Appendix 11.19a Multisystem Inflammatory Syndrome (MIS): Summary Information on the Reported Events During the Reporting Period with a Fatal Outcome: Case Listings

Case ID	Country	Report Type	PT	Event Seriousness	ALL PTs	Patient Age (Years)	Patient Gender	Event Outcome	Medical History	Concomitant Medications	Dose #	TTO All Doses	Primary Cause of Death	WW Identifier
[redacted]	TAIWAN, PROVINCE OF CHINA	Regulatory Authority	Haemophagocytic lymphohistiocytosis	Serious	Haemophagocytic lymphohistiocytosis, Stevens-Johnson syndrome, Toxic epidermal necrolysis	77.00	Female	Fatal	Mouth ulceration(H); Perineal ulceration(H)		Dose 2	11	Hemophagocytosis syndrome	[redacted]
	GERMANY	Regulatory Authority	Multiple organ dysfunction syndrome	Serious	Coagulopathy, COVID-19, Hepatic failure, Multiple organ dysfunction syndrome, Shock haemorrhagic, Thrombocytopenia	69.00	Female	Fatal	COVID-19(C); VAXZEVRIA; COMIRNATY		Unknown		Multiorgan failure	
	SINGAPORE	Literature-Non-Study	Multiple organ dysfunction syndrome	Serious	Cardiac arrest, Multiple organ dysfunction syndrome, Sepsis	33.00	Male	Fatal			Unknown		Consistent with multi organ failure following cardiac arrest	
	ITALY	Regulatory Authority	Septic shock	Serious	Acute kidney injury, Aphasia, Bladder sphincter atony, Cerebrovascular accident, Coma, Pneumonia, Respiratory failure, Septic shock	87.00	Male	Fatal	Chronic obstructive pulmonary disease(C); Hypertension(C); Cognitive disorder(H); Chronic kidney disease(C); COMIRNATY; COMIRNATY	NORVASC; KANRENOL; TRITTICO; QUETIAPINE; FOSTER [PIROXICAM]	Unknown		Shock septic	
	JAPAN	Spontaneous	Multiple organ dysfunction syndrome	Serious	Altered state of consciousness, Cerebral infarction, Heat illness, Movement disorder, Multiple organ dysfunction syndrome, Shock	76.00	Male	Fatal	COMIRNATY; COMIRNATY; Diabetes mellitus(C); Atrial fibrillation(C)		Unknown		Multiple cerebral infarction	
	ITALY	Regulatory Authority	Septic shock	Serious	Anuria, Multiple organ dysfunction syndrome, Septic shock	74.00	Male	Fatal	Respiratory failure(H); Amnestic disorder(H); Ex-tobacco user(H); Diabetic retinopathy(C); Sepsis(H); Diaphragmatic hernia(H); Peripheral arterial occlusive disease(H); Aortic valve replacement(H); Lactic acidosis(H); Hypertensive heart disease(H); Anaemia(H); Insulin-requiring type 2 diabetes mellitus(C); Hypertension(C); Hyperuricaemia(H); Atrial fibrillation(C); Hepatic steatosis(H); Acute pulmonary oedema(H); Cerebral infarction(H); Femur fracture(H); COMIRNATY; COMIRNATY	TOUJEO; TORVAST; CARDIOASPIRIN; LANOXIN; ELIQUIS; LASIX P; SERTRALINE; KANRENOL; SEQUACOR; LANSOX; NOVORAPID	Unknown		Shock septic	
	GERMANY	Regulatory Authority	Multiple organ dysfunction syndrome	Serious	Meningitis, Multiple organ dysfunction syndrome	69.00	Male	Fatal	COVID-19 VACCINE ASTRAZENECA; COMIRNATY		Dose 3	0	Multiple organ failure	
	UNITED STATES	Literature-Non-Study	Septic shock	Serious	Aplastic anaemia, Cardiac arrest, Clostridium difficile infection, Enterococcal infection, Febrile neutropenia, Pneumonia, Septic shock	60.00	Male	Fatal	Alcohol use(H); Nasal cavity packing; Clostridial infection(C)		Unknown		Cardiac arrest	
	SWEDEN	Regulatory Authority	Multiple organ dysfunction syndrome	Serious	Cardiac arrest, COVID-19 immunisation, Decreased appetite, Fatigue, General physical health deterioration, Malnutrition, Mobility decreased, Multiple organ dysfunction syndrome, Personality change	94.00	Female	Fatal	Upper limb fracture(H); Drug hypersensitivity; Colon cancer(H); Angina pectoris(C); Diarrhoea(H)		Unknown		Unspecified nutritional deficiency	
	JAPAN	Spontaneous	Multiple organ dysfunction syndrome	Serious	Altered state of consciousness, Depressed level of consciousness, Hypotension, Multiple organ dysfunction syndrome, Pyrexia, Rhabdomyolysis, Seizure, Sepsis, Status epilepticus	63.00	Male	Fatal	Epilepsy(C); Head injury(H)	ALEVIATIN MINO; LAMICTAL	Unknown		Convulsion	
	JAPAN	Spontaneous	Multiple organ dysfunction syndrome	Serious	Bacterial infection, Multiple organ dysfunction syndrome, Pneumonia, Pulmonary alveolar haemorrhage, Respiratory failure, Vasculitis	84.00	Female	Fatal	Back pain(C); Hypertension(C); Dementia(C); COMIRNATY; COMIRNATY		Unknown		Diffuse alveolar hemorrhage	
	SPAIN	Regulatory Authority	Vaccine associated enhanced respiratory disease	Serious	Atrial fibrillation, COVID-19 pneumonia, Pneumothorax, Vaccination failure, Vaccine associated enhanced respiratory disease	64.00	Male	Fatal	Peripheral venous disease(H); Mixed anxiety and depressive disorder(H)		Dose 2	227	COVID-19 pneumonia (10084380)	
	JAPAN	Spontaneous	Multiple organ dysfunction syndrome	Serious	Cerebral infarction, Diarrhoea, Herpes virus infection, Lung abscess, Multiple organ dysfunction syndrome, Pneumonia, Pyrexia, Respiratory failure	40.00	Male	Fatal			Unknown		Pneumonia	

Appendix 11.19b Multisystem Inflammatory Syndrome (MIS): Summary Information on the Reported Events During the Reporting Period with a Fatal Outcome: Narratives

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
[redacted]	This regulatory authority case was reported by an other health care professional and describes the occurrence of STEVENS-JOHNSON SYNDROME (Stevens-Johnson syndrome (SJS)), TOXIC EPIDERMAL NECROLYSIS (Toxic epidermal necrolysis (TEN)) and HAEMOPHAGOCYTIC LYMPHOHISTIOCYTOSIS (Macrophage activating syndrome) in a 77-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The patient's past medical history included Oral ulceration (presented with EM like lesion with oral/perineal ulcers, diagnosed at Tungs' Taichung MetroHarbor Hospital) on 04-Oct-2021 and Perineal ulceration (presented with EM like lesion with oral/perineal ulcers, diagnosed at Tungs' Taichung MetroHarbor Hospital) on 04-Oct-2021. On 04-Jul-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 23-Sep-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 04-Oct-2021, the patient experienced STEVENS-JOHNSON SYNDROME (Stevens-Johnson syndrome (SJS)) (seriousness criteria death and hospitalization prolonged), TOXIC EPIDERMAL NECROLYSIS (Toxic epidermal necrolysis (TEN)) (seriousness criteria death and hospitalization prolonged) and HAEMOPHAGOCYTIC LYMPHOHISTIOCYTOSIS (Macrophage activating syndrome) (seriousness criteria death and hospitalization). The patient died on 05-Dec-2021. The reported cause of death was hemophagocytosis syndrome, Acute cholecystitis and suspected vaccine adverse reactions. It is unknown if an autopsy was performed. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Concomitant medication of the patient was not reported. No treatment information was provided by the reporter. It was reported that on January 7, 2022, Wuqi Health Center assisted in handling the application for relief for harm from of vaccination and an application was made to close the case.	level 5	Unlikely	This healthcare professional reported case concerns a 77-year-old female patient with no medical history reported, who experienced Stevens-Johnson syndrome, Toxic epidermal necrolysis, and Haemophagocytic lymphohistiocytosis, 12 days after the second dose of mRNA-1273 vaccine with a fatal outcome. It reported that patient presented with erythema multiforme like lesion with oral/perineal ulcers diagnosed at hospital. The cause of death was reported as hemophagocytic syndrome, acute cholecystitis, and suspected vaccine adverse reaction. No information about MIS is provided although some clinical signs and symptoms may overlap reported hemophagocytic lymphohistocytosis. In addition, SJS/TEN seemed to be diagnosed at a hospital. This case is classified as level 5 given the differential diagnosis of HLH. Hyperinflammatory states as HLH has a similar disease presentation to that observed in MIS-C/A.. This case is considered unlikely.	[redacted]

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	Company Comment: This is a RA case concerning a 77-year-old female patient, with no medical history reported, who experienced the unexpected events of Stevens-Johnson syndrome (AESI), Toxic epidermal necrolysis (AESI), and Haemophagocytic lymphohistiocytosis. The patient completed primary vaccination for COVID-19 with mRNA-1273 vaccine, with an interval between doses of 81 days (Inappropriate schedule of vaccine administered). The events occurred 12 days after the second dose of mRNA-1273 vaccine, and had a fatal outcome, with death occurring 13 days after second dose of mRNA-1273 vaccine. It is unknown if an autopsy was performed. Cause of death was reported as hemophagocytic syndrome, acute cholecystitis, and suspected vaccine adverse reaction. The benefit-risk relationship of mRNA-1273 is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 25-Apr-2022: Follow up document received, contains no new information (NNI).				

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
[redacted]	This case was received via European Medicines Agency (Reference number: [redacted] on 01-Feb-2022 and was forwarded to Moderna on 01-Feb-2022. This regulatory authority case was reported by a physician and describes the occurrence of SHOCK HAEMORRHAGIC (Hemorrhagic shock), COAGULOPATHY (Clotting disorder), MULTIPLE ORGAN DYSFUNCTION SYNDROME (Multiple organ failure), HEPATIC FAILURE (Hepatic failure), COVID-19 (SARS-CoV-2 infection) and THROMBOCYTOPENIA (Thrombopenia) in a 69-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 000105A) for COVID-19 vaccination. Previously administered products included for COVID-19 vaccination: Vaxzevria COVID-19 Vaccine (ChAdOx1-S [recombinant])COVID-19 Vaccine AstraZeneca suspension for injectionCOVID-19 Vaccine AstraZeneca on 10-May-2021 and Comirnaty BNT162b2 on 02-Aug-2021. Past adverse reactions to the above products included No adverse event with Comirnaty BNT162b2 and Vaxzevria COVID-19 Vaccine (ChAdOx1-S [recombinant])COVID-19 Vaccine AstraZeneca suspension for injectionCOVID-19 Vaccine AstraZeneca. Concurrent medical conditions included SARS-CoV-2 infection. On 07-Jan-2022, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 09-Jan-2022, the patient experienced SHOCK HAEMORRHAGIC (Hemorrhagic shock) (seriousness criteria death, hospitalization and life threatening), COAGULOPATHY (Clotting disorder) (seriousness criteria death, hospitalization and life threatening), MULTIPLE ORGAN DYSFUNCTION SYNDROME (Multiple organ failure) (seriousness criteria death, hospitalization and life threatening), HEPATIC FAILURE (Hepatic failure) (seriousness criteria death, hospitalization and life threatening) and THROMBOCYTOPENIA (Thrombopenia) (seriousness criteria death, hospitalization and life threatening). On an unknown date, the patient experienced COVID-19 (SARS-CoV-2 infection) (seriousness criteria death, hospitalization and life threatening). The patient died on 09-Jan-2022. The reported cause of death was Multiorgan failure. An autopsy	level 5	unlikely	This case concerns a 69-year-old female patient with a history of Covid 19 infection, a previous vaccination with Vaxzevria recombinant COVID-19 Vaccine on 10-May-2021 and Comirnaty BNT162b2 on 02-Aug-2021 and no co meds reported, who experienced Shock Hemorrhagic, Coagulopathy, Multiple organ dysfunction syndrome, Hepatic failure and Thrombocytopenia, approximately 2 days after receiving a dose of mRNA-1273 Vaccine on 07-Jan-2022 and resulted in a fatal outcome. The reported cause of death was Multiorgan failure. An autopsy was not performed. No additional information is provided for an appropriate assessment. However, based on the limited information, it is likely that thrombocytopenia and coagulopathy led to hemorrhagic shock and multiple organ dysfunction, including liver failure. This case is considered level 5 according to the Brighton Collaboration case definition for MIS due to the alternative diagnosis reported of multiple organ dysfunction syndrome in the setting of coagulopathy and hemorrhagic shock. Although the events occurred within 2 days of receiving Spikevax, concurrent COVID-19 infection and past vaccinations with Vaxzevria and Comirnaty COVID-19 vaccines are significant confounders. The WHO causality assessment for this case is considered unlikely, as COVID-19 infection is a more plausible alternate etiology for these events.	[redacted]

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	was not performed. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. Concomitant medication was not provided. Treatment information was not provided. Company Comment: This case concerns a 69-year-old female patient, with relevant medical history of previous vaccination with Vaxzevria COVID-19 Vaccine and Comirnaty BNT162b2, who experienced the unexpected serious events of Shock Hemorrhagic, Coagulopathy, Multiple organ dysfunction syndrome, Hepatic failure and Thrombocytopenia. The events occurred approximately 2 days after receiving a dose of mRNA-1273 Vaccine and resulted in a fatal outcome. The unexpected serious AESI event of COVID-19 occurred on an unknown date. The reported cause of death was Multiorgan failure. An autopsy was not performed. The patient's medical history of previous vaccination with Vaxzevria COVID-19 Vaccine and Comirnaty BNT162b2, remain as confounders for the occurrence of the events. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report.				

