmetrical . Tests performed ECG: sinus, regular.	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.

Case ID	WW Identifier	Narrative	MAH Comment
		discrete sus ST (<2mm) in V2 / V3 - blood tests: GB = 7320 including 54% PNN, CRP <5 rets BS normal, too <10 and DDimeres = 211 <500. Reaction reported as severe. The symptoms are not resolved at the time of reporting. Further course not known. No treatment information was provided.	
4.1(b)	4.1(b)	This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS 4.1(b) in a 30-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination. Concurrent medical conditions included Smoker (Smoking:yes). On 15-Sep-2021, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form once a day. On 13-Oct-2021, received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) dosage was changed to 1 dosage form once a day. In October 2021, the patient experienced MYOCARDITIS 4.1(b) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS 4.1(b) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In October 2021, Echocardiogram: not reported (Inconclusive) test_result: TTE 4.1(b) In October 2021, Electrocardiogram: abnormal (abnormal) test_result: 4.1(b) EKG-4.1(b) In October 2021, Troponin: high (High) test_result: 4.1(b) For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered MYOCARDITIS 4.1(b) to be possibly related.	30 years old male with unknown medical history who at an unknown TTO after the 2nd dose was found to have elevated troponin, and abnormal EKG, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and EKG results; a causal relationship cannot be excluded.

Case ID	WW Identifier	Narrative	MAH Comment
		No concomitant medications were reported. Patient had No known pathologies, known smoker and rarely drinks alcohol. First dose presumably performed in September. In close time correlation with the vaccine (report sent on 19/10) he experiences myocarditis called 4.1(b) not serious'. Patient relevant Examinations performed was reported as Low ECG modification, increased troponin (high), irrelevant TTE. The reaction is reported to be severe and that caused hospitalization. The symptoms are not resolved at the time of reporting. Further course not known.	
4.1(b)	4.1(b)	This regulatory authority case was reported by a physician and describes the occurrence of CHEST PAIN (Chest Pain), PERICARDIAL RUB (pericardial), TACHYCARDIA (tachycardia), COUGH (tachycardia), PYREXIA (fever), FATIGUE (tiredness) and MYOCARDITIS (myocarditis) in an 18-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) (batch nos. 1. + 2. 4.1(b) 300 29 18 and 1. + 2. 4.1(b) 300 29 18) for COVID-19 vaccination. No Medical History information was reported. On 18-Jun-2021, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form once a day. On 16-Jul-2021, received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) dosage was changed to 1 dosage form. On 16-Jul-2021, the patient experienced CHEST PAIN (Chest Pain) (seriousness criterion medically significant), PERICARDIAL RUB (pericardial) (seriousness criterion medically significant), TACHYCARDIA (tachycardia)	18 years old male with unknown medical history who 2 days after the 2nd dose of Spikevax experienced fever, fatigue, chest pain, tachycardia, cough and found to have elevated troponin, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test 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.

Case ID	WW Identifier	Narrative	MAH Comment
		(seriousness criterion medically significant), COUGH (tachycardia) (seriousness criterion medically significant), PYREXIA (fever) (seriousness criterion medically significant), FATIGUE (tiredness) (seriousness criterion medically significant) and MYOCARDITIS (myocarditis) (seriousness criterion medically significant). On 05-Aug-2021, CHEST PAIN (Chest Pain), PERICARDIAL RUB (pericardial), TACHYCARDIA (tachycardia), COUGH (tachycardia), PYREXIA (fever), FATIGUE (tiredness) and MYOCARDITIS (myocarditis) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In 2021, Fibrin D dimer: negative (Negative) test_result = 4.1(b) In 2021, Laboratory test: test 10061576 (24.1) troponin (2021): troponin; te TEST 10061576 (24.1) troponin (2021): troponin; TEST 10016577 (24.1) D-dimers (2021): D-dimers neg.. In 2021, Troponin: negative (Negative) test_result = 4.1(b) For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered CHEST PAIN (Chest Pain), PERICARDIAL RUB (pericardial), TACHYCARDIA (tachycardia), COUGH (tachycardia), PYREXIA (fever), FATIGUE (tiredness) and MYOCARDITIS (myocarditis) to be related. Concomitant product was not provided by the reporter Patient was of 18 years, no pathology, pharmacotherapy, allergy, non-smoker and non-alcohol user, received Spikevax on 18-JUN-2021 and 16-JUL-2021 Two days after the last injection, on 16-JUL-2021, had developed myocarditis with fever, fatigue, chest pain, tachycardia, cough and 4.1(b) The patient, after 21 days, was said to	

Case ID	WW Identifier	Narrative	MAH Comment
		had recovered. ADDITIONAL DOCUMENTS: Source of this Case Safety Report in E2B (R3) Format: Additional documents;; Source of this Case Safety Report in E2B (R2) Format Lab data was provided as unknown with result as TEST 10061576 (24.1) troponin (2021): troponin; TEST 10016577 (24.1) D-dimers (2021): D-dimers neg on unknown date Treatment product was not provided by the reporter Company comment: This regulatory authority case concerns a 18-year-old male patient with no relevant medical history who experienced serious unexpected events of chest pain, pericardial rub, tachycardia, cough, pyrexia, fatigue and expected myocarditis, that occurred on the same day after the 2nd dose of the mRNA-1273 . No further details regarding the events were provided. The patient recovered 3 weeks later. The rechallenge was not applicable due to occurrence after the 2nd dose. The benefit-risk relationship of mRNA-1273 is not affected by this report.	
4.1(b)	4.1(b)	This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b)) on 09-Dec-2021 and was forwarded to Moderna on 14-Dec-2021. This case, initially reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by a physician, was received via the PMDA (Ref, 4.1(b)) The patient was receiving insulin degludec and insulin aspar as insulin injections. On an unspecified date in Jul-2021, the patient initiated the treatment with maintenance dialysis for diabetic nephropathy and continued maintenance dialysis. On 02-Sep-2021, the patient received the 1st dose of this vaccine.	38 years old male with medical history of Diabetes mellitus; Diabetic nephropathy; Diabetic retinopathy; Hypertension; and Dyslipidaemia and who was on dialysis for diabetic nephropathy. Patient 7 days after the 1st dose of Spikevax experienced dyspnea and was cardiopulmonary arrest on his way to the hospital. Patient's ECG showed ventricular fibrillation, he was hypotense, and had pericardial effusion detected by echo; had elevated troponin T and CKMB. He was diagnosed with a cardiac tamponade, myocarditis and pericarditis. The next day patient was found to have severe hypoxic encephalopathy and died two days later. The cause of death was reported to be multi-organ failure, and cardiac tamponade from acute pericarditis and myocarditis was considered to be the cause of the cardiopulmonary arrest. It is unknown if an autopsy was performed. No

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

Case ID	WW Identifier	Narrative	MAH Comment
		encephalopathy, and multi-organ failure was reported as fatal. Follow-up investigation will be made. Company Comment: The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	

20.11.12. Myocarditis/Pericarditis: CDC working case Definition: Case Listings

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

4.1(b)

Myocarditis	Serious	Myocarditis, Ventricular dysfunction	21	Male	Recovering/Resolving	Tobacco user(H)		2	2	Probable
Myocarditis	Serious	Dyspnoea, Myocarditis	25	Male	Recovering/Resolving			2	5	Probable
Myocarditis	Serious	Asthenia, Chest discomfort, Chest pain, Chills, Influenza like illness, Myocarditis, Presyncope, Vomiting	33	Male	Recovered/Resolved			2	1	Probable
Pericarditis	Serious	Chest pain, Pericarditis, Pyrexia	18	Female	Recovering/Resolving			2	1	Probable
Myocarditis	Serious	Myocarditis	18	Male	Recovered/Resolved			2	2	Probable
Myocarditis	Serious	Chest pain, Malaise, Myocarditis	29	Male	Not Recovered/Not Resolved			2	0	Probable
Myocarditis	Serious	Myocarditis, Pyrexia	18	Male	Recovering/Resolving			2	3	Probable
Myocarditis	Serious	Myocarditis, Pyrexia	18	Male	Recovering/Resolving			2	2	Confirmed
Pericarditis	Serious	Pericarditis	33	Male	Recovering/Resolving			2	0	Probable
Myocarditis	Serious	Myocarditis, Pyrexia	28	Male	Unknown			2	2	Probable
Myocarditis	Serious	Chest pain, Dyspnoea, Myocarditis, Palpitations, Pyrexia	23	Male	Recovering/Resolving			2	3	Probable
Myocarditis	Serious	Myocarditis, Ventricular extrasystoles	19	Female	Recovering/Resolving			2	0	Probable
Myocarditis	Serious	Myocarditis	19	Male	Recovering/Resolving			2	3	Probable
Myocarditis	Serious	Myocarditis	20	Male	Recovering/Resolving			2	2	Probable
Pericarditis	Serious	Myocarditis, Pericarditis	20	Male	Unknown			2	2	Probable
Pericarditis	Serious	Chest discomfort, Chest pain, Cough, Dyspnoea, Pericardial effusion, Pericarditis, Pyrexia	24	Male	Recovering/Resolving			2	1	Acute Pericarditis
Myocarditis	Serious	Chest pain, Myocarditis	18	Male	Unknown			2	2	Probable
Myocarditis	Serious	Acute myocardial infarction, Chest pain, Limb discomfort, Myocardial infarction, Myocarditis, Pain, Pain in extremity	37	Male	Unknown	Asthma(C); Arthritis(C); Drug hypersensitivity	SYMBICORT; 4.1(b) [SALBUTAMOL]; TYLENOL; IBUPROFEN	2	238	Probable
Myocarditis	Serious	Chest discomfort, Chest pain, Dyspnoea, Ejection fraction decreased, Myocardial oedema, Myocarditis, Pain, Pain in jaw, Pericardial effusion, Pericarditis, Pyrexia, Sleep disorder, Ventricular hypokinesia	21	Male	Recovered/Resolved		ASPIRIN (E.C.); COLCHICINE; IBUPROFEN; FENTANYL; METOPROLOL SUCCINATE	2	1	Probable
Myocarditis	Serious	Chest pain, Dyspnoea, Myocarditis	23	Male	Unknown			2	2	Probable
Myocarditis	Serious	Myocarditis, Pyrexia, Ventricular hypokinesia	18	Male	Recovering/Resolving			2	3	Probable
Pericarditis	Serious	Chest pain, Nausea, Pericarditis	19	Male	Unknown	Epilepsy(H)		2	1	Probable
Myocarditis	Serious	Chest pain, Myocarditis	18	Male	Recovered/Resolved			2	1	Probable
Myocarditis	Serious	Myocarditis	19	Male	Recovered/Resolved			2	0	Probable
Myocarditis	Serious	Myocarditis	22	Male	Unknown		IBUPROFEN	2	2	Probable
Myocarditis	Serious	Abdominal pain upper, Influenza like illness, Myocarditis	38	Male	Not Recovered/Not Resolved	Hypersensitivity; Nephrolithiasis(H); Hidradenitis(H); Ex-tobacco user(H)		2	0	Probable
Myocarditis	Serious	Myocarditis	25	Male	Recovered/Resolved			2	2	Probable
Myocarditis	Serious	Myocarditis	39	Male	Recovering/Resolving	Autoimmune thyroiditis(C)	EUTHYROX	2	2	Probable

4.1(b)

4.1(b)

Myocarditis	Serious	Myocarditis	29	Male	Recovering/Resolving	Adenoidectomy; Obesity(C); Drug hypersensitivity		2	1	Probable
Myocarditis	Serious	Enterocolitis, Myocarditis	26	Male	Recovering/Resolving	Hepatic function abnormal(C)		2	2	Probable
Myocarditis	Serious	Myocarditis, Pyrexia	22	Male	Recovering/Resolving			2	3	Probable
Myocarditis	Serious	Chest pain, Hyperhidrosis, Myocarditis	20	Male	Not Recovered/Not Resolved			2	3	Probable
Myocarditis	Serious	Medication error, Pericarditis	40	Male	Recovered/Resolved with Sequelae			2	8	Probable
Myocarditis	Serious	Chest pain, Myocarditis, Pericarditis	32	Male	Recovered/Resolved			2	4	Probable
Myocarditis	Serious	Chest pain, Myocarditis	25	Male	Unknown			2	3	Probable
Myocarditis	Serious	Chest pain, Myocarditis, Sensory disturbance	23	Male	Recovered/Resolved			2	2	Probable
Myocarditis	Serious	Chest pain, Myocarditis	34	Female	Recovered/Resolved			2	0	Probable
Myocarditis	Serious	Chills, Feeling abnormal, Myocarditis, Pyrexia	31	Male	Recovered/Resolved			2	3	Probable
Myocarditis	Serious	Myocarditis	22	Male	Recovered/Resolved	Drug hypersensitivity(H); Faropenem sodium(H)		2	1	Probable
Myocarditis	Serious	Myocarditis	27	Male	Recovered/Resolved			2	3	Probable
Myocarditis	Serious	Myocarditis	27	Male	Not Recovered/Not Resolved			2	4	Probable
Myocarditis	Serious	Myocarditis, Pyrexia	27	Male	Unknown			2	1	Probable
Myocarditis	Serious	Chest pain, Myocarditis, Pyrexia	25	Male	Recovered/Resolved			2	3	Probable
Myocarditis	Serious	Myocarditis	37	Male	Recovering/Resolving	Familial risk factorFH		2	3	Subclinical Probable
Myocarditis	Serious	Chest discomfort, Cough, Dyspnoea, Fatigue, Headache, Hyperhidrosis, Impaired work ability, Myocarditis, Pyrexia	19	Male	Recovering/Resolving	(H)		2	0	Probable
Myocarditis	Serious	Abdominal pain upper, Chest discomfort, Discomfort, Malaise, Musculoskeletal pain, Myocarditis, Pyrexia	21	Male	Recovering/Resolving	Asthma(C)		2	3	Probable
Myocarditis	Serious	Chest pain, Myocarditis	22	Male	Recovering/Resolving			2	4	Probable
Myocarditis	Serious	Myocarditis, Pericarditis	23	Male	Not Recovered/Not Resolved			2	2	Acute Pericarditis
Myocarditis	Serious	Myocarditis	30	Male	Recovering/Resolving			2	2	Probable
Myocarditis	Serious	Myocarditis, Pyrexia	37	Female	Not Recovered/Not Resolved	Palpitations(C)		2	7	acute pericarditis
Myocarditis	Serious	Myocarditis	35	Male	Recovering/Resolving	Tobacco user(C); Alcohol use(C); Seasonal allergy; Allergy to animal	DOXYCLIN [DOXYCYCLINE HYCLATE]	2	2	Probable
Myocarditis	Serious	Influenza like illness, Myocarditis	18	Male	Recovering/Resolving			2	2	Probable
Myocarditis	Serious	Abdominal pain upper, Chest pain, Malaise, Myocarditis, Palpitations, Pyrexia	21	Male	Recovering/Resolving	(H)		3	3	Probable
Myocarditis	Serious	Myocarditis	20	Male	Recovering/Resolving			2	3	Probable
Myocarditis	Serious	COVID-19 immunisation, Myocarditis	25	Male	Recovering/Resolving	Comirnaty		2	3	Probable
Myocarditis	Serious	Chest pain, COVID-19 immunisation, Pericarditis	33	Male	Unknown	COMIRNATY		2	0	acute pericarditis
Myocarditis	Serious	Chest pain, COVID-19 immunisation, Fatigue, General physical health deterioration, Myocarditis, Respiratory symptom	19	Male	Recovering/Resolving	Comirnaty; Comirnaty(H)		2	2	Probable

4.1(b)

4.1(b)	Myocarditis	Serious	Myocarditis	20	Male	Recovering/Resolving			2	1	Subclinical Probable	4.1(b)
	Myocarditis	Serious	Myocarditis	22	Male	Recovering/Resolving			2	3	Probable	
	Pericarditis	Serious	Chest discomfort, COVID-19 immunisation, Pericarditis	22	Male	Unknown			2	4	Probable	
	Myocarditis	Serious	Chest pain, Myocarditis, Tachycardia	22	Male	Unknown	Asthma(H)	ALVESCO; ZODAC	2	4	Confirmed	
	Myocarditis	Serious	Myocarditis	22	Male	Not Recovered/Not Resolved			2	2	Probable	
	Myocarditis	Serious	Chest discomfort, Myocarditis, Pain in jaw	26	Female	Unknown		MULTIVITAMIN [VITAMINS NOS]	2	3	Confirmed	
	Myocarditis	Serious	Abdominal pain upper, Cold sweat, COVID-19 immunisation, Influenza like illness, Myocarditis, Nausea, Vomiting	22	Male	Recovering/Resolving	Comirnaty(H)		2	2	Subclinical Probable	
	Pericarditis	Serious	COVID-19 immunisation, Pericarditis	35	Male	Unknown	Comirnaty(H)		2	3	Confirmed	
	Myocarditis	Serious	Chest pain, Myocarditis	18	Male	Recovering/Resolving	COMIRNATY(H)		2	3	Probable	
	Myocarditis	Serious	Chest pain, COVID-19 immunisation, Myocarditis	33	Male	Not Recovered/Not Resolved			2	4	Confirmed	
	Myocarditis	Serious	Chest pain, COVID-19 immunisation, Incorrect dose administered, Myocarditis	24	Male	Recovering/Resolving	Childhood asthma(C); Comirnaty(H)		2	2	Confirmed	
	Myocarditis	Serious	Chest pain, Myocarditis	29	Male	Recovering/Resolving			2	1	Probable	
	Myocarditis	Serious	Impaired work ability, Loss of personal independence in daily activities, Myocarditis	22	Male	Recovering/Resolving			2	1	Probable	
	Myocarditis	Serious	Myocarditis	33	Male	Not Recovered/Not Resolved	Alcohol use(C); Tobacco user(C)		2	42	Probable	
	Myocarditis	Serious	Abdominal pain, Chest pain, Headache, Limb discomfort, Myocarditis, Pyrexia	37	Male	Recovering/Resolving			2	4	Probable	
	Pericarditis	Serious	Pericarditis	28	Male	Unknown			2	1	Probable	
	Pericarditis	Serious	Pericarditis	28	Male	Recovered/Resolved			2	1	Probable	
	Myocarditis	Serious	Myocarditis, Pericarditis	26	Male	Recovering/Resolving			2	3	Confirmed	
	Pericarditis	Serious	Myocarditis, Pericarditis	26	Male	Recovering/Resolving			2	1	Confirmed	
	Myocarditis	Serious	Myocarditis	20	Male	Recovering/Resolving			2	2	Probable	
	Myocarditis	Serious	Myocarditis	25	Male	Recovering/Resolving			2	3	Probable	
	Myocarditis	Serious	Chest pain, Dyspnoea, Electrocardiogram change, Myocarditis, Troponin I increased	19	Male	Recovering/Resolving			2	1	Probable	
	Myocarditis	Serious	Myocarditis	18	Male	Recovered/Resolved			2	1	Probable	
	Myocarditis	Serious	Myocarditis, Pyrexia	23	Male	Unknown			2	2	Probable	
	Pericarditis	Serious	Abdominal distension, C-reactive protein increased, Chest discomfort, Chest pain, Cough, Deep vein thrombosis, Discomfort, Dizziness, Dyspnoea, Ejection fraction decreased, Hyperhidrosis, Myalgia, Myocarditis, Pain, Pain in extremity, Pericardial effusion, Pericardial fibrosis, Pericarditis, Peripheral swelling, Pyrexia, Red blood cell sedimentation rate increased, Troponin increased	30	Male	Not Recovered/Not Resolved	Dyslipidaemia(H)		2	1	Probable	

4.1(b)

Myocarditis	Serious	Abdominal distension, C-reactive protein increased, Chest discomfort, Chest pain, Cough, Deep vein thrombosis, Discomfort, Dizziness, Dyspnoea, Ejection fraction decreased, Hyperhidrosis, Myalgia, Myocarditis, Pain, Pain in extremity, Pericardial effusion, Pericardial fibrosis, Pericarditis, Peripheral swelling, Pyrexia, Red blood cell sedimentation rate increased, Troponin increased	30	Male	Not Recovered/Not Resolved	Dyslipidaemia(H)		2	1	Probable	
Pericarditis	Serious	Chest pain, Myocarditis, Palpitations, Pericarditis	35	Female	Not Recovered/Not Resolved	Food allergy		2	111	Probable	4.1(b)
Myocarditis	Serious	Chest pain, Myocarditis, Palpitations, Pericarditis	35	Female	Not Recovered/Not Resolved	Food allergy		2	111	Probable	
Myocarditis	Serious	Chest pain, Malaise, Myocarditis, Pyrexia	25	Male	Recovering/Resolving	Migraine(H); COMIRNATY; COVID-19 immunisation	ISOPTIN [VERAPAMIL]	2	3	Confirmed	
Myocarditis	Serious	Myocarditis	20	Male	Recovered/Resolved			2	4	Probable	
Myocarditis	Serious	Myocarditis	20	Male	Recovered/Resolved			2	2	Probable	
Myocarditis	Serious	Myocarditis	24	Male	Recovering/Resolving	Tobacco user(C)		2	2	Probable	
Myocarditis	Serious	Dyspnoea, Myocarditis, Palpitations	27	Male	Not Recovered/Not Resolved			2	2	Probable	
Myocarditis	Serious	Chest crushing, Chest discomfort, Chest pain, Hyperdynamic left ventricle, Myalgia, Myocarditis, Painful respiration, Pleuritic pain, Pyrexia	21	Male	Unknown	Asthma(C); Depression(C)		2	2	Probable	
Myocarditis	Serious	Arthralgia, Chest discomfort, Headache, Malaise, Myocarditis	20	Male	Recovering/Resolving	Seasonal allergy		2	4	Probable	
Myocarditis	Serious	Chest pain, Chills, Headache, Myocarditis	26	Male	Recovered/Resolved			2	2	Probable	
Myocarditis	Serious	Chest pain, Inappropriate schedule of product administration, Myocarditis	28	Male	Recovering/Resolving	Tobacco user(C)		2	3	Probable	
Myocarditis	Serious	Myocarditis	20	Male	Unknown			2	1	Probable	
Myocarditis	Serious	Myocarditis	21	Male	Unknown	Non-tobacco user(H)		2	1	Probable	
Myocarditis	Serious	Myalgia, Myocarditis, Pyrexia	21	Male	Not Recovered/Not Resolved	Tobacco user(C)		2	4	Probable	
Myocarditis	Serious	Chest discomfort, Chest pain, Left ventricular dysfunction, Myocarditis, Nasopharyngitis, Pericarditis, Sleep disorder, Stress	23	Male	Recovered/Resolved	Dyspnoea(C); Asthma(C); Depression(H)	4.1(b) [SALBUTAMOL]	2	2	Probable	
Myocarditis	Serious	Chest pain, Chills, Fatigue, Myalgia, Myocarditis, Nausea	27	Male	Recovered/Resolved	Food allergy	BUPROPION	2	4	Probable	
Myocarditis	Serious	Chest pain, Myocarditis	28	Male	Recovering/Resolving	Myocarditis(H); Familial risk factor(H); Seasonal allergy; Non-tobacco user(C)		2	3	Probable	
Myocarditis	Serious	Chest pain, Myocarditis, Product administered to patient of inappropriate age	17	Male	Recovered/Resolved	Type 1 diabetes mellitus(C)	INSULIN	1	1	Probable	
Myocarditis	Serious	Chest pain, Myocarditis, Palpitations, Product administered to patient of inappropriate age, Vaccination complication	15	Female	Recovered/Resolved	Tic(C)	GUANFACINE	Unknown	1	Probable	
Myocarditis	Serious	Myocarditis, Pyrexia	16	Male	Recovering/Resolving			2	2	Confirmed	
Pericarditis	Serious	Chest pain, Pericarditis, Pyrexia	14	Male	Recovering/Resolving			2	1	acute pericarditis	
Myocarditis	Serious	Chest pain, COVID-19 immunisation, Myocarditis	17	Female	Recovering/Resolving	Comirnaty(H)		2	0	Probable	
Myocarditis	Serious	Chest pain, Chills, Myalgia, Myocarditis, Pyrexia	28	Male	Recovered/Resolved	Not reported	VITAMIN D [VITAMIN D NOS]; FISH OIL; SIMVASTATIN	2	32	Probable	
Myocarditis	Serious	Cardiac arrest, Inappropriate schedule of product administration, Myocarditis, Pyrexia, Vaccination complication	55	Male	Recovering/Resolving	Hypertension(C)		2	5	Probable	
Pericarditis	Serious	Chest pain, Dyspnoea, Myocarditis, Nausea, Pericarditis	37	Male	Recovering/Resolving	Drug hypersensitivity	IBUPROFEN; PARACETAMOL; CARVEDILOL	2	31	Probable	