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
[redacted]	This literature-non-study case was reported in a literature article and describes the occurrence of MULTIPLE ORGAN DYSFUNCTION SYNDROME (Consistent with multi organ failure following cardiac arrest), CARDIAC ARREST (cardiac arrest due to right ventricular dysplasia) and SEPSIS (sepsis) in a 33-year-old male patient who received mRNA-1273 (COVID 19 Vaccine Moderna) for COVID-19 vaccination. LITERATURE REFERENCE: Yeo A,Kuek B, Lau M, Tan SR, Chan S. Post COVID-19 vaccine deaths - Singapore's early experience. Forensic Sci Int. 2022;332:111199 No Medical History information was reported. In 2021, the patient received second dose of mRNA-1273 (COVID 19 Vaccine Moderna) (unknown route) 1 dosage form. In 2021, the patient experienced MULTIPLE ORGAN DYSFUNCTION SYNDROME (Consistent with multi organ failure following cardiac arrest) (seriousness criteria death, hospitalization and medically significant) and CARDIAC ARREST (cardiac arrest due to right ventricular dysplasia) (seriousness criteria death, hospitalization and medically significant). 2021, the patient experienced SEPSIS (sepsis) (seriousness criteria death, hospitalization and medically significant). The patient died in 2021. The reported cause of death was consistent with multi organ failure following cardiac arrest, cardiac arrest due to right ventricular dysplasia and Sepsis. An autopsy was performed. Related DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Blood immunoglobulin E: 243 iu/ml 243 IU/mL. On an unknown date, C-reactive protein: 155 mg/l 155 mg/L. On an unknown date, Tryptase: 10.3 ug/l 10.3 ug/l. For mRNA-1273 (COVID 19 Vaccine Moderna) (Unknown), the reporter considered MULTIPLE ORGAN DYSFUNCTION SYNDROME (Consistent with multi organ failure following cardiac arrest), CARDIAC ARREST	level 5	Unlikely	This is a literature case that concerns a 33-year-old male patient with no medical history and no co meds reported, who experienced cardiac arrest due to right ventricular dysplasia one day after receiving the second dose of Spikevax. Lab tests included C-reactive protein high 155 mg/l. The autopsy-determined cause of death was multi organ failure (multiple organ dysfunction syndrome) with evidence of sepsis following cardiac arrest due to right ventricular dysplasia. There was no evidence of eosinophilic infiltration, myocarditis, or thrombosis and no signs of anaphylaxis, such as facial (including periorbital, lips etc.) or airway edema, skin changes (e.g. rash, urticaria). This case is considered level 5 according to the Brighton Collaboration case definition for MIS because of the alternative diagnosis of multiple organ dysfunction syndrome following cardiac arrest. The WHO causality assessment for this case is considered unlikely, as right ventricular dysplasia is a more plausible alternate etiology for these events.	[redacted]

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	(cardiac arrest due to right ventricular dysplasia) and SEPSIS (sepsis) to be related. No concomitant medication were provided. No treatment information were reported. A total of 34 deaths that occurred within 72 h of the deceased receiving their COVID-19 vaccination and autopsies, histological sampling and ancillary investigations consisting of total tryptase level, Immunoglobulin E (IgE), and C-reactive Protein (CRP), were performed on 29 of these cases. This case is related to patient number 27 as per article. It was reported that the patient in this case sustained neurological or cardiovascular compromise requiring medical resuscitation within 72 h of receiving the vaccine and subsequently demised after a period of hospitalization. There was no sign of Anaphylaxis such as facial (including periorbital, lips etc.) or airway edema, skin changes (e.g. rash, urticaria). And also no sign of Histological Features including the presence of eosinophilic infiltration, the presence of myocarditis and/or thrombosis. Company comment: This is a literature case that concerns a 33-year-old male patient with no medical history, who experienced the unexpected serious events of Multiple Organ Dysfunction Syndrome, Cardiac Arrest, and Sepsis. The events were medically significant, led to the hospitalization, and eventual demise of the patient. The events occurred on an unknown interval after receiving the second dose of mRNA-1273 Vaccine. The patient died on an unknown date. The reported cause of death was consistent with multi organ failure following cardiac arrest, cardiac arrest due to right ventricular dysplasia and Sepsis. An autopsy was performed, but no results were provided. No clinical or treatment details were given. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report. This case was linked to [redacted] (Patient Link). Most recent FOLLOW-UP information incorporated above includes:				

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	On 03-Feb-2022: Follow up received by safety on 03-Feb-2022 has Email with FTA received from SARA team and contains significant information. Authors, lab data, Hospitalization details, events and autopsy were added.				

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
[redacted]	This case was initially received via European Medicines Agency (Reference number [redacted] on 14-Feb-2022. The most recent information was received on 22-Feb-2022 and was forwarded to Moderna on 22-Feb-2022. This regulatory authority case was reported by a physician and describes the occurrence of RESPIRATORY FAILURE (sphincter release, aphasic, septic shock, coma state, respiratory failure, bilateral pneumonitis, suspected stroke, IRA), PNEUMONIA (sphincter release, aphasic, septic shock, coma state, respiratory failure, bilateral pneumonitis, suspected stroke, IRA), CEREBROVASCULAR ACCIDENT (sphincter release, aphasic, septic shock, coma state, respiratory failure, bilateral pneumonitis, suspected stroke, IRA), COMA (sphincter release, aphasic, septic shock, coma state, respiratory failure, bilateral pneumonitis, suspected stroke, IRA), BLADDER SPHINCTER ATONY (sphincter release, aphasic, septic shock, coma state, respiratory failure, bilateral pneumonitis, suspected stroke, IRA), ACUTE KIDNEY INJURY (sphincter release, aphasic, septic shock, coma state, respiratory failure, bilateral pneumonitis, suspected stroke, IRA), SEPTIC SHOCK (sphincter release, aphasic, septic shock, coma state, respiratory failure, bilateral pneumonitis, suspected stroke, IRA) and APHASIA (sphincter release, aphasic, septic shock, coma state, respiratory failure, bilateral pneumonitis, suspected stroke, IRA) in an 87-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3006322) for COVID-19 vaccination. The patient's past medical history included Neurocognitive deficit (MMSE 13/30) on 01-Apr-2021. Previously administered products included for SARS-CoV-2 vaccination: COMIRNATY (BIONTECH MANUFACTURING GMBH) (J07BX03) on 02-Apr-2021 and COMIRNATY (BIONTECH MANUFACTURING GMBH) (J07BX03) on 23-Apr-2021. Past adverse reactions to the above products included No adverse event with COMIRNATY (BIONTECH MANUFACTURING GMBH) (J07BX03) and COMIRNATY (BIONTECH MANUFACTURING GMBH) (J07BX03). Concurrent medical conditions included COPD, Hypertension arterial and Renal failure chronic. Concomitant products included AMLODIPINE BESILATE	level 5	unlikely	This case concerns an 87-year-old male patient with a medical history of SARS-CoV-2 vaccination with Comirnaty and neurocognitive deficit and concurrent medical conditions of COPD, hypertension arterial and renal failure chronic, who experienced respiratory failure, pneumonia, cerebrovascular accident, aphasia, bladder sphincter atony, acute kidney injury, septic shock and coma with a fatal outcome, approximately 59 days after a dose of mRNA-1273 vaccine administration. Concomitant medications included anti-hypertensive and anti-depression and antipsychotic: Norvasc, Kanrenol, Trittico, fluoxetine hydrochloride, Fostera and Quetiapine. SARS-CoV-2 test negative. Other labs including blood test, angiogram cerebral, chest x-ray, CT head, echocardiogram, electrocardiogram, electroencephalogram, culture for blood, CSF and tracheal aspirate were all inconclusive. Treatment information was unavailable. No reported MIS or information on fever, details of clinical features, lab evidence of inflammation and measures of disease activities associated with MIS. In addition, the information is insufficient for the medical assessment. The clinical presentation may likely be infectious pneumonia led to respiratory failure, septic shock, acute kidney failure and death under the condition of the various basic conditions especially COPD, chronic renal failure and CNS deficit in this aged patient. The case is considered level 5 for MIS, and unlikely for WHO due to vaccine/event TTO of two months and underlying confounding risks.	[redacted]

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	(NORVASC), POTASSIUM CANRENOATE (KANRENOL), TRAZODONE HYDROCHLORIDE (TRITTICO), QUETIAPINE and PIROXICAM (FOSTER [PIROXICAM]) for an unknown indication. On 23-Nov-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) .25 milliliter. On 21-Jan-2022, the patient experienced RESPIRATORY FAILURE (sphincter release, aphasic, septic shock, coma state, respiratory failure, bilateral pneumonitis, suspected stroke, IRA) (seriousness criterion death), PNEUMONIA (sphincter release, aphasic, septic shock, coma state, respiratory failure, bilateral pneumonitis, suspected stroke, IRA) (seriousness criterion death), CEREBROVASCULAR ACCIDENT (sphincter release, aphasic, septic shock, coma state, respiratory failure, bilateral pneumonitis, suspected stroke, IRA) (seriousness criterion death), COMA (sphincter release, aphasic, septic shock, coma state, respiratory failure, bilateral pneumonitis, suspected stroke, IRA) (seriousness criterion death), BLADDER SPHINCTER ATONY (sphincter release, aphasic, septic shock, coma state, respiratory failure, bilateral pneumonitis, suspected stroke, IRA) (seriousness criterion death), ACUTE KIDNEY INJURY (sphincter release, aphasic, septic shock, coma state, respiratory failure, bilateral pneumonitis, suspected stroke, IRA) (seriousness criterion death), SEPTIC SHOCK (sphincter release, aphasic, septic shock, coma state, respiratory failure, bilateral pneumonitis, suspected stroke, IRA) (seriousness criterion death) and APHASIA (sphincter release, aphasic, septic shock, coma state, respiratory failure, bilateral pneumonitis, suspected stroke, IRA) (seriousness criterion death). The patient died on 27-Jan-2022. The reported cause of death was Shock septic. An autopsy was not performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 21-Jan-2022, Angiogram cerebral: inconclusive (Inconclusive) Inconclusive. On 21-Jan-2022, Blood gases: inconclusive (Inconclusive) Inconclusive. On 21-Jan-2022, Blood test: inconclusive (Inconclusive) Inconclusive. On 21-Jan-2022, CSF culture: inconclusive (Inconclusive)				

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	Inconclusive. On 21-Jan-2022, Chest X-ray: inconclusive (Inconclusive) Inconclusive. On 21-Jan-2022, Computerised tomogram head: inconclusive (Inconclusive) Inconclusive. On 21-Jan-2022, Echocardiogram: inconclusive (Inconclusive) Inconclusive. On 21-Jan-2022, Electrocardiogram: inconclusive (Inconclusive) Inconclusive. On 21-Jan-2022, Electroencephalogram: inconclusive (Inconclusive) Inconclusive. On 21-Jan-2022, Physical examination: inconclusive (Inconclusive) Inconclusive. On 21-Jan-2022, SARS-CoV-2 test negative: inconclusive (Inconclusive) Inconclusive. On 22-Jan-2022, Blood culture: inconclusive (Inconclusive) Inconclusive. On 22-Jan-2022, Tracheal aspirate culture: inconclusive (Inconclusive) Inconclusive. On 25-Jan-2022, Specialist consultation: inconclusive (Inconclusive) Inconclusive. The action taken with mRNA-1273 (Spikevax) (Intramuscular) was unknown. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Treatment medication were not reported. Company comment: This regulatory case concerns an 87-year-old elderly male patient with medical history of COPD, hypertension arterial, renal failure chronic, neurocognitive deficit, and interchange of vaccine products (two doses of Comirnaty Covid19 vaccine), experienced the unexpected Fatal events Respiratory failure, Pneumonia, Cerebrovascular accident, Coma, bladder sphincter atony, Acute kidney injury, Septic shock, and Aphasia, one month twenty-nine days after a dose of mRNA-1273. The cause of death was reported as Septic shock. Autopsy was not performed. Advanced age of the patient could be a risk factor. Medical history of COPD, hypertension arterial, renal failure chronic could be				