4.1(b)

Myocarditis	Serious	Chest pain, Dyspnoea, Myocarditis, Nausea, Pericarditis	37	Male	Recovering/Resolving	Drug hypersensitivity	IBUPROFEN; PARACETAMOL; CARVEDILOL	2	31	Probable	
Myocarditis	Serious	Chest pain, Myocarditis, Pyrexia	32	Male	Recovering/Resolving	Not reported		2	5	Probable	
Myocarditis	Serious	Myocarditis	20	Male	Recovering/Resolving	Not reported		2	3	Probable	
Myocarditis	Serious	Myocarditis	27	Male	Not Recovered/Not Resolved	Not reported		2	2	Probable	
Myocarditis	Serious	Back pain, Chest pain, Dyspnoea, Myocarditis, Tachycardia	19	Male	Recovered/Resolved	Not reported	ZOLOFT	2	2	Probable	
Myocarditis	Serious	Chest pain, Myocarditis, Pyrexia	19	Male	Unknown	Type 1 diabetes mellitus(C); Dyslipidaemia(C)	INSULIN GLARGINE; INSULIN REGULAR [INSULIN BOVINE]; ZOCOR	2	1	Confirmed	
Myocarditis	Serious	Chest discomfort, Myocarditis, Pain	20	Male	Unknown	Not reported	4.1.1 4.1.1 XR ER; [DEXMETHYLPHENIDAT E HYDROCHLORIDE]; MINOCYCLINE	2	1	Confirmed	
Myocarditis	Serious	Chest pain, Myocarditis, Nausea, Sinus bradycardia, Vomiting	18	Male	Recovered/Resolved	Not reported		2	0	Probable	
Myocarditis	Serious	Chest pain, Myocarditis, Nausea	32	Male	Recovered/Resolved	Not reported	PROBIOTICS NOS	2	1	Probable	
Myocarditis	Serious	Chest discomfort, Chest pain, Headache, Lymphadenopathy, Myocarditis, Tachycardia	24	Male	Not Recovered/Not Resolved	Not reported		2	0	Probable	
Myocarditis	Serious	Acute myocardial infarction, Coronary artery disease, Myocarditis	52	Male	Unknown	Not reported		2	5	Confirmed	
Myocarditis	Serious	Myocarditis, Vaccination site reaction	36	Male	Not Recovered/Not Resolved	Not reported		2	3	Probable	
Myocarditis	Serious	Hyperthyroidism, Inappropriate schedule of product administration, Myocarditis	33	Male	Not Recovered/Not Resolved	Nicotine dependence(C); Overweight(C)		2	2 days	Probable	
Myocarditis	Serious	Myocarditis, Pericardial effusion	23	Male	Recovering/Resolving	Not reported	NEXIUM; AJOVY [FREMANEZUMAB VFRM]	2	4 days	Confirmed	
Myocarditis	Serious	Chest discomfort, Dyspnoea, Myocarditis	25	Male	Unknown	Not reported		2	3 days	Probable	
Myocarditis	Serious	Chest pain, Myocarditis	23	Male	Recovered/Resolved	Gout(C)	COLCHICINE; FAMOTIDINE	2	2 days	Probable	
Myocarditis	Serious	Myocarditis	36	Male	Not Recovered/Not Resolved	Not reported		2	2 days	Probable	
Pericarditis	Serious	Chest pain, Pericardial effusion, Pericarditis, Pleuritic pain	75	Male	Recovered/Resolved	Rhinitis allergic(C); Hypertension(C); Hyperlipidaemia(C)	ATENOLOL; MONTELUKAST; ROSUVASTATIN; OLMESARTAN; TAMSULOSIN; ACETYSALICYLIC ACID	2	0 day	Acute Pericarditis	
Myocarditis	Serious	Myocarditis	35	Male	Unknown	Not reported		2	1 day	Probable	
Myocarditis	Serious	Chest pain, Fatigue, Headache, Myocarditis, Pain, Sinus tachycardia	20	Male	Unknown	Not reported		2	0 day	Probable	
Myocarditis	Serious	Chest discomfort, Chest pain, Headache, Malaise, Myocarditis, Nausea, Painful respiration, Pyrexia	21	Male	Unknown	Not reported	FLONASE [FLUTICASONE PROPIONATE]	2	4 days	Probable	
Myocarditis	Serious	Chest pain, Myocarditis	20	Male	Recovered/Resolved	Drug hypersensitivity(C); Autism spectrum disorder(C)		2	2 days	Probable	
Viral myocarditis	Serious	Chest pain, Chills, Hyperhidrosis, Pain, Sinus bradycardia, Syncope, Ventricular extrasystoles, Viral myocarditis	23	Male	Recovered/Resolved	Drug hypersensitivity; Asthma(C)	VITAMIN D [VITAMIN D NOS]	2	3 days	Probable	
Myocarditis	Serious	Chest pain, Myocarditis	21	Male	Unknown	Not reported		2	2 days	Confirmed	
Myocarditis	Serious	Chest pain, Myocarditis, Thrombosis	23	Male	Recovered/Resolved	Not reported		2	3 days	Probable	
Pericarditis	Serious	Chest discomfort, General symptom, Pericarditis, Pleuritic pain	20	Male	Not Recovered/Not Resolved	Not reported		2	1 day	Acute Pericarditis	
Myocarditis	Serious	Dyspnoea, Malaise, Myocarditis, Pyrexia	37	Male	Recovered/Resolved	Factor V Leiden carrier(C); Drug hypersensitivity	TYLENOL	2	1 day	Confirmed	

4.1(b)

Myocarditis	Serious	Chest pain, Myocarditis	24	Male	Recovered/Resolved	Zoonotic bacterial infection(C); Bronchial hyperreactivity(C); Back pain(C)		2	3 days	confirmed	
Myocarditis	Serious	Chest pain, Incorrect route of product administration, Myocarditis, Pain, Painful respiration, Sleep disorder	18	Male	Unknown	Asthma exercise induced(H)		2	2 days	Confirmed	
Myocarditis	Serious	Chest pain, Dyspnoea, Fatigue, Myocarditis	46	Male	Not Recovered/Not Resolved	Post-traumatic stress disorder(C); Anxiety(C)	ESCITALOPRAM; VYVANSE; BUPROPION; OMEGA-3 FISH OIL; ALPRAZOLAM; ROSUVASTATIN; PRAZOSIN; CETIRIZINE; FAMOTIDINE	2	1 day	Confirmed	
Myocarditis	Serious	Chest pain, Dyspnoea, Myocarditis, Pyrexia	28	Male	Recovered/Resolved	Hypertension(C)	RAMIPRIL	2	1 month 6 days	Probable	
Myocarditis	Serious	Chest pain, Cough, Dyspnoea, Myocarditis	18	Male	Recovering/Resolving	No adverse event(H)		2	2 days	Probable	
Myocarditis	Serious	Chest pain, Myocarditis	23	Male	Not Recovered/Not Resolved	Not reported		2	3 days	Probable	
Myocarditis	Serious	Chest discomfort, Chest pain, Ejection fraction decreased, Inflammatory marker increased, Myocardial necrosis marker increased, Myocarditis	21	Male	Recovered/Resolved	Not reported		2	2 days	Probable	
Myocarditis	Serious	Chest pain, Myocarditis, Troponin increased	19	Male	Unknown	Not reported		2	1 day	Probable	
Myocarditis	Serious	Myocarditis	21	Male	Not Recovered/Not Resolved	Asthma(C)		2	2 days	Probable	
Myocarditis	Serious	Myocarditis	73	Male	Recovering/Resolving	Malignant melanoma(H)		2	1 month 8 days	Probable	
Myocarditis	Serious	Chest pain, Dyspnoea, Myocarditis	29	Male	Recovering/Resolving			Dose 2	4	Probable	
Pericarditis	Serious	Chest pain, Pericarditis, Pleuritic pain	20	Female	Not Recovered/Not Resolved	Drug hypersensitivity; Hypertension(C); 4.1(b) C; Aspergillus infection(H)	CELLCEPT [MYCOPHENOLATE MOFETIL]; LISINAPRIL; PLAQUENIL [HYDROXYCHLOROQUINE PHOSPHATE]; AMLODIPINE; CARVEDILOL; HYDRALAZINE; CRESEMBA	Dose 2	1	Acute Pericarditis	
Myocarditis	Serious	Myocarditis	18	Male	Not Recovered/Not Resolved			Dose 2	3	Probable	
Myocarditis	Serious	Chest pain, Feeling of body temperature change, Myalgia, Myocarditis	29	Male	Not Recovered/Not Resolved	Alcohol abuse(C); Tobacco user(C); Drug abuse(H)		Dose 2	2	Probable	
Myocarditis	Serious	Chest pain, Dyspnoea, Fatigue, Myocarditis, Pain, Palpitations, Tachycardia	30	Female	Not Recovered/Not Resolved	Migraine(C)	AMITRIPTYLINE; COVID-19 MRNA VACCINE BNT162B2	Dose 3	4	Probable	
Myocarditis	Serious	Myocarditis	35	Male	Recovering/Resolving	Viral myocarditis(H); Tobacco user(C); Allergy to chemicals		Dose 2	3	Probable	
Myocarditis	Serious	Myocarditis	19	Male	Recovered/Resolved			Dose 2	3	Probable	
Myocarditis	Serious	Asthenia, Chest discomfort, Chest pain, Cold sweat, Decreased appetite, Discomfort, Dizziness, Dyspnoea, General physical health deterioration, Head discomfort, Malaise, Musculoskeletal stiffness, Myocarditis, Palpitations	27	Male	Recovering/Resolving	Overweight(H)		Dose 2	33	Probable	
Myocarditis	Serious	Myocarditis, Pyrexia	29	Male	Recovered/Resolved	Seasonal allergy		Dose 2	3	Confirmed	
Myocarditis	Serious	Myocarditis	22	Female	Recovering/Resolving	Juvenile myoclonic epilepsy(C); Asthma(C)		Dose 2	16	Probable	

4.1(b)