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	confounding. 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 22-Feb-2022: Added patient's medical history, lab data, concomitant medications, events (bilateral pneumonia, stroke, coma, bladder sphincter atony, renal failure acute, aphasia), updated seriousness, verbatim for events (respiration failure, septic shock) and deleted event (sopor). On 07-Mar-2022: Non-significant follow up appended, Senders comment updated				

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
[redacted]	This case was initially received via Takeda Pharmaceuticals (Reference number: [redacted] on 16-Feb-2022. The most recent information was received on 16-Mar-2022 and was forwarded to Moderna on 24-Mar-2022. This case, initially reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by a physician, was received via the PMDA (Ref, [redacted]. On 16-Mar-2022, follow-up information was received from a physician. On an unknown date, the patient received the 1st dose of non-company coronavirus modified uridine RNA vaccine (SARS-CoV-2). On an unknown date, the patient received the 2nd dose of non-company coronavirus modified uridine RNA vaccine (SARS-CoV-2). On 12-Feb-2022, the patient received the 3rd vaccination with this vaccine. On 13-Feb-2022, around 16:00, consciousness disturbed developed. The patient was found collapsed and was transported by ambulance. The patient was suspected to have developed heat illness in a hot environment due to difficulty moving due to an unforeseen accident or a preceding disease. The patient was already in multi-organ failure, in shock, and difficult to save the patients life. CT showed the possibility of multiple cerebral infarctions but could not be confirmed. There was a suspected cerebral infarction due to chronic atrial fibrillation. On 14-Feb-2022, the patient was confirmed dead. The cause of death was heat illness. No autopsy was performed. The outcome of consciousness disturbed, possible multiple cerebral infarctions, difficulty in moving, suspected heat illness, multi-organ failure and shock was reported as fatal. No follow-up investigation will be made. Reporter's comment: The causal relationship between the progress and this vaccination is unknown. There is a possibility that cerebral infarction caused the difficulty in moving, resulting in heat illness, but the possibilities that the cause was atrial fibrillation, that the cerebral infarction was a result rather than a cause, and that the patient had no cerebral infarction from the beginning were also cannot be ruled out. Other factors include the possibility of suspected cerebral infarction due to chronic atrial fibrillation. The relationship between cause of death and adverse events is unknown. The cause of the heat illness was a fall in a bedrock bath facility, which may have been caused by cerebral infarction. Since it cannot be denied that cerebral infarction may be caused by thrombosis or chronic atrial fibrillation due to vaccination with this vaccine, it is unclear whether the occurrence of	level 5	unassessable	A physician reported case concerned a 76-year-old male who experienced Altered state of consciousness, Cerebral infarction, Heat illness, Movement disorder, Multiple organ dysfunction syndrome, and Shock on 13-Feb-2022, one day after he received the 3rd vaccination of mRNA-1273. He received two prior doses of non-company coronavirus modified uridine RNA vaccine on unknown dates. Medical history included diabetes mellitus and atrial fibrillation. The cause of the heat illness was said due to a fall in a bedrock bath facility. A CT showed the possibility of multiple cerebral infarctions but could not be confirmed. There was a suspected cerebral infarction due to chronic atrial fibrillation. He passed away on 14-Feb-2022 with the cause of death of heat illness. The case did not report a MIS-A, and no detail information to support a MIS-A. Based on the limited info provided, the clinical presentation may be that underlying atrial fibrillation led to suspected cerebral infarction led to altered consciousness and falling in a bedrock bath facility to cause heat illness, which led to shock, multiple organ dysfunction and death, in this elderly diabetic patient with atrial fibrillation. The case is considered level 5 for MIS-A due to an alternative etiology. It is thought to be unassessable because of the underlying risks, despite the TTO of 1 day.	[redacted]

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	adverse events is temporally related to the timing of administration of this vaccine. The occurrence of adverse events may be associated with pathological factors of chronic atrial fibrillation. Neither the presence or absence of cerebral infarction nor the association of cerebral infarction with this vaccination, if any, can be determined. Follow-up received on 16-MAR-2022 Updated: Patient Information, Other Relevant History, Lab Data, Event Information, Narrative, Reporter Comments LP Company Comment: As for heat illness, the event developed after the administration of ELASOMERAN, but it could also be due to the patient's environment, or other influences. As for cerebral infarction, the event developed after the administration of ELASOMERAN, but it could also be due to the patient's medical history or concurrent events, or other influences. Company comment: This spontaneous case concerns a 76-year-old, male patient with medical history of Diabetes mellitus and Atrial fibrillation, who experienced unexpected serious events of Cerebral infarction (seriousness criterion: Fatal, Hospitalisation, Medically significant), Heat illness (seriousness criterion: Fatal, Hospitalisation, Medically significant), Multiple organ dysfunction syndrome (seriousness criterion: Fatal, Medically significant), Shock (seriousness criterion: Fatal, Medically significant), Movement disorder (seriousness criterion: Fatal, Hospitalization) and Altered state of consciousness (seriousness criterion: Fatal, Hospitalisation, Medically significant). It was reported that a day after receiving the mRNA-1273 vaccine (as third dose), the patient developed disturbed consciousness. The patient was found collapsed and was transported by ambulance. The patient was suspected to had developed heat illness in a hot environment due to difficulty moving due to an unforeseen accident or a preceding disease. The patient was already in multi-organ failure and shock. CT showed the possibility of multiple cerebral infarctions due to chronic atrial fibrillation, but it could not be confirmed. The cause of death was heat illness and no autopsy was performed. The outcome of consciousness disturbed, possible multiple cerebral				

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	infarctions, difficulty in moving, suspected heat illness, multi-organ failure and shock was reported as fatal. Underlying medical history of atrial fibrillation remains a major confounder for Cerebral infarction which could contribute to movement disorder and altered state of consciousness. The patient's elderly age remains an additional confounder. Having in mind that this patient received Comrinaty vaccine prior to vaccination with the company product, Interchange of vaccine products should have been considered in this specific case. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report.				

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
[redacted]	This case was initially received via European Medicines Agency (Reference number: [redacted] on 17-Feb-2022. The most recent information was received on 07-Mar-2022 and was forwarded to Moderna on 07-Mar-2022. This regulatory authority case was reported by a physician and describes the occurrence of ANURIA (anuria, urinary septic shock with MOF, cardiopathic, diabetic, AOCP), MULTIPLE ORGAN DYSFUNCTION SYNDROME (anuria, urinary septic shock with MOF, cardiopathic, diabetic, AOCP) and SEPTIC SHOCK (anuria, urinary septic shock with MOF, cardiopathic, diabetic, AOCP) in a 74-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3005887) for COVID-19 vaccination. The patient's past medical history included Respiration failure on 01-Nov-2015, Amnestic disorder, Recovered smoker (end date- 01-Jan-1992), Septicaemia (01/10/2021: admitted again for septicemia) on 01-Jan-2020, Diaphragmatic hernia, Obstructive arteriosclerosis of lower extremities on 01-Sep-2021, Aortic valve replacement, Lactic acidosis (iatrogenic) on 01-Aug-2015, Hypertensive heart disease, Anemia (severe enteric loss anemia) on 01-Aug-2015, Hyperuricaemia, Hepatic steatosis on 01-Jan-2010, Acute pulmonary oedema on 01-Jan-2007, Cerebral infarct on 01-Jan-2007 and Femur fracture (dx) on 01-Jan-1972. Previously administered products included for SARS-CoV-2 immunisation: COMIRNATY (BIONTECH MANUFACTURING GMBH) (J07BX03) on 06-Apr-2021 and COMIRNATY (BIONTECH MANUFACTURING GMBH) (J07BX03) on 27-Apr-2021. Past adverse reactions to the above products included No adverse event with COMIRNATY (BIONTECH MANUFACTURING GMBH) (J07BX03) and COMIRNATY (BIONTECH MANUFACTURING GMBH) (J07BX03). Concurrent medical conditions included Diabetic retinopathy, Insulin-requiring type 2 diabetes mellitus on 01-Jan-2007, Hypertension arterial and Atrial fibrillation. Concomitant products included INSULIN GLARGINE (TOUJEO), ATORVASTATIN CALCIUM (TORVAST), ACETYLSALICYLIC ACID (CARDIOASPIRIN), DIGOXIN (LANOXIN), APIXABAN (ELIQUIS), FUROSEMIDE (LASIX P), SERTRALINE, POTASSIUM CANRENOATE (KANRENOL), BISOPROLOL	level 4	unassessable	A physician reported case concerned a 74-year-old male patient who experienced anuria, multiple organ dysfunction syndrome and septic shock on 30-Jan-2022, 8 days after he received a dose of mRNA-1273. Medical history included respiration failure, amnestic disorder, previous smoker, septicemia, obstructive arteriosclerosis of lower extremities, aortic valve replacement, lactic acidosis (iatrogenic), hypertensive heart disease, hyperuricemia, hepatic steatosis, acute pulmonary oedema, cerebral infarct. Concurrent medical conditions included Insulin-requiring type 2 diabetes mellitus, hypertension arterial and atrial fibrillation. Previous SARS-CoV-2 immunization with COMIRNATY on 06-Apr-2021 and 27-Apr-2021. He died on 10-Feb-2022 with shock septic as a reported cause of death. Relevant and meaningful lab tests were unavailable. The case did not report a MIS-A. septic shock may be one of the clinical presentation of MIS-A. however, detail information of clinical features and labs were not provided for assessment of the MIS. The case is considered level 4 for MIS-A due to lack of information for evaluating or differentiating a diagnosis. A causal relation between vaccination and the events are thought to be unassessable because of the unclear clinical process in this elderly patient with multiple underlying diseases, despite a TTO of 8 days.	[redacted]

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	FUMARATE (SEQUACOR), LANSOPRAZOLE (LANSOX) and INSULIN ASPART (NOVORAPID) for an unknown indication. On 22-Nov-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) .25 milliliter. On 30-Jan-2022, the patient experienced ANURIA (anuria, urinary septic shock with MOF, cardiopathic, diabetic, AOCP) (seriousness criterion death), MULTIPLE ORGAN DYSFUNCTION SYNDROME (anuria, urinary septic shock with MOF, cardiopathic, diabetic, AOCP) (seriousness criterion death) and SEPTIC SHOCK (anuria, urinary septic shock with MOF, cardiopathic, diabetic, AOCP) (seriousness criterion death). The patient died on 10-Feb-2022. The reported cause of death was Shock septic. An autopsy was not performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 30-Jan-2022, Blood test: inconclusive (Inconclusive) Inconclusive. On 30-Jan-2022, Chest X-ray: inconclusive (Inconclusive) Inconclusive. On 30-Jan-2022, SARS-CoV-2 test negative: inconclusive (Inconclusive) Inconclusive. On 30-Jan-2022, Vital signs measurement: inconclusive (Inconclusive) Inconclusive. On 31-Jan-2022, Blood gases: inconclusive (Inconclusive) Inconclusive. On an unknown date, Ultrasound scan: inconclusive (Inconclusive) Inconclusive. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Reporter states first dose on 06/04/2021 comirnaty vaccine lot: et7205 sc: 31/07/2021, the second dose on 27/04/2021 comirnaty vaccine lot: ex3599 sc: 31/08/2021. Concomitant pathologies includes diabetes mellitus, heart disease and aocp. Company Comment: This is a Regulatory case concerning a 74-year-old male patient with interchange of vaccine				

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	administration (COVID-19 vaccine, 2 doses of Comirnaty 6-7 months (interval of 21 days) prior to mRNA-1273 dose and medical history of Septicaemia (recurrence: 2020 & Oct 2021), Obstructive arteriosclerosis of lower extremities (2021), Aortic valve replacement, Severe enteric loss anemia (2015), Hepatic steatosis (2010), Hyperuricaemia, Acute pulmonary oedema (2007), Cerebral infarct (2007), and concurrent Type 2 diabetes mellitus (15y), Diabetic retinopathy, Hypertension arterial, Atrial fibrillation, Heart disease and AOCP. The patient experienced the serious fatal unexpected events of Anuria (AESI), Multiple Organ Dysfunction Syndrome and Septic shock. The events occurred approximately 2 months 9 days after a dose of mRNA-1273 received as the third dose for COVID-19 Vaccination. The patient died on 10-Feb-2022 (11 days after events onset). The reported cause of death was Shock septic. An autopsy was not performed. Diagnostic workup (Blood test, Chest X-ray, Vital signs, blood gases) was reported with inconclusive results, however an urinary origin of the septic shock was described. Treatment information was not provided. The increased risk of developing infections and sepsis due to type 2 diabetes remains a confounder. Suggestive urinary tract infection could be contributory for septic shock. Septic shock is a contributing cause of MODS and anuria. Patient's advanced age, vast comorbidities and heart disease remain as confounders and increase risk for fatal outcome. Moreover case could be confounded by polypharmacy. The benefit-risk relationship of COVID-19 Vaccine Moderna (mRNA-1273) is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 04-Mar-2022: Follow Up received with Non-Significant information. On 07-Mar-2022: Follow up received contains medical history, concomitant medications and event details.				

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
[redacted]	This case was received via European Medicines Agency (Reference number: [redacted] on 28-Feb-2022 and was forwarded to Moderna on 28-Feb-2022. This regulatory authority case was reported by a physician and describes the occurrence of MENINGITIS (Meningitis) and MULTIPLE ORGAN DYSFUNCTION SYNDROME (Multiple organ failure) in a 69-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. Date of death not given. First result of the autopsy with proof unspec. Coatings on the meninges in the sense of meningitis. Previously administered products included for COVID-19 vaccination: COMIRNATY and COVID-19 VACCINE ASTRAZENECA (Vaxzevria). Past adverse reactions to the above products included No adverse event with COMIRNATY and COVID-19 VACCINE ASTRAZENECA. On 16-Jan-2022, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 16-Jan-2022, the patient experienced MENINGITIS (Meningitis) (seriousness criteria death, hospitalization and life threatening) and MULTIPLE ORGAN DYSFUNCTION SYNDROME (Multiple organ failure) (seriousness criteria death, hospitalization and life threatening). The reported cause of death was Multiple organ failure. An autopsy was performed. The autopsy-determined cause of death was Meningitis. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. Concomitant medications were not provided. Treatment information was not provided. Company comment: This is a regulatory case concerning a 69 year-old, male patient with no reported medical history, who experienced the fatal serious unexpected, events of meningitis (AESI) and Multiple organ dysfunction syndrome, the same day after the mRNA-1273 vaccine, received as the booster	level 5	unassessable	A physician reported case concerned a 69-year-old male patient who experienced meningitis and multiple organ dysfunction syndrome with a fatal outcome above the same day after he received third dose of mRNA-1273. He previously received Covid 19 vaccine with COMIRNATY and Vaxzevria. Medical history, co-meds and treatment info were unavailable. Date of death was not provided. Autopsy reported an unspecific with meningitis as cause of death. The case did not report a MIS-A, and provide limited information relevant to MIS-A. The autopsy confirmed meningitis as the cause of death. No information on if autopsy included findings for multiple organ dysfunction. So, the clinical presentation was more likely a meningitis and not MIS-A. Because no information on prior and concurrent conditions was available, it may be hard to evaluate a causal relation between vaccine and event development, despite a TTO of the same day. The case is considered unassessable for WHO categories.	[redacted]

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	dose of the COVID-19 vaccination schedule. Patient´s death date was not provided but the duration of both events was reported as 2 days. The autopsy determined cause of death was meningitis and an additional cause of death reported in the case was Multiple organ dysfunction syndrome. Additionally, Interchange of vaccine products was noted in the case, vaccination with a dose of COVID-19 vaccine Tozinameran and a dose of NRVV AD (CHADOX1 NCOV-19) no dates provided. No further clinical information was available for medical review. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.				

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
[redacted]	This literature-non-study case was reported in a literature article and describes the occurrence of CARDIAC ARREST (Cardiac arrest), SEPTIC SHOCK (Septic shock), ENTEROCOCCAL INFECTION (high-grade vancomycin-resistant enterococcal infection), CLOSTRIDIUM DIFFICILE INFECTION (Clostridium difficile infection), APLASTIC ANAEMIA (Severe aplastic anemia), PNEUMONIA (Pneumonia) and FEBRILE NEUTROPENIA (Recurrent neutropenic fever) in a 60-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. LITERATURE REFERENCE: Sridhara S, Nair R, Stanek M. Severe aplastic anemia after receiving SARS-CoV-2 Moderna mRNA vaccination. J Hematol. 2022;11(1):34-9 The patient's past medical history included Alcohol use (rarely consumed alcohol.) and Nasal cavity packing (He had a nasal packing with no active bleeding and oral mucosa showed no petechiae). Concurrent medical conditions included Clostridial infection. On an unknown date, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On an unknown date, the patient experienced CARDIAC ARREST (Cardiac arrest) (seriousness criteria death, hospitalization prolonged and medically significant), SEPTIC SHOCK (Septic shock) (seriousness criteria death, hospitalization prolonged and medically significant), ENTEROCOCCAL INFECTION (high-grade vancomycin-resistant enterococcal infection) (seriousness criteria death, hospitalization prolonged and medically significant), CLOSTRIDIUM DIFFICILE INFECTION (Clostridium difficile infection) (seriousness criteria death, hospitalization prolonged and medically significant), APLASTIC ANAEMIA (Severe aplastic anemia) (seriousness criteria hospitalization prolonged and medically significant), PNEUMONIA (Pneumonia) (seriousness criteria hospitalization prolonged and medically significant) and FEBRILE NEUTROPENIA (Recurrent neutropenic fever) (seriousness criteria hospitalization and medically significant). The patient was treated with CYCLOSPORINE (oral) for	level 5	possible	Based on information from the original article, a 60-year-old male patient received the second dose of Moderna mRNA vaccination and experienced easy bruising on his arms and legs the following day after vaccination. After 2 weeks, he presented to the emergency department with worsening epistaxis but did not have a fever, chest pain, cough, shortness of breath or abdominal pain. He had no personal or family history of hematological conditions. He had bruises in various stages involving the upper and lower extremities. Laboratory data revealed white blood cell count of 1.2 ×103/mm3, hemoglobin of 8.0 g/dL, platelet count of 1 ×103/mm3, immature platelet fraction of 0.7%, absolute neutrophil count of 0 ×103/µL, lymphocytes of 1.1 ×103/µL, neutrophils of 3% and lymphocytes of 93%. He had normal liver and renal function tests. Bone marrow biopsy confirmed very severe aplastic anemia with severely hypocellular bone marrow. His platelets continued to downtrend despite platelet transfusions and steroids. He was treated with immunosuppressive therapy with cyclosporine, antithymocyte globulin, eltrombopag and prednisone. The patient was discharged but was readmitted to the hospital secondary to recurrent neutropenic fever and pneumonia. He had high-grade vancomycin resistant enterococcal infection and Clostridium difficile infection leading to septic shock and succumbing to cardiac arrest. The case did not report MIS-A. It presented a confirmed severe aplastic anemia, which may cause the recurrent neutropenic fever, pneumonia, enterococcal and clostridium infection leading to shock and cardiac arrest with a fatal outcome. The case is considered level 5 for MIS-A due to an alternative etiology. A causal relation for vaccine and event may be possible based on a TTO of 1 day.	[redacted]

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	Immunosuppression, at a dose of 250 milligram twice a day; ANTITHYMOCYTE IMMUNOGLOBULIN (intravenous) for Immunosuppression, at a dose of 3200 milligram once a day; ELTROMBOPAG (oral) ongoing since an unknown date for Immunosuppression, at a dose of 150 milligram once a day; PREDNISONE for Immunosuppression, at an unspecified dose and frequency; CEFEPIME ongoing since an unknown date for Neutropenic fever, at an unspecified dose and frequency; FLUCONAZOLE ongoing since an unknown date for Neutropenic fever, at an unspecified dose and frequency; VALACYCLOVIR [VALACICLOVIR] ongoing since an unknown date for Neutropenic fever, at an unspecified dose and frequency; METHYLPREDNISOLONE ongoing since an unknown date for Adverse event, at an unspecified dose and frequency; LEVOFLOXACIN ongoing since an unknown date for Antibiotic prophylaxis, at an unspecified dose and frequency; VANCOMYCIN ongoing since an unknown date for Clostridial infection, at an unspecified dose and frequency; AZITHROMYCIN ongoing since an unknown date for Adverse event, at an unspecified dose and frequency; DAPTOMYCIN ongoing since an unknown date for Adverse event, at an unspecified dose and frequency; MICAFUNGIN ongoing since an unknown date for Adverse event, at an unspecified dose and frequency; CEFTAROLINE ongoing since an unknown date for Adverse event, at an unspecified dose and frequency and TIGECYCLINE ongoing since an unknown date for Adverse event, at an unspecified dose and frequency. The patient died on an unknown date. The reported cause of death was Cardiac arrest and Septic shock. It is unknown if an autopsy was performed. At the time of death, APLASTIC ANAEMIA (Severe aplastic anemia), PNEUMONIA (Pneumonia) and FEBRILE NEUTROPENIA (Recurrent neutropenic fever) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 04-May-2021, Abdomen scan: exam did not reveal any hepatosplenomegaly exam did not reveal any hepatosplenomegaly. On 04-May-2021, Adenovirus test: negative (Negative) Negative. On 04-May-2021, Antineutrophil cytoplasmic antibody: negative (Negative) Negative. On 04-May-2021, Antinuclear antibody: 42 iu/ml 42 IU/mL				

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	were detected with normal complements (dsDNA antibody reference index < 4 IU/mL). On 04-May-2021, Auscultation: the chest was clear the chest was clear. On 04-May-2021, Biopsy bone marrow: very severe aplastic anaemia very severe aplastic anemia with severely hypocellular bone marrow. On 04-May-2021, Blood culture: did not reveal any bacterial growth (Negative) did not reveal any bacterial growth.. On 04-May-2021, Blood electrolytes: normal (normal) Normal. On 04-May-2021, Blood fibrinogen (200 mg/dl-465 mg/dl): 478 mg/dl (High) 478 mg/dL. On 04-May-2021, Blood lactate dehydrogenase (135 u/l-225 u/l): 203 u/l (normal) 203 U/L. On 04-May-2021, Blood pressure measurement: 125/71 mm hg 125/71 mm Hg. On 04-May-2021, Body temperature: 37.3 degree c 37.3 degree C. On 04-May-2021, Culture urine: did not reveal any bacterial growth. (Negative) did not reveal any bacterial growth.. On 04-May-2021, Cytomegalovirus test: negative (Negative) Negative and igg positive (Positive) IgG positive. On 04-May-2021, Electrophoresis protein: hypoalbuminemia (Low) hypoalbuminemia. On 04-May-2021, Epstein-Barr virus test: negative (Negative) Negative, viral capsid antigen (vca) igg index at 7.5 (Positive) viral capsid antigen (VCA) IgG index at 7.5 and nuclear antigen index 7.6 (Positive) nuclear antigen index 7.6. On 04-May-2021, Flow cytometry: no immunophenotypic evidence of lymphoproliferativ no immunophenotypic evidence of lymphoproliferative disorder, acute leukemia, or plasma cell neoplasm. On 04-May-2021, HIV test: negative (Negative) Negative. On 04-May-2021, Haemoglobin (13.5 g/dl-17g/dl): 8.0 g/dl (Low) 8.0 g/dL. On 04-May-2021, Haptoglobin (43 mg/dl-212 mg/dl): 242 mg/dl (High) 242 mg/dL. On 04-May-2021, Heart rate: 80/min 80/min. On 04-May-2021, Hepatitis B core antibody: negative (Negative) Negative. On 04-May-2021, Hepatitis B surface antigen: negative (Negative) Negative.				