Myocarditis	Serious	Cardiomyopathy, Chest pain, Myocarditis, Oedema	22	Male	Unknown	Drug hypersensitivity; Depression(C); Anxiety(C); Vitamin D deficiency(C); Hepatic steatosis(H); COVID-19(H)	ESCITALOPRAM OXALATE; VITAMIN D [VITAMIN D NOS]; MULTIVITAMIN [VITAMINS NOS]; FLAX OIL	Dose 3	6	Confirmed	
Myocarditis	Serious	Myocarditis	37	Male	Recovering/Resolving			Dose 2	3	Confirmed	
Myocarditis	Serious	Myocarditis, Pyrexia	15	Male	Unknown			Dose 2	2	Probable	
Myocarditis	Serious	Chest pain, Myocardial necrosis marker increased, Myocarditis	28	Male	Recovering/Resolving			Dose 2	3	Confirmed	
Myocarditis	Serious	Chest pain, Myocarditis	23	Male	Unknown			Dose 2	1	Probable	
Myocarditis	Serious	Chest pain, Discomfort, Myocarditis, Pyrexia	38	Male	Recovering/Resolving			Dose 2	59	Probable	
Myocarditis	Serious	Myocarditis	19	Male	Recovering/Resolving			Dose 2	2	Probable	
Myocarditis	Serious	Chest pain, Cold sweat, Dyspnoea, Fatigue, Illness, Malaise, Myocarditis, Palpitations, Pericarditis, Tachycardia	24	Male	Recovering/Resolving			Dose 2	1	Probable	
Myocarditis	Serious	Myocarditis	39	Male	Unknown	4.1(b) (H)		Dose 2	3	Probable	
Myocarditis	Serious	Blood test abnormal, Cardiac monitoring, Chest discomfort, Chest pain, Chest X-ray normal, Dyspnoea, Electrocardiogram, Hypopnoea, Monocyte count increased, Myocarditis, Neutrophil count increased, Painful respiration, Respiratory viral panel, Troponin increased, White blood cell count increased	25	Male	Not Recovered/Not Resolved			Dose 2	1	Probable	
Myocarditis	Serious	Arthralgia, Chest pain, Dyspnoea, Ejection fraction decreased, Erectile dysfunction, Fatigue, Heart rate, Hyperhidrosis, Incoherent, Myocarditis, Night sweats, Pain, Palpitations, Paraesthesia, Pyrexia, Tachycardia, Urinary retention	29	Male	Not Recovered/Not Resolved			Dose 2	2	Probable	
Myocarditis	Serious	Myocarditis	16	Male	Not Recovered/Not Resolved	Drug hypersensitivity; Food allergy		Dose 2	2	Probable	
Myocarditis	Serious	Myalgia, Myocarditis, Pyrexia	18	Male	Recovered/Resolved			Dose 2	1	Probable	
Myocarditis	Serious	Arthralgia, Chills, Eye pain, Headache, Myalgia, Myocarditis, Pyrexia, Troponin increased	20	Male	Unknown			Dose 2	24	Probable	
Myocarditis	Serious	Chest pain, Chills, Dizziness, Dyspnoea, Myocarditis, Nausea, Pyrexia, Vomiting	30	Male	Recovering/Resolving	COVID-19 VACCINE MODERNA(H)		Dose 2	5	Probable	
Myocarditis	Serious	Myocarditis	20	Male	Recovering/Resolving			Dose 2	1	Probable	
Myocarditis	Serious	Myocarditis	28	Male	Recovered/Resolved			Dose 2	3	Probable	
Pericarditis	Serious	Malaise, Pericarditis, Pyrexia	17	Male	Recovering/Resolving			Dose 2	1	Acute Pericarditis	
Myocarditis	Serious	Myocarditis	14	Male	Recovering/Resolving			Dose 2	1	Probable	
Myocarditis	Serious	Myocarditis	17	Male	Unknown			Dose 2	4	Probable	
Myocarditis	Serious	Cerebral infarction, Embolic stroke, Myocarditis	38	Female	Recovering/Resolving			Dose 2	29	Confirmed	
Myocarditis	Serious	Chest discomfort, Chest pain, Headache, Myocarditis, Pericarditis, Pyrexia	14	Male	Recovered/Resolved			Dose 2	1	Probable	
Myocarditis	Serious	Myocarditis, Pyrexia	17	Male	Recovered/Resolved			Dose 2	3	Probable	
Myocarditis	Serious	Myocarditis	22	Male	Recovering/Resolving			Dose 2	2	Probable	
Pericarditis	Serious	Myocarditis, Pericarditis	22	Male	Recovering/Resolving	Food allergy; Milk allergy	EFFEXOR SR; EFFEXOR SR; 4.1(b)	Dose 2	2	Probable	

4.1(b)

Myocarditis	Serious	Anxiety, C-reactive protein increased, Cardiac imaging procedure abnormal, Chest discomfort, Chest pain, Chills, Cough, Ear pain, Echocardiogram normal, Ejection fraction normal, Electrocardiogram abnormal, Electrocardiogram T wave inversion, Fatigue, Headache, Hyperhidrosis, Left ventricular dilatation, Magnetic resonance imaging heart, Malaise, Myocardial oedema, Myocarditis, N-terminal prohormone brain natriuretic peptide increased, Nausea, Pain, Pericardial fibrosis, Pleuritic pain, Pyrexia, Red blood cell sedimentation rate increased, Retching, Sleep disorder, Troponin increased, Ventricular hypokinesia, Vomiting	39	Female	Recovered/Resolved	Drug hypersensitivity; Drug hypersensitivity		Dose 3	0	Confirmed	
Myocarditis	Serious	Chest pain, Dyspnoea, Fatigue, Myocarditis, Tachycardia	19	Female	Recovering/Resolving			Dose 2	3	Probable	
Myocarditis	Serious	Chest pain, Myocarditis	25	Male	Recovering/Resolving			Dose 2	4	Probable	
Pericarditis	Serious	Myocarditis, Pericarditis	21	Male	Recovering/Resolving	Bundle branch block right(H)		Dose 2	3	Confirmed	
Pericarditis	Serious	Atrioventricular block second degree, Chest discomfort, Headache, Hypoaesthesia, Malaise, Myocarditis, Pericarditis, Platelet count increased, Pyrexia	34	Male	Recovering/Resolving	Sinusitis(H); Gastric cancer(C); Lung neoplasm malignant(C); Aneurysm ruptured(H)		Dose 2	5	Confirmed	
Myocarditis	Serious	Arthralgia, Fatigue, Myocarditis, Pyrexia	21	Male	Unknown			Dose 2	3	Probable	
Myocarditis	Serious	C-reactive protein increased, Carditis, Chest discomfort, Chest pain, Chest X-ray normal, Dyspnoea, Echocardiogram, Electrocardiogram abnormal, Hypoaesthesia, Laboratory test, Lymphadenopathy, Myocarditis, Pain in extremity, Paraesthesia, Troponin increased	34	Female	Not Recovered/Not Resolved			Dose 3	1	Probable	
Myocarditis	Serious	Blood creatine phosphokinase increased, C-reactive protein increased, Chest pain, Dyspnoea, Echocardiogram, Ejection fraction, Myalgia, Myocarditis, Pyrexia, Troponin increased	19	Male	Unknown			Dose 2	2	Probable	
Myocarditis	Serious	Blood creatine phosphokinase increased, Chest pain, Chills, Diarrhoea, Echocardiogram normal, Electrocardiogram abnormal, Electrocardiogram ST segment elevation, Fatigue, Hyperhidrosis, Myocarditis, Pericarditis, Pyrexia, SARS-CoV-2 test negative, Troponin I increased, Viral test negative, Vomiting	26	Female	Recovered/Resolved			Dose 3	3	Probable	
Myocarditis	Serious	Abdominal pain upper, Abnormal faeces, Angina pectoris, Asthenia, Back pain, Burning sensation, Chest pain, Chills, Condition aggravated, Decreased appetite, Disorientation, Dizziness, Dyspepsia, Dyspnoea, Fatigue, Headache, Heart rate increased, Hypoaesthesia, Loss of personal independence in daily activities, Muscle twitching, Myocarditis, Pain in extremity, Palpitations, Pyrexia, Restlessness	27	Male	Unknown			Dose 2	144	Probable	4.1(b)
Myocarditis	Serious	Myocarditis	34	Female	Recovering/Resolving			Dose 2	2	Probable	
Myocarditis	Serious	Myocarditis	30	Male	Recovering/Resolving			Dose 2	3	Probable	
Myocarditis	Serious	Myocarditis	26	Male	Recovering/Resolving			Dose 2	3	Probable	
Myocarditis	Serious	Myocarditis	24	Male	Recovering/Resolving			Dose 2	3	Probable	

4.1(b)

Myocarditis	Serious	Myocarditis	35	Female	Recovering/Resolving	Mitral valve prolapse(C)		Dose 2	8	Probable
Myocarditis	Serious	Myocarditis	15	Male	Recovered/Resolved with Sequelae	Overweight(C)		Dose 2		Probable
Myocarditis	Serious	Chest discomfort, Chest pain, Hypoxia, Myocarditis, Palpitations	25	Male	Unknown	Asthma(C); COMIRNATY		Dose 2		Probable
Myocarditis	Serious	Myocarditis	25	Male	Recovered/Resolved			Dose 2	1	Probable
Pericarditis	Serious	Arthralgia, Chest pain, Dyspnoea, Echocardiogram abnormal, Pain, Pericardial effusion, Pericarditis	40	Male	Recovered/Resolved	End stage renal disease(C); Blood cholesterol increased(C); Hypertension(C); Gout(C); 4.1(b)		Dose 2	31	Acute Pericarditis
Myocarditis	Non Serious	C-reactive protein decreased, Chest pain, Dyspnoea, Echocardiogram abnormal, Electrocardiogram abnormal, Fatigue, Headache, Myocarditis, Nausea, Pericarditis, Pyrexia, Sinus tachycardia, Troponin normal, Vomiting	21	Female	Recovered/Resolved	Obesity(H)		Dose 2	1	Probable
Myocarditis	Serious	Chest pain, Dyspnoea exertional, Electrocardiogram abnormal, Electrocardiogram ST segment elevation, Myocarditis, Pyrexia, Troponin increased	30	Male	Unknown			Dose 2	1	Probable
Myocarditis	Serious	Chest pain, Dyspnoea, Fatigue, Hospitalisation, Myocarditis, Tachycardia	18	Male	Recovering/Resolving	Asthma(C); SARS-COV-2 VACCINE; COVID-19 VACCINE	SALBUTAMOL	Dose 3	4	Probable
Myocarditis	Serious	Myocarditis	28	Male	Recovering/Resolving			Dose 2	3	Probable
Pericarditis	Serious	Chest pain, Dyspnoea, Fatigue, Flank pain, Gastric ulcer, Palpitations, Pericarditis, Peripheral swelling	38	Male	Not Recovered/Not Resolved	COVID-19 VACCINE MODERNA(H); Herpes zoster oticus(H)	COVID-19 VACCINE MODERNA	Dose 2	71	Probable
Myocarditis	Serious	Chest discomfort, Dyspnoea, Malaise, Myalgia, Myocarditis, Pyrexia	28	Male	Recovering/Resolving	Substance use(H); Tobacco user(C); SPIKEVAX(H)		Dose 2	1	Probable
Myocarditis	Serious	Chest pain, Myocarditis	16	Male	Recovered/Resolved			Dose 2	2	Probable
Myocarditis	Serious	Chest pain, Dyspnoea, Fatigue, Myocarditis, Pain, Pericardial effusion, Pericarditis, Tachycardia	39	Female	Not Recovered/Not Resolved		COVID-19 VACCINE ASTRAZENECA	Dose 3	1	Probable
Myocarditis	Serious	Chills, Myocarditis, Nausea, Vomiting	20	Male	Unknown	Substance use(C)		Dose 2		Confirmed
Myocarditis	Serious	Influenza like illness, Myocarditis	21	Male	Unknown			Dose 2		Confirmed
Myocarditis	Serious	C-reactive protein increased, Chest pain, Myocarditis, Troponin	25	Male	Not Recovered/Not Resolved			Dose 3	1	Probable
Myocarditis	Serious	C-reactive protein increased, Chest pain, Chest X-ray normal, Computerised tomogram thorax normal, Echocardiogram abnormal, Effusion, Electrocardiogram abnormal, Fatigue, Fibrin D dimer increased, Magnetic resonance imaging abnormal, Myocarditis, Nausea, Tachycardia, Troponin increased	23	Male	Not Recovered/Not Resolved	Schizophrenia(C)		Dose 3	4	Confirmed
Myocarditis	Non Serious	C-reactive protein increased, Echocardiogram normal, Electrocardiogram ST segment elevation, Myocarditis, Troponin increased	24	Male	Not Recovered/Not Resolved	4.1(b) (C); Scoliosis(C); Anxiety(C); Depression(C)		Dose 3	3	Probable
Myocarditis	Serious	Myocarditis	20	Male	Unknown	Myocarditis(H)		Dose 2	2	Confirmed
Myocarditis	Serious	Chest pain, Feeling cold, Malaise, Myocarditis	33	Male	Recovering/Resolving	SPIKEVAX		Dose 2	1	Probable

4.1(b)

4.1(b)	Myocarditis	Serious	Adenovirus test, Cardiac telemetry normal, Chest pain, Echocardiogram, Electrocardiogram normal, HIV test negative, Human metapneumovirus test, Human rhinovirus test, Influenza A virus test negative, Influenza B virus test, Influenza virus test negative, Myocarditis, Respiratory syncytial virus test negative, SARS-CoV-2 test negative, Troponin increased	25	Male	Not Recovered/Not Resolved			Dose 3	1	Probable	4.1(b)
	Myocarditis	Serious	Myocarditis, Pyrexia	21	Male	Recovering/Resolving			Dose 2	3	Probable	
	Myocarditis	Serious	Myocarditis	22	Male	Recovering/Resolving			Dose 2	3	Confirmed	
	Myocarditis	Serious	Myocarditis	14	Male	Recovering/Resolving			Dose 2	3	Confirmed	
	Myocarditis	Serious	Chest pain, Myocarditis	33	Female	Unknown	COVID-19(H); Myocardial ischaemiaFH		Dose 2		Probable	
	Myocarditis	Serious	Back pain, Chest discomfort, Cough, Dyspnoea, Maternal exposure during pregnancy, Myocarditis, Night sweats, Palpitations	30	Female	Unknown	Hypothyroidism(C)	LEVOTHYROXINE	Dose 2		Probable	
	Pericarditis	Serious	Pericarditis	17	Male	Recovered/Resolved			Dose 2	4	Probable	
	Myocarditis	Serious	Myocarditis	34	Male	Recovering/Resolving	Tobacco user(C)		Dose 2	45	Confirmed	
	Myocarditis	Serious	Chest pain, Myocarditis, Pyrexia	19	Female	Not Recovered/Not Resolved		COLCHICINE; DOXYCYCLINE; MEBEVERINE; SUMATRIPTAN	Dose 2	3	Probable	
	Pericarditis	Serious	Chest pain, Fatigue, Pericarditis	22	Male	Recovering/Resolving		COVID-19 VACCINE MODERNA; COVID-19 VACCINE MODERNA	Dose 3	1	Probable	
	Myocarditis	Serious	Chest pain, Dyspnoea, Fatigue, Myocarditis, Palpitations	34	Male	Recovering/Resolving	Electrocardiogram(H)		Dose 3	2	Probable	
	Myocarditis	Serious	Chest pain, Myocarditis	35	Male	Not Recovered/Not Resolved	Congenital cystic kidney disease(C)	COVID-19 VACCINE ASTRAZENECA	Dose 3	4	Probable	
	Myocarditis	Serious	Chest pain, Chills, Dyspnoea, Fatigue, Myalgia, Myocarditis, Palpitations, Pyrexia, Syncope	29	Male	Not Recovered/Not Resolved			Dose 3	0	Probable	
	Myocarditis	Serious	Myocarditis	16	Male	Recovering/Resolving			Dose 2	2	Confirmed	
	Myocarditis	Serious	Chest pain, Echocardiogram, Electrocardiogram, Electrocardiogram T wave inversion, Flank pain, Hyperhidrosis, Myocarditis, Pain, Pericardial effusion, Troponin, Vomiting	35	Male	Unknown	Renal cell carcinoma(H); Drug hypersensitivity; Drug hypersensitivity		Dose 3	2	Probable	
	Myocarditis	Serious	Myocarditis	39	Male	Recovering/Resolving			Dose 3		Probable	
	Pericarditis	Serious	Chest pain, Dyspnoea, Hypoaesthesia, Influenza like illness, Pericarditis, Pyrexia, Syncope	29	Male	Recovering/Resolving	Temporomandibular joint syndrome(H); Tuberculosis(H)	PFIZER BIONTECH COVID-19 VACCINE; PFIZER BIONTECH COVID-19 VACCINE	Dose 3	0	Probable	
	Myocarditis	Serious	Chest pain, Left ventricular dysfunction, Myocarditis, Palpitations, Tachycardia	21	Male	Recovering/Resolving		PFIZER BIONTECH COVID-19 VACCINE; PFIZER BIONTECH COVID-19 VACCINE	Dose 3	2	Confirmed	

4.1(b)		Myocarditis	Serious	Blood potassium decreased, Cardiac telemetry, Chest discomfort, Chest pain, Differential white blood cell count, Echocardiogram, Electrocardiogram normal, Fibrin D dimer normal, Full blood count, Hypokalaemia, Laboratory test abnormal, Myocarditis, Nausea, Sleep disorder, Troponin increased	21	Male	Unknown	Urticaria(H)		Dose 3	2	Probable	
		Myocarditis	Serious	Cardiomyopathy, Catheterisation cardiac abnormal, Chest pain, Echocardiogram, Ejection fraction, Electrocardiogram ST segment elevation, Myocarditis, Troponin increased, Vaccination complication	23	Male	Not Recovered/Not Resolved			Dose 3	0	Probable	4.1(b)
		Myocarditis	Serious	Anticoagulant therapy, Blood creatine phosphokinase abnormal, Blood creatine phosphokinase MB, C-reactive protein abnormal, Chest pain, Chest X-ray, Differential white blood cell count abnormal, Echocardiogram, Electrocardiogram, Fibrin D dimer increased, Full blood count abnormal, Influenza A virus test, Influenza B virus test, Laboratory test abnormal, Metabolic function test abnormal, Myocarditis, N-terminal prohormone brain natriuretic peptide abnormal, SARS-CoV-2 test, Troponin I abnormal	31	Male	Unknown			Dose 3	5	Probable	
		Myocarditis	Serious	Abdominal pain upper, Back pain, Chest pain, Dyspnoea, Myocarditis, Palpitations, Pyrexia, Troponin I abnormal	30	Male	Unknown			Dose 2	3	Probable	
		Myocarditis	Serious	Cardiac failure, Chest pain, Chest X-ray, Computerised tomogram thorax abnormal, Electrocardiogram, Haematology test, Hilar lymphadenopathy, Left atrial enlargement, Lung disorder, Mediastinitis, Myocarditis, Pain, Pain in extremity, Pleural effusion, Pulmonary oedema, Tissue infiltration, Troponin increased	26	Male	Not Recovered/Not Resolved	Mite allergy; Asthma(H); Supraventricular tachycardia(H); Myopia(H); Obesity(H); Vitamin D deficiency(H); Congenital diaphragmatic hernia(H)		Dose 3	7	Probable	
		Myocarditis	Serious	Blood creatine phosphokinase MB increased, Blood creatine phosphokinase normal, Chest pain, Chest X-ray normal, Computerised tomogram thorax normal, Echocardiogram normal, Electrocardiogram ST segment elevation, Full blood count normal, Myocarditis, Pericarditis, SARS-CoV-2 test negative, Troponin increased	19	Male	Recovered/Resolved	Food allergy; Food allergy		Dose 2	0	Probable	
		Pericarditis	Serious	Chest pain, Pericarditis	39	Female	Recovering/Resolving	Hypothyroidism(C)	T4	Dose 2	5	Acute Pericarditis	
		Myocarditis	Serious	Myocarditis	15	Female	Recovering/Resolving			Dose 2	5	Confirmed	
		Pericarditis	Serious	Chest discomfort, Dyspnoea, Fatigue, Pericarditis	38	Female	Recovering/Resolving	Thrombosis(H)		Dose 2		Acute Pericarditis	
		Pericarditis	Serious	Pericarditis	31	Unknown	Not Recovered/Not Resolved			Dose 2	54	Acute Pericarditis	
		Myocarditis	Serious	Myocarditis	30	Male	Not Recovered/Not Resolved	Tobacco user(H)		Dose 2		Probable	
		Myocarditis	Serious	Chest pain, Cough, Fatigue, Myocarditis, Pericardial rub, Pyrexia, Tachycardia	18	Male	Recovered/Resolved			Dose 2	2	Probable	
4.1(b)	JAPAN	Myocarditis	Serious	Cardiac tamponade, Cardio-respiratory arrest, Hypoxic-ischaemic encephalopathy, Multiple organ dysfunction syndrome, Myocarditis, Pericarditis	38	Male	Fatal	Diabetes mellitus(C); Diabetic nephropathy(C); Diabetic retinopathy(C); Hypertension(C); Dyslipidaemia(C)	NEXIUM EBB; ALFACALCIDOL; CANDESARTAN; NIFEDIPINE; CALTAN; NOVORAPID	Unknown		Probable	

20.11.13. Myocarditis/Pericarditis: CDC working case Definition: Case Narratives

Case ID	WW Identifier	Narrative	MAH Comment
4.1(b)	4.1(b)	This case was initially received via European Medicines Agency (Reference number: 4.1(b)) on 05-Oct-2021. The most recent information was received on 15-Oct-2021 and was forwarded to Moderna on 15-Oct-2021. This regulatory authority case was reported by a physician and describes the occurrence of CHEST DISCOMFORT (Chest pressure), CHEST PAIN (Chest pain), MALAISE (General malaise), VOMITING (Vomiting), ASTHENIA (Weakness), MYOCARDITIS (Perimyocarditis) and MYOCARDITIS INFECTIOUS (Myocarditis infectious) in a 15-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 3004954 and 3004954) for COVID-19 immunisation. No Medical History information was reported. On 13-Aug-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 13-Sep-2021, received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to 1 dosage form. On 14-Sep-2021, the patient experienced CHEST DISCOMFORT (Chest pressure) (seriousness criteria hospitalization and life threatening), CHEST PAIN (Chest pain) (seriousness criteria hospitalization and life threatening), MALAISE (General malaise) (seriousness criteria hospitalization and life threatening), VOMITING (Vomiting) (seriousness criteria hospitalization and life threatening), ASTHENIA (Weakness) (seriousness criteria hospitalization and life threatening), MYOCARDITIS (Perimyocarditis) (seriousness criteria hospitalization and medically significant) and MYOCARDITIS INFECTIOUS (Myocarditis infectious) (seriousness criteria hospitalization, medically significant and life threatening). At the time of the report, CHEST DISCOMFORT (Chest pressure), CHEST PAIN (Chest pain), MALAISE (General malaise), VOMITING (Vomiting), ASTHENIA (Weakness), MYOCARDITIS (Perimyocarditis) and MYOCARDITIS INFECTIOUS (Myocarditis infectious) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):	15 years old male with unknown medical history who next days after the 2nd dose experienced chest pain, chest discomfort, malaise, vomiting, and asthenia, was hospitalized was diagnosed with myocarditis. Laboratory values showed elevated troponin, elevated CRP, abnormal ECG, and Echo. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for any other infectious process. There is a diagnosis of myocarditis infectious but no information provided for this diagnosis. 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 September 2021, C-reactive protein: high (High) 68 (increased) mg/mL. In September 2021, Echocardiogram: abnormal (abnormal) OBS slightly decreased left ventricle function. In September 2021, Ejection fraction: 45 (abnormal) 45 (%percent) and 45 (Low) low. In September 2021, Electrocardiogram: abnormal (abnormal) Monstrous ST-elevations. In September 2021, Troponin T: 2289.3 (High) 2289.3 (increased) ng/L. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Concomitant medications was not reported. Treatment history was not reported. Company Comment: This case concerns a 15 year old male with no reported medical history , who experienced expected event of myocarditis and other unexpected events of chest pain, chest pressure, weakness , asthenia and malaise . These events occurred 2 days after vaccination with the 2nd dose of mRNA-1273 (Spikevax) and 1 month and 2 days post vaccination with the 1st dose. The rechallenge for this case is not applicable. The benefit risk relationship of mRNA-1273 (Spikevax) is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 15-Oct-2021: Follow-up received on 15-oct-2021. Significant follow up- seriousness criteria updated and new event added	

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 07-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 25-Aug-2021, the patient received the 1st dose of this vaccine. After the vaccination, there was no problem. On 22-Sep-2021, in the morning, the patient received the 2nd dose of this vaccine. On 25-Sep-2021, at 03:15, chest pain developed on admission, and troponin, CKMB, and CRP were increased. The patient was diagnosed with myocarditis based on the clinical course. On 26-Sep-2021, electrocardiogram showed negative T wave. Cardiac function was normal by echocardiography. On 01-Oct-2021, after oral administration of loxoprofen sodium hydrate and colchicine, inflammation and cardiac enzymes decreased to within the normal range. The patient was discharged from the hospital. On 02-Oct-2021, the symptoms were resolving. The outcome of myocarditis was reported as resolving. Follow-up investigation will be made. Company Comment: The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	17 years old male with unknown medical history who 3 days after the 2nd dose experienced chest pain and was found to have elevated troponin, CK and CRO, and abnormal ECG, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and ECG results; a causal relationship cannot be excluded due to the lack of other information.