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	On 04-May-2021, Hepatitis C antibody: negative (Negative) Negative. On 04-May-2021, Herpes simplex test: negative (Negative) Negative. On 04-May-2021, Human metapneumovirus test: negative (Negative) Negative. On 04-May-2021, Human rhinovirus test: negative (Negative) Negative. On 04-May-2021, Influenza A virus test: negative (Negative) Negative. On 04-May-2021, Influenza B virus test: negative (Negative) Negative. On 04-May-2021, Legionella test: negative (Negative) Negative. On 04-May-2021, Liver function test: normal (normal) Normal. On 04-May-2021, Lymphocyte count: 1.1x10^3/microl 1.1x10^3/microL. On 04-May-2021, Monocyte count (0.2 × 103/µl-1.0 × 103/µl): 0.0 × 103/µl (Low) 0.0 × 103/µL. On 04-May-2021, Neutrophil count (1.5x10^3/microl-7.8x10^3/microl): 0x10^3/microl (Low) 0x10^3/microL and 3% 3%. On 04-May-2021, Parvovirus B19 test: negative (Negative) Negative. On 04-May-2021, Platelet count (130 x10^3/mm^3-450 x10^3/mm^3): 1 x10^3/mm^3 (Low) 1 x10^3/mm^3. On 04-May-2021, Prothrombin time (9.4 s-12.5 s): 12.7 s (High) 12.7 s. On 04-May-2021, Renal function test: normal (normal) Normal. On 04-May-2021, Respiratory syncytial virus test: negative (Negative) Negative. On 04-May-2021, Reticulocyte count (26 × 103/µl-168 × 103/µl): 4 × 103/µl (Low) 4 × 103/µL. On 04-May-2021, SARS-CoV-2 RNA: negative (Negative) Negative. On 04-May-2021, SARS-CoV-2 antibody test (Unknown-0.99): positive igg index at greater than 20 (Positive) positive IgG index at greater than 20 suggestive of recent vaccination. On 04-May-2021, Serum ferritin (20 ng/ml-250 ng/ml): 534 ng/ml (High) 534 ng/mL. On 04-May-2021, Smear test: pancytopenia with a marked				

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	decrease in granulocyte pancytopenia with a marked decrease in granulocytes, normocytic anemia with non-specific anisocytosis, thrombocytopenia with unremarkable platelets and there were no schistocytes. Lymphocytes with mature chromatin, abundant cytoplasm and occasional forms with concentric irregular cytoplasmic projections concerning an atypical population were present.. On 04-May-202				

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[redacted]	This case was received via European Medicines Agency (Reference number: [redacted] on 06-May-2022 and was forwarded to Moderna on 06-May-2022. This regulatory authority case was reported by a consumer and describes the occurrence of MALNUTRITION (Prolonged nutrient deficiency), CARDIAC ARREST (Advanced age with concomitant cardiac arrest), MOBILITY DECREASED (Inferior mobility), DECREASED APPETITE (Do not want to eat, do not drink), PERSONALITY CHANGE (Personality-changed (dropped a little of his good temper and mischievousness)), COVID-19 IMMUNISATION (Revaccination with different covid-19 vaccine), FATIGUE (Wearers and need to bed earlier, just want to sleep), GENERAL PHYSICAL HEALTH DETERIORATION (Tackled by) and MULTIPLE ORGAN DYSFUNCTION SYNDROME (Multiorgan failure) in a 94-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 016G21A) for COVID-19 vaccination. Co-suspect products included non-company products INFLUENZA VACCINE INACT SPLIT 4V (EFLUELDA) for an unknown indication, TOZINAMERAN (COMIRNATY) for an unknown indication and TOZINAMERAN (COMIRNATY) for an unknown indication. The patient's past medical history included Arm fracture, Colon cancer and Diarrhoea (as an allergic reaction after a penicillin cure after urinary tract infections.). Concurrent medical conditions included Penicillin allergy and Angina pectoris. On 04-Jun-2021, the patient received first dose of TOZINAMERAN (COMIRNATY) (unknown route) 1 dosage form. On 21-Jul-2021, the patient received second dose of TOZINAMERAN (COMIRNATY) (unknown route) 1 dosage form. On 04-Nov-2021, the patient received dose of INFLUENZA VACCINE INACT SPLIT 4V (EFLUELDA) (unknown route) .7 milliliter. On 28-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. In 2021, the patient experienced FATIGUE (Wearers and need to bed	level 5	n/a	This regulatory authority case reported by a consumer concerned a 94-year-old female patient who experienced malnutrition, cardiac arrest, mobility decreased, decreased appetite, personality change, covid-19 immunization (revaccination with different covid-19 vaccine), fatigue, general physical health deterioration and multiple organ dysfunction syndrome with a fatal outcome within an unspecified day after she received the mRNA-1273 vaccination. The medical history included colon cancer and allergic diarrhea, penicillin allergy and angina pectoris. Information on concomitant medications and treatment was unavailable. Co-suspect products included non-Moderna influenza vaccine (Efluelda) and Covid 19 vaccine Tozinameran (Comirnaty). The patient received first and second dose of vaccine on 04-Jun and 21-Jul-2021, respectively. On 04-Nov-2021, the patient received a dose of influenza vaccine (Efluelda). Information regarding the adverse reactions was unavailable for the two doses of Tozinameran and the one dose of Efluelda vaccination. On 28-Dec-2021, the patient received third dose of Covid 19 vaccine with mRNA-1273. In an unspecified day in 2021, the patient experienced the above events and died on 15-Jan-2022. The cause of death was reported as unspecified nutritional deficiency, cardiac arrest and multi organ failure. The case did not report a MIS-A. No detailed information was provided for assessment of MIS. Of note, the patient had medical history of colon cancer and angina pectoris and underlying nutritional deficiency, which may confound the clinical presentations, including cardiac arrest and multi organ failure. The case is considered level 5 for MIS-A, based on the confounding risks and alternative etiologies.	[redacted]

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	earlier, just want to sleep) (seriousness criteria death and medically significant). In December 2021, the patient experienced MOBILITY DECREASED (Inferior mobility) (seriousness criteria death and medically significant), DECREASED APPETITE (Do not want to eat, do not drink) (seriousness criteria death and medically significant), PERSONALITY CHANGE (Personality-changed (dropped a little of his good temper and mischievousness)) (seriousness criteria death and medically significant) and GENERAL PHYSICAL HEALTH DETERIORATION (Tackled by) (seriousness criteria death and medically significant). On 28-Dec-2021, the patient experienced COVID-19 IMMUNISATION (Revaccination with different covid-19 vaccine) (seriousness criteria death and medically significant). On an unknown date, the patient experienced MALNUTRITION (Prolonged nutrient deficiency) (seriousness criteria death and medically significant), CARDIAC ARREST (Advanced age with concomitant cardiac arrest) (seriousness criteria death and medically significant) and MULTIPLE ORGAN DYSFUNCTION SYNDROME (Multiorgan failure) (seriousness criteria death and medically significant). The patient died on 15-Jan-2022. The reported cause of death was Unspecified nutritional deficiency, Cardiac arrest and Multi organ failure. It is unknown if an autopsy was performed. The action taken with mRNA-1273 (Spikevax) (Unknown) was unknown. No concomitant medications were provided. No treatment information was provided. COMPANY COMMNET: This regulatory authority case concerns a 94 years old female patient with relevant past medical history of colon cancer, who experienced unexpected fatal serious events of malnutrition, cardiac arrest, mobility decreased, decreased appetite, personality change, fatigue, general physical health deterioration, multiple organ dysfunction, which occurred unspecified days after third dose of mRNA-1273 vaccine. Additionally Covid-19 immunization is also reported. The patient was noted to have received two				

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	doses with COMINARTY 5 months 7 days prior to mRNA-1273 (Interchange of vaccine products). Patient died on 15-Jan-2022. Reported cause of death was Unspecified nutritional deficiency, Cardiac arrest and Multi organ failure. It is unknown if an autopsy was performed. past medical history of colon cancer remains as confounding for the events malnutrition, decreased appetite, fatigue. The benefit-risk relationship of mRNA-1273 is not affected by this report. The event was assessed as serious as per Regulatory Authority´s report.				

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
[redacted]	This case was initially received via Takeda Pharmaceuticals (Reference number: [redacted] on 06-May-2022. The most recent information was received on 02-Jun-2022 and was forwarded to Moderna on 10-Jun-2022. This case, initially reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by a physician, was received via the PMDA (Ref, [redacted]. On 02-Jun-2022, follow-up information was received from a physician. On an unknown date, the patient received the 1st dose of a novel coronavirus vaccine (product name unknown). On an unknown date, the patient received the 2nd dose of a novel coronavirus vaccine (product name unknown). On 11-Apr-2022, the patient received the 3rd vaccination with this vaccine. On 12-Apr-2022, the patient experienced a pyrexia in the 38 degrees Celsius range. Around 13:00, due to the sudden onset of convulsions, the patient visited the emergency room of the reporting hospital by ambulance. The patient was status epilepticus at the time of the visit, and anticonvulsants were administered, which stopped the convulsions. Hypotension was observed, and vasoconstrictor was administered, and the patient was weaned from circulatory disorder. Due to persisting consciousness disturbed, endotracheal intubation was performed, and the patient was admitted to the intensive care unit for ventilatory management. The patient was hospitalized. On 13-Apr-2022, the patient developed acute liver disorder, acute kidney injury, and rhabdomyolysis, and was observed to have multi-organ failure. On 17-Apr-2022, hemodialysis was started. On 20-Apr-2022, a tracheostomy was performed. On 21-Apr-2022, the patient was in a state of multi-organ failure with disturbed consciousness with semi-comatose, acute kidney injury requiring dialysis, and persistent liver disorder when leaving the intensive care unit. On 06-May-2022, the patient experienced sepsis and entered the intensive care unit. On 13-May-2022, the patient left the intensive care unit. On 21-May-2022, the patient died. The cause of death was multi-organ failure. No autopsy was performed. The outcome of pyrexia was reported as ongoing and unchanged. The outcome of hypotension, consciousness disturbed, rhabdomyolysis, and semi-coma was unknown. The outcome of convulsion, status epilepticus, multi-organ failure, and sepsis was reported as fatal. No follow-up investigation will be made. Reporter comments continuation: The relationship between the occurrence of adverse events and concomitant drugs is unknown. The relationship between the occurrence of adverse	level 3a	conditional	This regulatory case reported by a physician was concerned a 63 years-old male patient who experienced altered state of consciousness, depressed level of consciousness, hypotension, multiple organ dysfunction syndrome, Pyrexia, Rhabdomyolysis, Seizure, Sepsis and Status epilepticus about 1 day after he received third dose of mRNA-1273. No information on medical history and co meds was available. He started to experience a pyrexia in the 38 degrees Celsius range first (ongoing during the disease process), status epilepticus and hypotension. He then developed acute liver disorder, acute kidney injury, and rhabdomyolysis, and multi-organ failure. He further experienced sepsis and died despite intensive medical attentions about 40 days after the vaccination. The cause of death was multi-organ failure. No autopsy was performed. The case did not report MIS-A. However, the patient had a fever > 3 consecutive days. His clinical features included hypotension and neurologic sign convulsion. The case lacked lab evidence of inflammation and measures of disease activity , such as elevated BNP or NT-proBNP or troponin, cardiac involvement by echocardiography or physical stigmata of heart failure, or EKG changes consistent with myocarditis or myo-pericarditis. in addition, it was heavily confounded by the diagnosis of sepsis, acute liver disorder, lack of information on medical history. It is considered conditional for MIS-A. . WHO causality is considered possible based on the time to onset for the events. Of note, no prior and concurrent medical conditions and co meds were provided for the case, confounding risks may not be fully assessed.	[redacted]

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	events and pathological factors of underlying diseases and complications is unknown. The relationship between the cause of death and adverse events is unknown because the patient died of multi-organ failure after convulsion. The patient with symptomatic epilepsy experienced pyrexia and convulsion and died of multi-organ failure probably due to status epilepticus after receiving this vaccine, although the relationship is unclear. Follow-up received on 02-JUN-2022 Updated: Patient Information, Other Relevant History, Lab Data, Product Information, Event Information, Narrative, Reporter Comments Company Comment: Status epilepticus developed after the administration of ELASOMERAN, factors such as concurrent conditions may have also had an influence. Pyrexia, seizure, hypotension, altered state of consciousness, rhabdomyolysis, multiple organ dysfunction syndrome, depressed level of consciousness, and sepsis developed after the administration of ELASOMERAN and there is temporal relationship.				