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 (Sep 21, 2nd dose of the Moderna Covid-19 vaccine; Sep 25, chest tightness and pain, troponin I elevation up to 4561 ng/L and CRP, waiting to perform cardiac MRI, suspected myocarditis) and CHEST PAIN 4.1(b) in a 15-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 immunisation. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Troponin I increased on 25-Sep-2021 and Protein C increased on 25-Sep-2021. On 21-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 25-Sep-2021, the patient experienced MYOCARDITIS (Sep 21, 2nd dose of the Moderna Covid-19 vaccine; Sep 25, chest tightness and pain, troponin I elevation up to 4561 ng/L and CRP, waiting to perform cardiac MRI, suspected myocarditis) (seriousness criteria hospitalization and medically significant), CHEST PAIN 4.1(b) (seriousness criterion hospitalization) and CHEST DISCOMFORT (chest tightness). At the time of the report, MYOCARDITIS (Sep 21, 2nd dose of the Moderna Covid-19 vaccine; Sep 25, chest tightness and pain, troponin I elevation up to 4561 ng/L and CRP, waiting to perform cardiac MRI, suspected myocarditis), CHEST PAIN 4.1(b) and CHEST DISCOMFORT (chest tightness) was resolving.	15 years old male with unknown medical history who 4 days after the 2nd dose experienced chest pain, chest discomfort and was found to have elevated troponin, and was diagnosed with myocarditis. ECG and cMRI results pending. No other information was 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
		For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. On 25-SEP-2021 the patient had an Echocardiogram and Troponin I done, Troponin was elevated to 4561 ng/L and CRP was done. Patient was waiting to perform Cardiac MRI which resulted in myocarditis. Patient was suspected to myocarditis with a peak TNL 4500 ng/ml and chest pain in remission and TNL declining and after few days of second vaccination patient had preserved cardiac function and was awaiting for Cardiac MRI. Concomitant medications and treatment information was not provided. Patient had took the second dose on 21-SEP-2021 and on 25-SEP-2021 experienced chest tightness and pain. Lab data: On unknown date Echocardiogram was done with unknown results. On 25 Sep 2021: MRI, Troponin I, Blood test was done with unknown results. Most recent FOLLOW-UP information incorporated above includes: On 08-Oct-2021: Translation received on 12-OCT-2021 contains: Event Verbatim Updated and Reporter's comment updated in narrative. On 12-Oct-2021: Significant follow up received lab data and events were added.	

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 08-Oct-2021. The most recent information was received on 14-Oct-2021 and was forwarded to Moderna on 14-Oct-2021. This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myopericarditis in a patient who recently had the MODERNA Covid vaccine. Blood tests carried out : -CRP 61 - troponin 4700 - serodiagnosis in progress) in a 17-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 214027 and 214019) for SARS-CoV-2 vaccination. No Medical History information was reported. On 13-Aug-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 24-Sep-2021, received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to 1 dosage form. On 27-Sep-2021, the patient experienced MYOCARDITIS (Myopericarditis in a patient who recently had the MODERNA Covid vaccine. Blood tests carried out : -CRP 61 - troponin 4700 - serodiagnosis in progress) (seriousness criterion medically significant). At the time of the report, MYOCARDITIS (Myopericarditis in a patient who recently had the MODERNA Covid vaccine. Blood tests carried out : -CRP 61 - troponin 4700 - serodiagnosis in progress) was resolving. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Concomitant product information was not provided. Treatment information was not provided. Laboratory data was mentioned as on an unknown date patient took blood test and it shows CRP value as 61 and Troponin value as 4700. Company comment: This case concerns a 17 year old male patient with no relevant medical history, who experienced the expected AESI event of myocarditis. The event occurred approximately 44 days after	17 years old male with unknown medical history who 3 days after the 2nd dose was found to have elevated troponin, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin; a causal relationship cannot be excluded due to the lack of other information.

Case ID	WW Identifier	Narrative	MAH Comment
		the fist dose and 3 days after the second dose of the Moderna COVID-19 vaccine. The rechallenge was not applicable. The benefit-risk relationship of the Moderna COVID-19 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 14-Oct-2021: Follow-up received contains added Route of administration and Indication for use. On 14-Oct-2021: Translation received on 20-Oct-2021 contains no new information	

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 this vaccine. On 02-Oct-2021, the patient received the 2nd dose of this vaccine. On 04-Oct-2021, chest pain and vomiting developed. On 05-Oct-2021, the patient visited the reporting hospital. The patient was diagnosed with myocarditis due to abnormally high troponin I level. The patient was transported to an advanced treatment hospital and was hospitalized. On 09-Oct-2021, the symptoms were resolving, and the patient was discharged from the hospital. The outcome of myocarditis was reported as resolving. Follow-up investigation will be made. Company Comment: The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	

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 20-Oct-2021. This case, initially reported to the 4.1(b) (physician), was received via the 4.1(b) (Ref, 4.1(b)) On an unknown date, the patient received the 1st dose of this vaccine. On 26-Sep-2021, the patient received the 2nd dose of this vaccine. On 27-Sep-2021, pyrexia in the 38 degrees Celsius developed. On 28-Sep-2021, in the morning, acute myocarditis developed. Chest tightness developed. The patient visited a nearby physician. Electrocardiogram showed extensive ST elevation. Blood test showed increased CK, CK-MB, CRP, and WBC. On 29-Sep-2021, the patient was referred to the reporting department. Echocardiography showed no abnormalities, but troponin I was elevated. The patient was hospitalized with a diagnosis of acute myocarditis. On 02-Oct-2021, the symptoms were confirmed as resolved. The outcome of pyrexia and acute myocarditis was reported as resolved. Follow-up investigation will be made. Company Comment: The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	

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 22-Oct-2021. This case, initially reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref, 4.1(b)) On an unknown date, the patient received the 1st dose of the vaccine. On 09-Oct-2021, the patient received the 2nd dose of the vaccine. From 10-Oct-2021 to 11-Oct-2021, the patient had pyrexia of 38s degrees Celsius. On 12-Oct-2021, at 03:00, the patient was aware of pain in the left chest for approximately 10 minutes. As chest discomfort sensation persisted thereafter, the patient visited a hospital. An electrocardiogram showed ST elevations in II, III, and aVF, and the result of blood sampling revealed an inflammatory response and elevated cardiac enzymes. Echocardiography showed enhanced pericardium brightness and accumulation of pericardial fluid. The patient was admitted to the hospital for suspected myopericarditis. On an unspecified date, as of the date, any virus that can cause myocarditis had not been detected. Cardiac contrast-enhanced MRI showed findings suggestive of myocarditis. The result of myocardial biopsy showed normal findings of myocardium. After being hospitalized, the patient had no chest pain, cardiac failure, or arrhythmia, and the course of the disease was favorable without transformation to fulminant myocarditis. The symptoms had not resolved. The outcome of pyrexia and myopericarditis was reported as ongoing and unchanged. Follow-up investigation will be made. Company Comment: The events developed after the administration of COVID-19 vaccine mRNA	17 years old male with unknown medical history who next day after the 2nd dose of Spikevax developed pyrexia and the next day experienced chest discomfort and was found to have elevated cardiac enzymes (not specified), abnormal ECG, abnormal Echo with pericardial fluid. Myocardial biopsy showed normal findings. Patient was diagnosed with myopericarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated cardiac enzymes and ECG results; a causal relationship cannot be excluded due to the lack of other information.

Case ID	WW Identifier	Narrative	MAH Comment
		(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 25-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, body temperature before the vaccination: 36.3 degrees Celsius. On 05-Oct-2021, the patient received the 1st dose of this vaccine. On 08-Oct-2021, myocarditis developed. Anterior chest pain and numbness of limbs were noted, and the patient was raced to a hospital. Troponin I increased to 0.707 and CK to 354. Acetaminophen 500 mg was intravenously infused for chest pain. Thereafter, the patient was hospitalized. On 09-Oct-2021, 12 lead electrocardiogram showed no changes in ST. Blood test showed troponin positive at 0.053 and CK was 225. Heart rate was 60 to 70 beats/min. Electrocardiogram showed negative T wave in V1 and aVL and early repolarization in V2 to V6. The patient did not have subjective symptoms. On 10-Oct-2021, normalization was confirmed with troponin of 0021 and CK of 125. No subjective symptoms were noted. On 11-Oct-2021, electrocardiogram showed no change in symptoms. On 12-Oct-2021, recovery of the symptoms was noted, and the patient was discharged from the hospital. The outcome of myocarditis and numbness of the limbs was reported as recovered. Follow-up investigation will be made. Company Comment: The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	16 years old male with unknown medical history who 3 days after the 1st dose experienced chest pain and numbness of limbs and was found to have elevated troponin, Ck, and abnormal ECG, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and ECG results; a causal relationship cannot be excluded due to the lack of other information.

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, 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)) Acute myocarditis was assessed as serious by the MAH. On 24-Sep-2021, at 17:00, the patient received the 1st dose of this vaccine. On 17-Oct-2021, at 13:00, the patient received the 2nd dose of this vaccine. On 18-Oct-2021, pyrexia of 39 degrees Celsius developed. On 19-Oct-2021, around 13:15, acute myocarditis developed with chest pain at rest. Improvement was poor, and the patient made an emergency visit at the reporting hospital. ECG showed ST segment elevation in leads 1, 2, aVF, and V3 -6, and ST segment depression in leads V1 and aVR. Echocardiography showed decreased wall motion localized to the apex. Increased cardiac enzymes were noted with CK 263 U/L, CK-MB 20.1 ng/mL, and troponin I 2,234 pg/mL. On 22-Oct-2021, resolving of the symptoms was confirmed. The outcome of acute myocarditis was reported as resolving. Follow-up investigation will be made. Company Comment: The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	15 years old male with unknown medical history who the next day after the the 2nd dose developed pyrexia and the next day chest pain at rest and was found to have elevated troponin, CK, CK-MB, and abnormal ECG, and Echo and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and ECG and Echo results; a causal relationship cannot be excluded due to the lack of other information.

Case ID	WW Identifier	Narrative	MAH Comment
4.1(b) [REDACTED]	4.1(b) [REDACTED]	This case was received via European Medicines Agency (Reference number: 4.1(b) [REDACTED]) on 29-Oct-2021 and was forwarded to Moderna on 29-Oct-2021. This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myocarditis) and CHEST PAIN (Precordial pain) in a 15-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. No Medical History information was reported. On 08-Oct-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 10-Oct-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). On an unknown date, the patient experienced CHEST PAIN (Precordial pain) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Myocarditis) had not resolved and CHEST PAIN (Precordial pain) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Blood creatine phosphokinase: abnormal (High) ABNORMAL. On an unknown date, Troponin: 24.815,6 (High) 24.815,6 pg/ml. The action taken with mRNA-1273 (Spikevax) (Intramuscular) was unknown. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Concomitant and treatment medications were not reported. Company comment: This is a regulatory case concerning a 15 year-old, male patient with no relevant history, who experienced the unexpected serious events of chest pain, and the expected serious event of myocarditis. The event occurred approximately 3 days after the 1st dose of mRNA-1273 Moderna vaccine. The rechallenge was not applicable	15 years old male with unknown medical history who 2 days after the 1st dose experienced chest pain and was found to have elevated troponin, Ck, and was diagnosed with myocarditis. No other information was provided. 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
		(information about 2nd dose was not provided). relevant lab data reported: Blood creatine phosphokinase: abnormal (High), Troponin: 24.815,6 pg/ml (High) The benefit-risk relationship of mRNA-1273 Moderna vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 29-Oct-2021: Follow up received on 29-Oct-2021 contains no new information.	

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 01-Oct-2021 and was forwarded to Moderna on 01-Oct-2021. This regulatory authority case was reported by a pharmacist and describes the occurrence of PALPITATIONS (palpitations), MALAISE (Generally unwell), ELECTROCARDIOGRAM QT PROLONGED (qtc prolonged) and MYOCARDITIS (Myocarditis) in a 37-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for Vaccination. The patient's past medical history included Anxiety. Family history included Hypertension (Both parents have hypertension.) since an unknown date. On 01-Aug-2021, the patient received first dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 26-Sep-2021, received second dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 27-Sep-2021, after starting mRNA-1273 (Moderna CoviD-19 Vaccine), the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). On an unknown date, the patient experienced PALPITATIONS (palpitations) (seriousness criteria hospitalization and medically significant), MALAISE (Generally unwell) (seriousness criteria hospitalization and medically significant) and ELECTROCARDIOGRAM QT PROLONGED (qtc prolonged) (seriousness criteria hospitalization and medically significant). At the time of the report, PALPITATIONS (palpitations), MALAISE (Generally unwell) and ELECTROCARDIOGRAM QT PROLONGED (qtc prolonged) had resolved and MYOCARDITIS (Myocarditis) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 28-Sep-2021, SARS-CoV-2 test: negative (Negative) No - Negative COVID-19 test. The action taken with mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown) was unknown.	37 years old male with medical history of anxiety and hypertension who reported having palpitations after the 1st dose and then next day after the 2nd dose with malaise, was hospitalized and was diagnosed with myocarditis. Lab results showed prolonged QTs in the EKG, and hypertension. Elevated troponin, elevated CRP, D-dimer. SARS-CoV-2 test negative. No other information was provided. Important information is missing in the report including patient's medical history, concomitant medications as well as any other laboratory test conducted, including testing for any infectious process. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and abnormal EKG; a causal relationship cannot be excluded due to the lack of other information.

Case ID	WW Identifier	Narrative	MAH Comment
		For mRNA-1273 (Moderna Covid-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. No concomitant product was reported. Patient previously had heavy alcohol during COVID lockdown but none recently and denied any drugs specifically cocaine. The patient received 1st dose 8 weeks ago and developed palpitations after and settled after a couple of weeks and had 2nd dose on Sunday developed palpitations and felt generally unwell after. The patient found to have BP greater than 200. The patient was advised to go to Emergency Department. On an unknown date, in morning patient took BP and was still greater than 200, went to Emergency Department. It was Shortness of Breath with palpitation but no acute SOB. The patient had muscle aches. Patient stated that he had an abnormal ECHO as a child but that resolved. Patient took paracetamol and ephedrine OTC. Looked well. Pain was then settled. HS normal, Chest clear, JVP not raised, legs not swollen. Various Investigations included CRP 22.1, WCC 13.41, neutrophil 11.27, Creatinine 122, Troponin T 19, D-dimer 3.11, LFTs and bone NAD, CK, Mg and TFTs normal, Lact 1.1, ECGs - Variable Ant T inv. Sinus tachycardia. QTc prolonged. The patient diagnosis as had Myocarditis which was possibly secondary to COVID vaccine viral. Patient was given Bisoprolol 2.5mg and Malodipine 5mg then. Cardiology review was done and telemetry EDD 2-3 days. This case concerns a 58-year-old female patient, with relevant medical history of hypertension and anxiety, who experienced the unexpected serious event of Palpitations, Malaise, Electrocardiogram QT prolonged and expected serious event myocarditis. Additionally, the unexpected serious event blood pressure increased is also reported. The events occurred on an	

Case ID	WW Identifier	Narrative	MAH Comment
		unknown date after the second dose of Spikevax. The rechallenge was not applicable as the AEs occurred after the second dose and we are not expecting another dose. The medical history hypertension remains a confounder. The benefit-risk relationship of Spikevax is not affected by this report.	

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-Oct-2021 and was forwarded to Moderna on 04-Oct-2021. This regulatory authority case was reported by a physician and describes the occurrence of CHEST PAIN 4.1(b), HEART RATE INCREASED 4.1(b), COVID-19 IMMUNISATION 4.1(b) and PERICARDITIS 4.1(b) in a 37-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 3005697) for Vaccination. Previously administered products included for Vaccination: Comirnaty. Past adverse reactions to the above products included Adverse event with Comirnaty. On 25-Aug-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. In 2021, the patient experienced COVID-19 IMMUNISATION 4.1(b) (seriousness criterion hospitalization). On 28-Aug-2021, the patient experienced CHEST PAIN 4.1(b) (seriousness criterion hospitalization) and PERICARDITIS 4.1(b) (seriousness criteria hospitalization and medically significant). On 18-Sep-2021, the patient experienced HEART RATE INCREASED 4.1(b) (seriousness criterion hospitalization). At the time of the report, CHEST PAIN 4.1(b), HEART RATE INCREASED 4.1(b), COVID-19	37 years old female with unknown medical history, who received as her first dose the Cominarty vaccine at an unknown date, and was seeing in the doctor's office because of reported chest pressure since July, and worsening 3 days after receiving the 2nd dose with Spikevax. At CV examination patient was found to have pericardial fluid, heart rate increased, chest pain, her Echo was abnormal and she was diagnosed with pericarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any laboratory test conducted, including testing for SARS-CoV-2, and any information related to her previous chest pain history. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, a causal relationship cannot be excluded due to the lack of other information.

Case ID	WW Identifier	Narrative	MAH Comment
		IMMUNISATION 4.1(b) [REDACTED] and PERICARDITIS 4.1(b) [REDACTED] was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 31-Aug-2021, Cardiovascular examination: abnormal (abnormal) A 1 cm fluid brake was detected behind the left ventricle. Interpreted as possible pericarditis.. On 18-Sep-2021, C-reactive protein: 5 (Inconclusive) 5. On 18-Sep-2021, Cardiovascular examination: abnormal (abnormal) Approx. 1 cm pericardial fluid brake was detected at the right atrium and approx. 0.5 cm at right ventricle.. On 18-Sep-2021, Red blood cell sedimentation rate: 26 (slightly elevated) (High) 26 (slightly elevated). On 21-Sep-2021, Echocardiogram: abnormal (abnormal) Unchanged amount of pericardial fluid. For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered CHEST PAIN 4.1(b) [REDACTED], HEART RATE INCREASED 4.1(b) [REDACTED] and PERICARDITIS 4.1(b) [REDACTED] to be possibly related. No further causality assessment was provided for COVID-19 IMMUNISATION 4.1(b) [REDACTED]. No relevant concomitant medications were reported. The Patient was examined on 31 AUG 2021 because she had felt episodic pressure on the chest since July, with worsening on 28 AUG 2021. No treatment information was provided. Company comment: This case concerns a 37-year-old, female patient with no relevant medical history, who experienced, serious unlisted AESI of pericarditis, among other serious events. The event occurred 4	

Case ID	WW Identifier	Narrative	MAH Comment
		days after the dose of Moderna COVID-19 Vaccine. However, only the second dose was Moderna COVID-19 Vaccine and details of the first dose was not provided. The administration of two different vaccines remains a confounder. The rechallenge was unknown as the event occurred after second vaccine dose. The benefit-risk relationship of Moderna COVID-19 Vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 04-Oct-2021: Translation received on 06-Oct-2021 included updated event related information and updated narrative	

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-Oct-2021 and was forwarded to Moderna on 04-Oct-2021. This regulatory authority case was reported by a physician and describes the occurrence of ACUTE PULMONARY OEDEMA (Acute pulmonary edema) and MYOCARDITIS (Myocarditis) in a 37-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3003604) for Vaccination. The occurrence of additional non-serious events is detailed below. Previously administered products included for Vaccination: COMIRNATY. Past adverse reactions to the above products included No adverse reaction with COMIRNATY. On 08-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 11-Sep-2021, the patient experienced ACUTE PULMONARY OEDEMA (Acute pulmonary edema) (seriousness criteria hospitalization and medically significant) and MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). On an unknown date, the patient experienced COVID-19 IMMUNISATION (Revaccination with different COVID-19). On 13-Sep-2021, ACUTE PULMONARY OEDEMA (Acute pulmonary edema) and MYOCARDITIS (Myocarditis) had resolved. At the time of the report, COVID-19 IMMUNISATION (Revaccination with different COVID-19) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 11-Sep-2021, Computerised tomogram thorax: abnormal (abnormal) Changes mostly suspect for interstitial alveolar edema, alt. infection less probable.. On 11-Sep-2021, Ejection fraction: abnormal (abnormal) Left ventricle ejection fraction just below 40 % on admission to hospital and also on 12/Sep/2021. On 13-Sep-2021, Ejection fraction: abnormal (abnormal) Completely normalized. In September 2021, C-reactive protein: 4-126 (abnormal) 4-126.	37 years old male with unknown medical history who received Cominarty as the 1st dose of his COVID-19 vaccination and same day after the 2nd dose with SpikevX experienced acute myocardial infarction and was diagnosed with myocarditis. Lab results showed elevated troponin, abnormal catheterization and EKG. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and EKG and catheterization results and a causal relationship cannot be excluded due to the lack of other information.

Case ID	WW Identifier	Narrative	MAH Comment
		In September 2021, Echocardiogram: abnormal (abnormal) Reduced cardiac function. In September 2021, Troponin T: high (High) Slightly elevated. 118-135-82.. For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered ACUTE PULMONARY OEDEMA (Acute pulmonary edema) and MYOCARDITIS (Myocarditis) to be possibly related. No further causality assessment was provided for COVID-19 IMMUNISATION (Revaccination with different COVID-19). The reporter considered the patient most likely experienced acute pulmonary edema due to myocarditis which was secondary to the second dose with mRNA Covid-19 vaccine. However, Troponin T was not very high and clinical and echocardiographic recovering was very quick, so the causal relation is uncertain. Concomitant product usage were not provided. The patient was hospitalized on 12 Sep 2021. Treatment details were not provided. Company comment This case concerns a 37-year-old, male patient with no relevant medical history, who experienced the unexpected event of Acute pulmonary oedema, Myocarditis and Covid-19 immunisation. The events of Acute pulmonary oedema, Myocarditis occurred 3 days after the second dose of Moderna Covid-19 vaccine. The rechallenge was not applicable, as the event happened only after the second dose. The events were considered related to the product per the reporter's assessment. The benefit-risk relationship of Moderna Covid-19 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 04-Oct-2021: Translation received on 06-Oct-2021 included hospitalization details updated in narrative. On 08-Oct-2021: Follow-up contains non-significant information.	

Case ID	WW Identifier	Narrative	MAH Comment
4.1(b) [REDACTED]	4.1(b) [REDACTED]	This case was initially received via 4.1(b) [REDACTED] (Reference number: 4.1(b) [REDACTED]) on 05-Oct-2021. The most recent information was received on 21-Oct-2021 and was forwarded to Moderna on 21-Oct-2021. This regulatory authority case was reported by a physician and describes the occurrence of CHEST PAIN (Chest pain), PAIN IN JAW (Pain in jaw), HEART RATE INCREASED (Heart rate high) and MYOCARDITIS (Acute myocarditis) in a 19-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) (batch no. 3004668) for COVID-19 vaccination and Ill-defined disorder. Concurrent medical conditions included Myocarditis. On 30-Sep-2021, the patient received second dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) .5 ml. On 03-Oct-2021, received dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 03-Oct-2021, after starting mRNA-1273 (Moderna CoviD-19 Vaccine), the patient experienced MYOCARDITIS (Acute myocarditis) (seriousness criteria hospitalization and medically significant). On an unknown date, the patient experienced CHEST PAIN (Chest pain) (seriousness criteria hospitalization and medically significant), PAIN IN JAW (Pain in jaw) (seriousness criteria hospitalization and medically significant) and HEART RATE INCREASED (Heart rate high) (seriousness criteria hospitalization and medically significant). At the time of the report, CHEST PAIN (Chest pain), PAIN IN JAW (Pain in jaw) and HEART RATE INCREASED (Heart rate high) outcome was unknown and MYOCARDITIS (Acute myocarditis) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 03-Oct-2021, Troponin: high (High) Trop 1318 rise to 2370, 3 days after second vaccine. On 04-Oct-2021, Magnetic resonance imaging: abnormal (abnormal) Consultant confirmed myocarditis. On 04-Oct-2021, Troponin: 1700 (Low) Slightly decreased to 1700.	19 years old male with unknown medical history who 3 days after the 2nd dose experienced chest pain, pain in jaw, and heart rate increased and was diagnosed with myocarditis. Laboratory values showed elevated troponin, and abnormal cMRI. ECH and Echo were normal. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for any other infectious process that may had explained the cough and the malaise and the previous symptoms he was feeling for a week. According to 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
		On an unknown date, Blood pressure measurement: normal (normal) normal. On an unknown date, Echocardiogram: normal (normal) normal. On an unknown date, Electrocardiogram: normal (normal) normal. On an unknown date, Heart rate: inconclusive (Inconclusive) 90s. For mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Concomitant medications was not reported. The patient experienced chest pains and pain in jaw on left side of the body. He went to hospital accident and emergency (a and e) as they suspected a heart attack. The hospital admitted him to the CCU (Coronary care unit) on 03-Oct-2021, placed on unspecified beta blockers 2.5 milligram (mg) to slow heart rate from high 90s, so no more strain was placed on the heart muscle. He had not tested positive for COVID-19 since having the vaccine, and not enrolled in clinical trial. Adverse reaction did not occur as a result of an exposure during pregnancy. Company comment: This case concerns a 19-year-old, male patient with no medical history reported, who experienced serious expected AESI of Myocarditis after second dose of mRNA-1273. The event occurred 5 days after the second dose of mRNA-1273. The re-challenge is unknown as the adverse event occurred after second dose and the outcome is recovering.. The benefit-risk relationship of Moderna covid -19 vaccine, is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 21-Oct-2021: Significant Follow-up Appended, Events, Lab data, Product Information was updated.	