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
[redacted]	This case was received via Takeda Pharmaceuticals (Reference number: [redacted] on 23-May-2022 and was forwarded to Moderna on 24-May-2022. This case, initially reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by a physician, was received via the PMDA (Ref, [redacted]. On an unknown date, the patient received the 1st dose of non-company coronavirus modified uridine RNA vaccine (SARS-CoV-2). On an unknown date, the patient received the 2nd dose of non-company coronavirus modified uridine RNA vaccine (SARS-CoV-2). On 27-Feb-2022, the patient received the 3rd vaccination with this vaccine. On an unknown date, the patient experienced severe vasculitis. On 01-Mar-2022, diffuse alveolar haemorrhage and respiratory failure developed. Pyrexia of 38.3 degrees Celsius was noted. On 02-Mar-2022, the patient was referred to a nearby physician with a diagnosis of severe pneumonia. Computed tomography (CT) on admission showed diffuse infiltrative shadows mainly in the upper lung fields of both lungs. On 03-Mar-2022, the respiratory status was rapidly deteriorated. Since SpO2 became 70% to 80% even with oxygen of 15 L/min, intubation was performed, and artificial respiration was started. A large amount of foamy bloody sputum was aspirated via the intubation tube. The patient was diagnosed with diffuse alveolar hemorrhage. Steroid pulse therapy was started. On 15-Mar-2022, the mechanical ventilation was removed. On 22-Mar-2022, respiratory status worsened again, and the patient was intubated again. Pneumonia in both lower lobes was shown on the image. MRSA was detected by culture. Bacterial infection was observed. Antibiotic treatment was performed. On an unknown date, the patient suffered multiple organ failure. On 11-Apr-2022, the patient died. The outcome of severe pneumonia, and vasculitis was unknown. The outcome of diffuse alveolar hemorrhage, respiratory failure, multi-organ failure, and bacterial infection was reported as fatal. Follow-up investigation will be made. Company Comment: The events developed after the administration of ELASOMERAN and there is temporal relationship.	level 5	n/a	This pharmacist reported case concerned a 64-year-old male patient who experienced vaccination failure, COVID-19 pneumonia, atrial fibrillation, pneumothorax and vaccine associated enhanced respiratory disease with a fatal outcome about 7.5 months after he received his second dose of mRNA-1273. Past medical history included Chronic venous insufficiency and Anxio-depressive syndrome. On 13-May-2021, he received second dose of mRNA-1273. On 26-Dec-2021, the patient experienced above events, and died on 20-Jan-2022. The reported cause of death was covid-19 pneumonia. SARS-CoV-2 test was positive. The case did not report MIS-A. No information was provided for assessment of MIS-A. The events occurred over 7 months after last vaccination. Furthermore, there was concurrent Covid 19 infection. The case is considered level 5 for MIS-A.	[redacted]

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
[redacted]	This case was received via European Medicines Agency (Reference number: [redacted] on 24-May-2022 and was forwarded to Moderna on 24-May-2022. This regulatory authority case was reported by a pharmacist and describes the occurrence of VACCINATION FAILURE (Vaccination failure), COVID-19 PNEUMONIA (Bilateral pneumonia), ATRIAL FIBRILLATION (Fibrillation), PNEUMOTHORAX (Pneumothorax) and VACCINE ASSOCIATED ENHANCED RESPIRATORY DISEASE (Vaccine associated enhanced respiratory disease) in a 64-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 3001532 and 3001177) for COVID-19 vaccination. The patient's past medical history included Chronic venous insufficiency and Anxiodepressive syndrome. On 14-Apr-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 13-May-2021, received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. On 26-Dec-2021, the patient experienced VACCINATION FAILURE (Vaccination failure) (seriousness criterion death), COVID-19 PNEUMONIA (Bilateral pneumonia) (seriousness criterion death), ATRIAL FIBRILLATION (Fibrillation) (seriousness criterion death) and VACCINE ASSOCIATED ENHANCED RESPIRATORY DISEASE (Vaccine associated enhanced respiratory disease) (seriousness criterion death). On 01-Jan-2022, the patient experienced PNEUMOTHORAX (Pneumothorax) (seriousness criterion death). The patient died on 20-Jan-2022. The reported cause of death was covid-19 pneumonia (10084380). It is unknown if an autopsy was performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 25-Dec-2021, SARS-CoV-2 test positive: positive (Positive) Positive. On 26-Dec-2021, Blood test: abnormal Blood count at admission: Hb 14.2, hto 41. Leukocytes 6830.83% Gr. Lymphocytes 440 Platelets 171000. - Coagulation at admission: INR 1.19 - D-dimer: 962 - Biochemistry: Glu 127, urea 38, Cr 0.94, FG 85, albumin 4, LDH 276, GOT 24, GPT	level 5	n/a	This consumer reported case concerned a 47-year-old female patient who experienced cerebral venous sinus thrombosis, vaccination failure and vaccine associated enhanced respiratory disease more than 7 months after she received her second dose of mRNA-1273. Her past medical history included COVID-19 infection in January 2022, Microalbuminuria, Brucellosis, Sacroiliitis and Hypothyroidism. Previously administered products included Enalapril. No concomitant medication and treatment medications were reported. On 07-Jul-2021, the patient received second dose of mRNA-1273. On 14-Feb-2022, she experienced the above events. The case did not report MIS-A. No information relevant for assessment of MIS-A was available. Rather alternative etiologies and events were provided. The events occurred over 7 months after her last vaccination. The case is considered level 5 for MIS-A.	[redacted]

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	17 - PCT at admission: 0.17 - PCR at admission 195 - Tp I 15.85 - ProBNP: 1900 - GAB: ph 7.48, pCO2 33, Po2 51, Sat 89%. On 26-Dec-2021, Chest X-ray: bilateral infiltrates patched in tarnished glass bilateral infiltrates patched in tarnished glass. On 26-Dec-2021, Electrocardiogram: fa at 120 bpm (after taking bisoprolol 2.5 and afe FA at 120 bpm (after taking bisoprolol 2.5 and afebryl, FA at 100 bpm). On 28-Dec-2021, Chest X-ray: worsening worsening with respect to previous RX with progression of alveolo-interstitial infiltrates in both HT.. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. No concomitant medications were reported. No treatment medications were reported. Company comment: This fatal regulatory authority case concerns 64-year-old male patient, with no relevant medical history, who experienced the unexpected, serious (due to death) events of VACCINATION FAILURE, PNEUMOTHORAX and VACCINE ASSOCIATED ENHANCED RESPIRATORY DISEASE; and the unexpected, serious (due to death) AESIs of COVID-19 PNEUMONIA and ATRIAL FIBRILLATION. The events VACCINATION FAILURE, VACCINE ASSOCIATED ENHANCED RESPIRATORY DISEASE, COVID-19 PNEUMONIA and ATRIAL FIBRILLATION occurred 7 months after the second dose of mRNA-1273 vaccine; a week later PNEUMOTHORAX developed. He died twenty days later. The cause of death was covid-19 pneumonia. A positive SARS-CoV-2 test was performed and the chest X-ray showed initially bilateral infiltrates patched in tarnished glass, and two days later showed worsening with progression of alveolo-interstitial infiltrates. It is unknown if an autopsy was performed. The benefit-risk relationship of mRNA-1273 is not affected by this report. Event´s seriousness assessed as per Regulatory Authority's report.				

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
[redacted]	This case was initially received via Takeda Pharmaceuticals (Reference number: [redacted] on 03-Jun-2022. The most recent information was received on 09-Jun-2022 and was forwarded to Moderna on 15-Jun-2022. This case was reported by a pharmacist via a medical representative. On 06-Jun-2022, additional information, reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by a physician, was received via the PMDA (Ref, [redacted]. On 09-Jun-2022, additional information, reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by a physician, was received via the PMDA (Ref, [redacted]. On an unknown date, the patient received the 1st dose of this vaccine. On 01-Nov-2021, the patient received the 2nd dose of this vaccine. Around 14:00, the patient experienced pyrexia, respiratory discomfort, and diarrhea. On 03-Nov-2021, pneumonia, dyspnea, and multi-organ failure developed. The house-visiting physician examined the patient and made an emergency call. Hyperthermia, tachypnea, and cyanosis were noted, and the patient was transported to the medical emergency center of the reporting hospital. An image of pneumonia was shown on the result of CT examination, and the patient was diagnosed with pneumonia. The patient was intubated and put on mechanical ventilator. Steroid pulse therapy was performed, but multi-organ failure including lung progressed. On 07-Nov-2021, the patient was transferred to another hospital as ECMO was indicated. Lung abscess also developed. On 26-Nov-2021, the patient was readmitted to the reporting hospital because the patient was able to be weaned from ECMO. The patient's general condition did not improve thereafter. On 27-Dec-2021, the patient died. On an unknown date, the results of the pathological autopsy revealed that respiratory failure due to lung abscess was the main cause of death and that there were multiple small cerebral infarctions and herpes simplex infection due to decreased immunocompetence associated with infection. The outcome of pyrexia, respiratory failure, diarrhea, pneumonia, multi-organ failure, and lung abscess was reported as fatal. The outcome of multiple small cerebral infarction and herpes simplex infection was unknown. Follow-up investigation will be made. Follow-up received on 09-JUN-2022 Updated: Event Information, Narrative, Reporter Comments Company Comment: The events developed after the administration of ELASOMERAN and there is temporal relationship.	level 5	n/a	This case reported by a pharmacist and a physician concerned a 40-year-old male patient, who experienced pyrexia, respiratory discomfort, and diarrhea on same day after receiving his second dose of Moderna mRNA vaccine. Two days later, he developed pneumonia confirmed by CT examination, dyspnea, lung abscess and multi-organ failure with a fatal outcome. The case did not report MIS-A. The clinical course may be more likely a concurrent respiratory bacterial infection origin, led to lung abscess, presenting fever, dyspnea, and diarrhea, and further led to multi organ failure and a fatal outcome. The case is considered level 5 for MIS-A due to an alternative etiology presence.	[redacted]

Appendix 11.19c Multisystem Inflammatory Syndrome (MIS): Information on MIS-C Related Events for the reporting period: Case Listings

Case ID	Country	Report Type	PT	Event Seriousness	ALL PTs	Patient Age (Years)	Patient Gender	Event Outcome	Medical History	Concomitant Medications	Dose #	TTO All Doses	Primary Cause of Death	WW Identifier
[redacted]	[redacted]	Literature-Non-Study	Multisystem inflammatory syndrome in adults	Serious	Cerebellar stroke, Chest pain, Dyspnoea, Embolic stroke, Hypersensitivity, Intensive care unit acquired weakness, Multisystem inflammatory syndrome in adults, Muscle necrosis, Oedema peripheral, Peripheral artery occlusion, Polyneuropathy, Respiratory failure, Vasoplegia syndrome	21.00	Female	Recovered/Resolved with Sequelae	COVID-19(H)		Unknown			[redacted]
		Literature-Non-Study	Multisystem inflammatory syndrome in children	Serious	Multisystem inflammatory syndrome in children	12.00	Female	Recovered/Resolved	Thyroiditis(C)		Unknown			
		Literature-Non-Study	Multisystem inflammatory syndrome in children	Serious	Multisystem inflammatory syndrome in children	13.00	Male	Recovered/Resolved			Unknown			
		Regulatory Authority	Septic shock	Serious	Cough, Nausea, Pyrexia, Respiratory failure, Septic shock, Vomiting	18.00	Male	Not Recovered/Not Resolved		ACETAMINOPHEN; ACETYLSALICYLIC ACID; OLANZAPINE; RISPERIDONE	Unknown			

Appendix 11.19d Multisystem Inflammatory Syndrome (MIS): Information on MIS-C Related Events for the reporting period: Narratives

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
[redacted]	This literature-non-study case was reported in a literature article and describes the occurrence of MULTISYSTEM INFLAMMATORY SYNDROME IN ADULTS (Multisystem inflammatory syndrome), OEDEMA PERIPHERAL (Leg edema), CHEST PAIN (Chest pain), DYSPNOEA (Dyspnea), HYPERSENSITIVITY (Allergic reaction), VASOPLEGIA SYNDROME (vasoplegia), RESPIRATORY FAILURE (hypoxic respiratory failure), PERIPHERAL ARTERY OCCLUSION (right common femoral artery occlusion), CEREBELLAR STROKE (cerebellar stroke), INTENSIVE CARE UNIT ACQUIRED WEAKNESS (critical illness polyneuropathy), MUSCLE NECROSIS (Muscle necrosis), EMBOLIC STROKE (Cardioembolic stroke) and POLYNEUROPATHY (Bilateral Polyneuropathy) in a 21-year-old female patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for COVID-19 vaccination. LITERATURE REFERENCE: Lieu A, Mah J, Church D. A case of multisystem inflammatory syndrome in adults following natural infection and subsequent immunization. Int J Infect Dis. 2022;116:34-7 The patient's past medical history included SARS-CoV-2 infection (previously received positive test results, 6 weeks before this acute illness. Patient was asymptomatic at the time of testing. Notably, 27 days after the patient tested positive, received the first dose of the messenger RNA (mRNA) vaccine (Moderna) without immediate adverse reactions.) on 30-Apr-2021. On an unknown date, the patient received first dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 02-Nov-2021, the patient experienced MUSCLE NECROSIS (Muscle necrosis) (seriousness criterion medically significant), EMBOLIC STROKE (Cardioembolic stroke) (seriousness criterion medically significant) and POLYNEUROPATHY (Bilateral Polyneuropathy) (seriousness criterion medically significant). On an unknown date, after	Level 2b	Unlikely	This case concerns a 21-year-old female patient with medical history of SARS-CoV-2 infection 27 days before her 1st dose of Spikevax who experienced edema peripheral, chest pain, dyspnea, hypersensitivity, vasoplegia syndrome, respiratory failure, peripheral artery occlusion, intensive care unit acquired weakness, and multisystem inflammatory syndrome and cerebellar stroke, approximately in 10 days after receiving the first dose of mRNA-1273 Vaccine. The patient started headache, nausea, vomiting, diarrhea, followed by rash and fever. Her symptoms were later associated with progressive shortness of breath and chest pain, leading to her ED presentation. Patient received fluid resuscitation, broad-spectrum antibiotics, and was admitted to the ICU to initiate inotropes. The patient was started on intravenous glucocorticoids, intravenous immunoglobulins, and aspirin. Cardiogenic shock ensued over the next 48 hours, and the patient required intubation because of hypoxic respiratory failure. The patient had a precipitous decline in cardiac function, as documented on serial TTEs. Anakinra was initiated for the cytokine storm and MIS-A. The patient had persistent hypoxic failure and vasoplegia, which required venous-arterial extracorporeal membrane oxygenation (VA-ECMO). Her clinical status improved. It was reported that the outcome of the events was resolving. Relevant exams and tests included SARS-CoV-2 test positive by a PCR 6 weeks before this acute illness, Body temperature 38.0 degree, Blood pressure measurement 80/50 mm hg, left ventricular ejection function decreased, CRP, ALT, CK, troponin, NT-proBNP and ferritin increased. The case presented fever, clinical features, lab evidence of inflammation and measures of disease activity for MIS-A. however, due to insufficient information on the duration of fever, it is considered level 2b for MIS. The recent history of COVID-19 infection is an important risk factor that provides a more plausible explanation for the occurrence of the reported event of MIS-A. According to the WHO causality assessment this report is considered unlikely and more likely explained by MIS-A due to COVID-19.	[redacted]

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	starting mRNA-1273 (Moderna CoviD-19 Vaccine), the patient experienced MULTISYSTEM INFLAMMATORY SYNDROME IN ADULTS (Multisystem inflammatory syndrome) (seriousness criteria hospitalization, medically significant and life threatening), OEDEMA PERIPHERAL (Leg edema) (seriousness criterion hospitalization), CHEST PAIN (Chest pain) (seriousness criterion hospitalization), DYSPNOEA (Dyspnea) (seriousness criterion hospitalization), HYPERSENSITIVITY (Allergic reaction) (seriousness criterion hospitalization), VASOPLEGIA SYNDROME (vasoplegia) (seriousness criteria hospitalization and medically significant), RESPIRATORY FAILURE (hypoxic respiratory failure) (seriousness criteria hospitalization and medically significant), PERIPHERAL ARTERY OCCLUSION (right common femoral artery occlusion) (seriousness criteria hospitalization and medically significant), CEREBELLAR STROKE (cerebellar stroke) (seriousness criteria hospitalization and medically significant) and INTENSIVE CARE UNIT ACQUIRED WEAKNESS (critical illness polyneuropathy) (seriousness criterion hospitalization). The patient was treated with ASPIRIN [ACETYLSALICYLIC ACID] for Adverse event, at an unspecified dose and frequency; ANAKINRA (intravenous) from 15-Jun-2021 to 28-Jun-2021 for Adverse event, at a dose of 100 milligram every twelve hours; IMMUNOGLOBULINS NOS (intravenous) on 14-Jun-2021 for Adverse event, at a dose of 2 gram per kilogram; METHYLPREDNISOLONE (intravenous) on 14-Jun-2021 for Adverse event, at a dose of 1 gram once a day and PREDNISONE for Adverse event, at an unspecified dose and frequency. At the time of the report, MULTISYSTEM INFLAMMATORY SYNDROME IN ADULTS (Multisystem inflammatory syndrome) had resolved with sequelae, OEDEMA PERIPHERAL (Leg edema), CHEST PAIN (Chest pain), DYSPNOEA (Dyspnea), HYPERSENSITIVITY (Allergic reaction), VASOPLEGIA SYNDROME (vasoplegia), RESPIRATORY FAILURE (hypoxic respiratory failure), PERIPHERAL ARTERY OCCLUSION (right common femoral artery occlusion), CEREBELLAR STROKE (cerebellar				

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	stroke) and INTENSIVE CARE UNIT ACQUIRED WEAKNESS (critical illness polyneuropathy) was resolving and MUSCLE NECROSIS (Muscle necrosis), EMBOLIC STROKE (Cardioembolic stroke) and POLYNEUROPATHY (Bilateral Polyneuropathy) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 01-May-2021, SARS-CoV-2 test: positive (Positive) Positive. On 14-Jun-2021, Alanine aminotransferase: 74 u/l (High) On Day 0 ALT was 74 (U/L) Normal range less than 39 U/L. On 14-Jun-2021, Blood albumin (30-45): 29 g/l (normal) 29 g/L. On 14-Jun-2021, Blood creatinine (40-100): 89 µmol/l (normal) On Day 0 her Creatinine was 89 (µmol/L). On 14-Jun-2021, Blood fibrinogen (1.6-4.1): 7.3 g/l (normal) 7.3 g/L. On 14-Jun-2021, Brain natriuretic peptide: 1641 ng/l (High) 1641 Normal range less than 300 ng/L. On 14-Jun-2021, C-reactive protein (0.0-8.0): 315.0 mg/l (High) On Day 0 her C-reactive protein was 315.0 (mg/L). On 14-Jun-2021, Chest X-ray: normal (normal) Lungs are clear, heart size is normal. On 14-Jun-2021, Electrocardiogram: abnormal (abnormal) Sinus tachycardia, QTc 435ms otherwise normal. On 14-Jun-2021, Fibrin D dimer: 2.09 mg/l (High) 2.09 mg/L normal range less than or equal to 0.50 mg/L FEU. On 14-Jun-2021, Lymphocyte count (0.5-3.3): 0.8 10^9/l (Low) On Day 0 her Lymphocytes was 0.8 (10^9/L). On 14-Jun-2021, Neutrophil count (2-9): 15.7 10^9/l On Day 0 her Neutrophils-15.7 (10^9/L). On 14-Jun-2021, Platelet count (150-400): 186 10^9/l (normal) On Day 0 her Platelet count was 186 (10^9/L). On 14-Jun-2021, Prothrombin time (0.9-1.1): 1.6 (High) 1.6 INR. On 14-Jun-2021, Serology test: positive (Positive) IgG serological test for antibodies directed toward the				

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	SARS-CoV-2 nucleocapsid protein was positive.. On 14-Jun-2021, Serum ferritin (20-300): 668 ug/l (High) On Day 0 her Ferritin was 668 (ug/L). On 14-Jun-2021, Troponin (0-13): 808 ng/l (High) On Day 0, Troponin was 808 (ng/L). On 14-Jun-2021, White blood cell count (4-11): 17.7 10⁹/l (High) On Day 0, Leucocytes was 17.7 (10⁹/L). On 15-Jun-2021, Alanine aminotransferase: 51 u/l (High) On Day 1 her ALT 51 (U/L) Normal range less than 39 U/L. On 15-Jun-2021, Blood creatinine (40-100): 73 µmol/l (normal) On Day 1 her Creatinine was 73 (µmol/L). On 15-Jun-2021, Blood lactate dehydrogenase (100-235): 317 u/l (High) 317 U/L. On 15-Jun-2021, C-reactive protein (0.0-8.0): 292.5 mg/l (High) On Day 1 her C-reactive protein was 292.5 (mg/L). On 15-Jun-2021, Echocardiogram: abnormal (abnormal) LV EF 30-35%, R Vsignificantly imapired, severe TR, small percaridal effusion. On 15-Jun-2021, Lymphocyte count (0.5-3.3): 0.2 10⁹/l (Low) Day 1 her Lymphocytes was 0.2 (10⁹/L). On 15-Jun-2021, Neutrophil count (2-9): 19.2 10⁹/l On Day 1 her Neutrophils - 19.2 (10⁹/L). On 15-Jun-2021, Platelet count (150-400): 202 10⁹/l (normal) On Day 0 her Platelet count was 202 (10⁹/L). On 15-Jun-2021, Prothrombin time (0.9-1.1): 1.5 (High) 1.5 INR. On 15-Jun-2021, Troponin (0-13): 1306 ng/l (High) On Day 1, Troponin was 1306 (ng/L). On 15-Jun-2021, White blood cell count (4-11): 21.2 10⁹/l (High) On Day 1, Leucocytes was 21.2 (10⁹/L). On 16-Jun-2021, Activated partial thromboplastin time (28-38): 91.6 seconds (High) 91.6 seconds. On 16-Jun-2021, Alanine aminotransferase: 102 u/l (High) On Day 2 her ALT was 102 (U/L) Normal range less than 39 U/L. On 16-Jun-2021, Blood creatinine (40-100): 75 µmol/l (normal) On Day 2 her Creatinine was 75 (µmol/L). On 16-Jun-2021, Blood fibrinogen (1.6-4.1): 5.1 g/l (normal) 5.1 g/L. On 16-Jun-2021, Brain natriuretic peptide: 27699 ng/l (High) 27699 ng/L Normal range less than 300 ng/L.				

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	On 16-Jun-2021, C-reactive protein (0.0-8.0): 281.1 mg/l (High) On Day 2 her C-reactive protein was 281.1 (mg/L). On 16-Jun-2021, Chest X-ray: abnormal (abnormal) Findings consistent with congestive heart failure. On 16-Jun-2021, Lymphocyte count (0.5-3.3): 0.3 10^9/l (Low) On Day 2 her Lymphocytes was 0.3 (10^9/L). On 16-Jun-2021, Neutrophil count (2-9): 15.5 10^9/l On Day 2 her Neutrophils-15.5 (10^9/L). On 16-Jun-2021, Platelet count (150-400): 251 10^9/l (normal) Day 2 Platelet count 251 (10^9/L). On 16-Jun-2021, Prothrombin time (0.9-1.1): 1.4 (High) 1.4 INR. On 16-Jun-2021, Serum ferritin (20-300): 1342 ug/l (High) On Day 2, Ferritin was 1342 (ug/L). On 16-Jun-2021, Troponin (0-13): 689 ng/l (High) On Day 2, Troponi				

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
[redacted]	This literature-non-study case was reported in a literature article and describes the occurrence of MULTISYSTEM INFLAMMATORY SYNDROME IN CHILDREN (Multisystem inflammatory syndrome in children) in a 12-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. LITERATURE REFERENCE: Ouldali N, Bagheri H, Salvo F, Antona D, Pariente A, Leblanc C, et al. Hyper inflammatory syndrome following COVID-19 mRNA vaccine in children: A national post-authorization pharmacovigilance study. Lancet Reg Health Eur. 2022;00:100393 Concurrent medical conditions included Thyroiditis. On an unknown date, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On an unknown date, received first dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. In October 2021, after starting mRNA-1273 (Spikevax), the patient experienced MULTISYSTEM INFLAMMATORY SYNDROME IN CHILDREN (Multisystem inflammatory syndrome in children) (seriousness criteria hospitalization and medically significant). The patient was hospitalized for 5 days due to MULTISYSTEM INFLAMMATORY SYNDROME IN CHILDREN. The patient was treated with IMMUNOGLOBULINS NOS (IMMUNOGLOBULIN I.V) ongoing since an unknown date for MIS-C, at an unspecified dose and frequency. At the time of the report, MULTISYSTEM INFLAMMATORY SYNDROME IN CHILDREN (Multisystem inflammatory syndrome in children) had resolved. Related DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, C-reactive protein: 150 mg/l 150 mg/L. On an unknown date, Ejection fraction: yes (50%) Yes	level 1	possible	This literature non-study case concerns a 12-year-old female patient, who experienced Multisystem inflammatory syndrome in children (MIS-C) 24 days after receiving the 2nd dose of mRNA-1273 vaccine. Her medical history included transit thyroiditis. According to the authors, she had fever > 3 days, mucocutaneous involvement, shock, cardiac involvement, coagulopathy, acute gastrointestinal symptoms, elevated markers of inflammation after vaccination with no other obvious microbial cause. Other manifestations were cytolytic hepatitis, hepato-splenomegaly and lymphopenia. The abnormal lab tests included CRP 150 mg/L. No history of SARS-CoV-2 infection was reported. SARS-CoV-2 test was negative. Considering > 3 days fever, additional clinical features, lab evidence of inflammation and measures of disease activity, the case is considered level 1 for MIS-C. based on the TTO of 24 days in the absence of covid 19 infection, it is considered possible for WHO causality. As the authors stated: "A causal association between COVID-19 mRNA vaccines and hyper-inflammatory syndrome could not be asserted. Indeed, despite extensive investigation for previous SARS-CoV-2 infection in all cases, pauci or asymptomatic SARS-CoV-2 infections are frequent in children, and may not have been documented. Furthermore, false negatives can be observed for anti-Nucleocapsid serology. Thus, we cannot exclude that some of the cases reported here could be related to undiagnosed SARS-CoV-2 infections."	[redacted]