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

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 05-Oct-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of DYSPNOEA (Dyspnoea/Feeling short of breath), CHEST PAIN (Chest pain) and MYOCARDITIS (Myocarditis) in a 33-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 002F21A and 053E21A) for COVID-19 vaccination. No Medical History information was reported. On 20-Sep-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 20-Sep-2021, the patient experienced DYSPNOEA (Dyspnoea/Feeling short of breath) (seriousness criteria hospitalization and life threatening), CHEST PAIN (Chest pain) (seriousness criteria hospitalization and life threatening) and MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization, medically significant and life threatening). The patient was treated with ASPIRIN [ACETYLSALICYLIC ACID] for Chest pain, at an unspecified dose and frequency. On 20-Sep-2021, CHEST PAIN (Chest pain) had resolved. At the time of the report, DYSPNOEA (Dyspnoea/Feeling short of breath) and MYOCARDITIS (Myocarditis) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 20-Sep-2021, Troponin: increased (High) Troponin on arrival was 1.4 and peaked at 2.4.. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medication was given. Laboratory data was mentioned as on 20-Sep-2021 patient took the tests for blood magnesium, blood phosphorus, C-reactive	33 years old male with unknown medical history who same day after the 2nd dose experienced dyspnoea and chest pain and was diagnosed with myocarditis. Laboratory values showed elevated troponin and normal ECH, Echo, and chest x-ray. Patient was admitted to hospital overnight. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events as well as elevated troponin. A causal relationship cannot be excluded due to the lack of other information.

Case ID	WW Identifier	Narrative	MAH Comment
		protein, full blood count, lipase, metabolic function test, red blood cell sedimentation rate and SARS-CoV-2 test but the results was not given. On 20-Sep-2021 Chest X-ray, Echocardiogram and Electrocardiogram were performed and results were normal. Patient had short of breath a few hours later, and chest pain at evening and he was admitted to hospital overnight for myocarditis monitoring. Company comment: This case concerns a 33-year-old male patient, with no reported medical history who experienced the unexpected event of dyspnoea, chest pain, and expected event of myocarditis. The events occurred on the same day after the second dose of mRNA-1273 (Moderna COVID-19 Vaccine). The rechallenge was unknown as no details about the first dose was disclosed. Causality for the reported events were not provided. The event pf myocarditis is consistent with the current understanding of the mechanism of action of the vaccine. The benefit-risk relationship of Moderna COVID-19 Vaccine is not affected by this report. Event assessed as serious per Regulatory authority as event required hospitalization. Myocarditis is an adverse event of special interest.	

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 02-Oct-2021 and was forwarded to Moderna on 06-Oct-2021. This case, initially reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref, 4.1(b)) On an unknown date, the patient received the 1st dose of this vaccine. On an unknown date, body temperature before the vaccination: 36.4 degrees Celsius. On 28-Sep-2021, at 13:30, the patient received the 2nd dose of this vaccine. On 29-Sep-2021, pyrexia of 40 degrees Celsius developed. On 01-Oct-2021, at 07:00, the patient was raced to a hospital for chest discomfort. Since an abnormally high level of troponin I of 1,700 was confirmed, the patient was hospitalized on the same day for suspected myocarditis. The outcome of pyrexia and suspected myocarditis was unknown. Follow-up investigation will be made. Company Comment: The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	20 years old male with unknown medical history who 3 days after the 2nd dose experienced chest discomfort and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events as well as elevated troponin. A causal relationship cannot be excluded due to the lack of other information.

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 02-Oct-2021 and was forwarded to Moderna on 06-Oct-2021. This case, initially reported to the 4.1(b) by a (physician), was received via the 4.1(b) (Ref, 4.1(b)) On an unknown date, the patient received the 1st dose of this vaccine. On an unknown date, body temperature before vaccination: 36.6 degrees Celsius. On 24-Sep-2021, at 17:00, the patient received the 2nd dose of this vaccine. On 25-Sep-2021, pyrexia of 38.0-38.9 degrees Celsius developed. On 26-Sep-2021, fever went down to 37 degrees Celsius. At 17:00, myocarditis developed. Chest pain and respiratory discomfort were noted. On 27-Sep-2021, the patient's symptoms did not improve, and the patient visited a nearby physician. ECG showed ST-segment elevation in 1, aVL, and V2. The patient was referred to another hospital, and emergency catheterization was performed. The coronary artery was normal. The patient was hospitalized on the same day. There were no abnormalities in blood pressure and SPO2. Blood test showed increased CK and troponin I. Around 29-Sep-2021, ST tended to improve on ECG. Around 30-Sep-2021, subjective symptoms improved. On 01-Oct-2021, recovery of symptoms was confirmed. The patient was discharged from the hospital. The outcome of pyrexia and myocarditis was reported as recovered. Follow-up investigation will be made. Company Comment:	28 years old male with unknown medical history who 3 days after the 2nd dose experienced chest pain and respiratory discomfort, and was diagnosed with myocarditis. Laboratory values showed elevated troponin and CK, and abnormal 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 elevated troponin and abnormal ECG. A causal relationship cannot be excluded due to the lack of other information.

Case ID	WW Identifier	Narrative	MAH 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 05-Oct-2021 and was forwarded to Moderna on 05-Oct-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of ACUTE MYOCARDIAL INFARCTION (Acute myocardial infarction), MYOCARDIAL INFARCTION (Myocardial infarction), CHEST PAIN (Chest pain), DYSPNOEA (Dyspnoea), TROPONIN INCREASED (Troponin increased) and MYOCARDITIS (Myocarditis) in a 25-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. Concurrent medical conditions included Allergy to vaccine (Pertussis Toxoid). On 17-Sep-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 17-Sep-2021, the patient experienced ACUTE MYOCARDIAL INFARCTION (Acute myocardial infarction) (seriousness criteria hospitalization and medically significant) and MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). 17-Sep-2021, the patient experienced MYOCARDIAL INFARCTION (Myocardial infarction) (seriousness criteria hospitalization and medically significant), CHEST PAIN (Chest pain) (seriousness criterion hospitalization), DYSPNOEA (Dyspnoea) (seriousness criterion hospitalization) and TROPONIN INCREASED (Troponin increased) (seriousness criterion hospitalization). The patient was hospitalized on 19-Jul-2021 due to TROPONIN INCREASED, then on 19-Sep-2021 due to ACUTE MYOCARDIAL INFARCTION, CHEST PAIN, DYSPNOEA, MYOCARDIAL INFARCTION and MYOCARDITIS. At the time of the report, ACUTE MYOCARDIAL INFARCTION (Acute myocardial infarction), MYOCARDIAL INFARCTION (Myocardial infarction), CHEST PAIN (Chest pain), DYSPNOEA (Dyspnoea), TROPONIN INCREASED (Troponin increased) and MYOCARDITIS (Myocarditis) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):	25 years old male with unknown medical history who same day after the 2nd dose experienced acute myocardial infarction and was diagnosed with myocarditis. Lab results showed elevated troponin, abnormal catheterization and EKG. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and EKG and catheterization results and a causal relationship cannot be excluded due to the lack of other information.

Case ID	WW Identifier	Narrative	MAH Comment
		On 19-Sep-2021, Electrocardiogram: st elevation (abnormal) ST elevation consider inferolateral injury or acute infarct. On 19-Sep-2021, Troponin: 869 (High) 869. On 20-Sep-2021, Catheterisation cardiac: acute st-elevation mi (abnormal) Acute ST-elevation myocardial infarction (MI). This appears to be related to myocarditis.. On 20-Sep-2021, Troponin: 1799 (High) 1799. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Concomitant product use was not provided by the reporter. No treatment information was provided. Patient reported worsening chest pain (8 out of 10) and shortness of breath. On 17 Sep 2021, echocardiogram and magnetic resonance imaging heart was performed (results were pending). Company comment: This case concerns a 25-year-old, male patient with no previous relevant medical history reported, who experienced the unexpected events of acute myocardial infarction, myocardial infarction, chest pain, dyspnoea, myocarditis and troponin increased. The events occurred the same day after the second dose of mRNA-1273. The rechallenge was not applicable since the events happened after the second dose. The benefit-risk relationship of mRNA-1273 is not affected by this report.	

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 06-Oct-2021. This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDIAL INFARCTION (heart attack), ELECTROCARDIOGRAM NORMAL (ECG normal) and MYOCARDITIS (Myocarditis) in a 19-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) (batch no. 3004668) for COVID-19 vaccination. No Medical History information was reported. On 30-Sep-2021, the patient received second dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 03-Oct-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). On an unknown date, the patient experienced MYOCARDIAL INFARCTION (heart attack) (seriousness criteria hospitalization and medically significant) and ELECTROCARDIOGRAM NORMAL (ECG normal) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDIAL INFARCTION (heart attack) and ELECTROCARDIOGRAM NORMAL (ECG normal) had resolved and MYOCARDITIS (Myocarditis) was resolving. The action taken with mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown) was unknown. No concomitant medication was provided by reporter. Patient experienced chest pain and pain in jaw on left side of the body. Doctor advised to go to hospital as doctor suspected a heart attack. Patient was admitted to coronary care unit on 03-Oct-2021. The ECG, echocardiogram and blood pressure was normal; Troponin was 1318 which then increased to more than 2000. Patient was placed on beta blockers 2.5mg to slow	19 years old male with unknown medical history who 3 days after the 2nd dose experienced chest pain and pain was found to have elevated troponin, cMRI abnormal, that confirmed the diagnosis of myocarditis, with normal ECH and normal Echo. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the 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
		heart rate from high 90 so no more strain was placed on the heart muscle. Troponin level on 04-Oct-2021 was 1700. The MRI on 04-Oct-2021, the myocarditis was confirmed. No treatment drug was provided by reporter. Company Comment: This case concerns a 19-year-old, male patient with no relevant medical history, who experienced the unexpected events of Myocardial infarction, Electrocardiogram normal and the expected event of Myocarditis. The event of Myocarditis occurred approximately 3 days after the second dose of Moderna vaccine. The rechallenge was unknown as no information was provided about the first dose. The events were considered related to the product per the reporter's assessment. The event of Myocarditis is consistent with the current understanding of the mechanism of action of the vaccine. The benefit-risk relationship of Moderna Covid-19 vaccine is not affected by this report.	

Case ID	WW Identifier	Narrative	MAH Comment
4.1(b)	4.1(b)	This case was initially received via 4.1(b) (Reference number: 4.1(b) on 01-Oct-2021. The most recent information was received on 06-Oct-2021 and was forwarded to Moderna on 19-Oct-2021. This case, reported by a pharmacist, was received by 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 06-Oct-2021, follow-up information, initially reported by a pharmacist, was received by 4.1(b) via Moderna's adverse reaction reporting site 4.1(b) On 07-Oct-2021, follow-up information, initially reported to the 4.1(b) by a pharmacist, was received via the 4.1(b) (Ref, 4.1(b) On 31-Aug-2021, the patient received the 1st dose of this vaccine. On 28-Sep-2021, the patient received the 2nd dose of this vaccine. On 30-Sep-2021, severe chest pain developed. It was considered that acute myocarditis developed. On 01-Oct-2021, the patient visited a medical institution. Electrocardiogram showed extensive ST elevation, and echocardiography showed decreased wall hypokinesia. CK: 698, CK-MB: 52, TnT: 0.818, NT-proBNP: 148, which increased. Myocarditis after the vaccination with this vaccine was suspected. The patient was hospitalized in the reporting hospital. On an unknown date, after the hospitalization, follow-up was performed, and CK and NT-proBNP levels returned to normal. On 04-Oct-2021, the recovery was confirmed, and the patient was discharged from the hospital. The outcome of acute myocarditis was reported as recovered.	21 years old male with unknown medical history who 3 days after the 2nd dose experienced chest pain and was found to have elevated troponin, Ck, NT-proBNP, abnormal ECG, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and ECG results; a causal relationship cannot be excluded due to the lack of other information.

Case ID	WW Identifier	Narrative	MAH Comment
		No follow-up investigation will be made. Follow-up received on 06-OCT-2021 Updated: Lab Data, Product Information, Event Information, Narrative Company Comment: The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	