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	(50%). On an unknown date, Haemoglobin: 11.8 g/dl 11.8 g/dL. On an unknown date, Lymphocyte count: 580/mm3 580/mm3. On an unknown date, Neutrophil count: 9,560 /mm3 9,560 /mm3. On an unknown date, Platelet count: 2,20,000/mm3 2,20,000/mm3. On an unknown date, SARS-CoV-2 antibody test: negative (Negative) Anti-N: negative. On an unknown date, SARS-CoV-2 test: negative (Negative) Negative. On an unknown date, White blood cell count: 10,400 /mm3 10,400 /mm3. For mRNA-1273 (Spikevax) (Unknown), the reporter considered MULTISYSTEM INFLAMMATORY SYNDROME IN CHILDREN (Multisystem inflammatory syndrome in children) to be related. Concomitant medication was not reported. PICU transfer was reported as no. Delay from first vaccine injection to SARS-CoV-2 antibody testing was 50 days. The impressive number of suspected adverse drug reaction reports (>80,000 between January 2021 and January 2022 in [redacted] suggest that underreporting may have been very rare, especially for serious adverse drug reactions. Company Comment: This literature non-study case concerns a 12-year-old female patient, with medical history of thyroiditis, overweight, who experienced the unexpected serious medically significant AESI Multisystem inflammatory syndrome in children that occurred 24 days (48 days from first injection) after receiving the 2nd dose of mRNA-1273 vaccine. Patient had fever > 3 days, mucocutaneous involvement, shock, cardiac involvement, coagulopathy, acute gastrointestinal symptoms, elevated markers of inflammation, and no other obvious microbial cause. Other manifestations reported were cytolytic hepatitis, hepato-splenomegaly				

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	and lymphopenia. The following lab tests were performed: CRP 150 mg/L, hemoglobin 11.8 g/dl, leucocytes 10400 / mm3, neutrophils 9560 / mm3, lymphocytes 580 / mm3, platelets 220000 / mm3, and LVEF 50%. Patient has no past history of SARS-CoV-2 infection. SARS-CoV-2 test was negative. SARS-CoV-2 antibody Anti-Spike reported positive and Anti-N negative. Patient did not require intensive care nor hemodynamic support. Patient was started on intravenous immunoglobulins plus steroids therapy with favorable outcome and was discharged fully recovered after 5 days of hospitalization. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Event's seriousness assessed based on medical judgement. This case was linked to [redacted] (E2B Linked Report).				
[redacted]	This literature-non-study case was reported in a literature article and describes the occurrence of MULTISYSTEM INFLAMMATORY SYNDROME IN CHILDREN (Multisystem inflammatory syndrome in children) in a 13-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. LITERATURE REFERENCE:	level 3a	possible	This literature non-study case concerns a 13-year-old male patient who experienced Multisystem inflammatory syndrome in children (MIS-C) 1 day after receiving the 2nd dose of mRNA-1273 vaccine. No medical history was reported. The patient presented with fever > 3 days, mucocutaneous involvement, coagulopathy, acute gastrointestinal symptoms, neurological involvement and elevated markers of inflammation following vaccination with	[redacted]

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	Ouldali N, Bagheri H, Salvo F, Antona D, Pariente A, Belot A, et al. Hyper inflammatory syndrome following COVID-19 mRNA vaccine in children: A national post-authorization pharmacovigilance study. Lancet Public Health. 2022;00 No Medical History information was reported. On an unknown date, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On an unknown date, received first dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. On an unknown date, the patient experienced MULTISYSTEM INFLAMMATORY SYNDROME IN CHILDREN (Multisystem inflammatory syndrome in children) (seriousness criteria hospitalization and medically significant). The patient was hospitalized for 5 days due to MULTISYSTEM INFLAMMATORY SYNDROME IN CHILDREN. At the time of the report, MULTISYSTEM INFLAMMATORY SYNDROME IN CHILDREN (Multisystem inflammatory syndrome in children) had resolved. Related DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, C-reactive protein: 109 mg/l CRP was 109 mg/L. On an unknown date, Eosinophil count: 320 mm3 Eosinophils was 320 mm3. On an unknown date, Haemoglobin: 13.4 g/dl Hemoglobin was 13.4 g/dL. On an unknown date, Lymphocyte count: 510 mm3 Lymphocytes was 510 mm3. On an unknown date, Neutrophil count: 6730 mm3 Neutrophils was 6730 mm3. On an unknown date, Platelet count: 192000 mm3 Platelets was 192000 mm3. On an unknown date, SARS-CoV-2 antibody test: negative (Negative) Negative. On an unknown date, SARS-CoV-2 test: negative (Negative) Nasopharyngeal SARS-CoV-2 PCR was			no other obvious microbial cause. Other manifestations were cytolytic hepatitis, lymphopenia, poly-arthralgia, and myalgia. The abnormal lab tests included CRP 109 mg/L. SARS-CoV-2 test was negative. In consideration of > 3 days fever, additional clinical features, lab evidence of inflammation but with no information on measures of disease activity, the case is considered level 3a for MIS-C. based on the TTO of 1 day in the absence of covid 19 infection, it is considered possible for WHO causality. As the authors stated: "A causal association between COVID-19 mRNA vaccines and hyper-inflammatory syndrome could not be asserted. Indeed, despite extensive investigation for previous SARS-CoV-2 infection in all cases, pauci or asymptomatic SARS-CoV-2 infections are frequent in children, and may not have been documented. Furthermore, false negatives can be observed for anti-Nucleocapsid serology. Thus, we cannot exclude that some of the cases reported here could be related to undiagnosed SARS-CoV-2 infections."	

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	negative. On an unknown date, White blood cell count: 8000 mm3 Leucocytes was 8 000 mm3. For mRNA-1273 (Spikevax) (Unknown), the reporter considered MULTISYSTEM INFLAMMATORY SYNDROME IN CHILDREN (Multisystem inflammatory syndrome in children) to be related. No concomitant product reported. Patient reported specific therapy as steroids. Patient had no past history of SARS-CoV-2 infection. It was reported that patient did not required PICU transfer Hemodynamic support.Patient was not overweight and also did not have any comorbidity condition. Cytolytic hepatitis, lymphopenia, myalgia and arthralgia all were manifestation reported. Symptoms onset date was reported as Oct-2021. Delay from COVID-19 mRNA last injection to symptoms onset was 1 days from first injection. Details of MIS-C WHO criteria were Fever > 3 days, Mucocutaneous involvement, Coagulopathy, Acute gastrointestinal symptoms, Elevated markers of inflammation, No other obvious microbial cause. Delay from first vaccine injection to SARS-CoV-2 antibody testing was of 24 days. Company Comment: This literature non-study case concerns a 13-year-old male patient, with no reported medical history, who experienced the unexpected serious medically significant AESI Multisystem inflammatory syndrome in children that occurred 1 day (21 days from first injection) after receiving the 2nd dose of mRNA-1273 vaccine. Patient presented with fever > 3 days, mucocutaneous involvement, coagulopathy, acute gastrointestinal symptoms, elevated markers of inflammation. No other obvious microbial cause. Other manifestations were cytolytic hepatitis, lymphopenia,				

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	poly-arthralgia neurological involvement, and myalgia. The following lab tests were performed: CRP 109mg/L, hemoglobin 13.4g/dl, leucocytes 8000/ mm3, neutrophils 6730/ mm3, lymphocytes 510 mm3, eosinophils 320/ mm3, and platelets 192000/ mm3. SARS-CoV-2 test was negative. SARS-CoV-2 antibody (Anti-N) negative. Patient did not require intensive care nor hemodynamic support. Patient was started on steroids therapy with favorable outcome and was discharged fully recovered after 5 days of hospitalization. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. This case was linked to [redacted] (E2B Linked Report).				
[redacted]	This regulatory authority case was reported by a physician and describes the occurrence of SEPTIC SHOCK (Septic shock//Fever//Nausea//Vomiting//Cough//Respiratory insufficiency), PYREXIA (Septic shock//Fever//Nausea//Vomiting//Cough//Respiratory insufficiency), NAUSEA (Septic shock//Fever//Nausea//Vomiting//Cough//Respiratory insufficiency), VOMITING (Septic shock//Fever//Nausea//Vomiting//Cough//Respiratory insufficiency), COUGH (Septic shock//Fever//Nausea//Vomiting//Cough//Respiratory insufficiency) and RESPIRATORY FAILURE (Septic shock//Fever//Nausea//Vomiting//Cough//Respiratory insufficiency) in an 18-year-old male patient who received mRNA-1273 (COVID 19 Vaccine Moderna) for COVID-19 prophylaxis. Concomitant products included ACETAMINOPHEN, ACETYLSALICYLIC ACID, OLANZAPINE and RISPERIDONE for an unknown indication. On an unknown date, the patient received dose of mRNA-1273 (COVID 19 Vaccine Moderna) (unknown route) 1 dosage form. On an unknown date, the patient experienced SEPTIC SHOCK (Septic shock//Fever//Nausea//Vomiting//Cough//Respiratory insufficiency) (seriousness criterion medically	level 3b	possible	This regulatory authority case reported by a physician concerned an 18-year-old male who experienced septic shock, pyrexia, nausea, vomiting, cough, and respiratory failure on an unknown date after he received mRNA-1273 vaccine on an unknown date. No medical history was provided. Co meds included acetaminophen, acetylsalicylic acid, olanzapine, and risperidone. No treatment medications were reported. The case is considered level 3b for MIS-C, as the case is medically confirmed, the patient had fever of unknown period, and clinical presentations showed GI and circulation involvement, but no Laboratory evidence of inflammation and measures of disease activity are available. The respiratory failure could be the outcome of shock. However, the WHO is considered unassessable due to lack of sufficient information, including TTO for events.	[redacted]

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	significant), PYREXIA (Septic shock//Fever//Nausea//Vomiting//Cough//Respiratory insufficiency) (seriousness criterion medically significant), NAUSEA (Septic shock//Fever//Nausea//Vomiting//Cough//Respiratory insufficiency) (seriousness criterion medically significant), VOMITING (Septic shock//Fever//Nausea//Vomiting//Cough//Respiratory insufficiency) (seriousness criterion medically significant), COUGH (Septic shock//Fever//Nausea//Vomiting//Cough//Respiratory insufficiency) (seriousness criterion medically significant) and RESPIRATORY FAILURE (Septic shock//Fever//Nausea//Vomiting//Cough//Respiratory insufficiency) (seriousness criterion medically significant). At the time of the report, SEPTIC SHOCK (Septic shock//Fever//Nausea//Vomiting//Cough//Respiratory insufficiency), PYREXIA (Septic shock//Fever//Nausea//Vomiting//Cough//Respiratory insufficiency), NAUSEA (Septic shock//Fever//Nausea//Vomiting//Cough//Respiratory insufficiency), VOMITING (Septic shock//Fever//Nausea//Vomiting//Cough//Respiratory insufficiency), COUGH (Septic shock//Fever//Nausea//Vomiting//Cough//Respiratory insufficiency) and RESPIRATORY FAILURE (Septic shock//Fever//Nausea//Vomiting//Cough//Respiratory insufficiency) had not resolved. 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. No treatment medications were reported. Company comment: This regulatory authority case concerns an 18-year-old male patient with no reported medical history, who experienced the unexpected serious (medically significant) events of Septic shock,				

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	Pyrexia, Nausea, Vomiting, Cough, and Respiratory failure which occurred unknown days after administration of an unspecified dose of mRNA-1273 vaccine. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Events' seriousness assessed as per Regulatory Authority's report.				

Appendix 11.19e Multisystem Inflammatory Syndrome (MIS): Brighton Collaboration Summary Information Level 1 to 3 for the Reporting Period: Case Listings

Case ID	Country	Report Type	PT	Event Seriousness	ALL PTs	Patient Age (Years)	Patient Gender	Event Outcome	Medical History	Concomitant Medications	Dose #	TTO All Doses	Primary Cause of Death	WW Identifier
[redacted]	[redacted]	Literature-Non-Study	Multisystem inflammatory syndrome in adults	Serious	Cerebellar stroke, Chest pain, Dyspnoea, Embolic stroke, Hypersensitivity, Intensive care unit acquired weakness, Multisystem inflammatory syndrome in adults, Muscle necrosis, Oedema peripheral, Peripheral artery occlusion, Polyneuropathy, Respiratory failure, Vasoplegia syndrome	21.00	Female	Recovered/Resolved with Sequelae	COVID-19(H)		Unknown			[redacted]
[redacted]	[redacted]	Literature-Non-Study	Multisystem inflammatory syndrome in adults	Serious	Atrial fibrillation, COVID-19, Multisystem inflammatory syndrome in adults	63.00	Female	Recovering/Resolving	Hypertension(C); Type 2 diabetes mellitus(C); End stage renal disease(C); Dialysis; Cardiac failure(C); Cerebrovascular accident(C); Coronary artery bypass; Percutaneous coronary intervention		Unknown			[redacted]
[redacted]	JAPAN	Spontaneous	Multiple organ dysfunction syndrome	Serious	Altered state of consciousness, Depressed level of consciousness, Hypotension, Multiple organ dysfunction syndrome, Pyrexia, Rhabdomyolysis, Seizure, Sepsis, Status epilepticus	63.00	Male	Fatal	Epilepsy(C); Head injury(H)	ALEVIATIN MINO; LAMICTAL	Unknown		Convulsion	[redacted]
[redacted]	[redacted]	Literature-Non-Study	Multisystem inflammatory syndrome	Serious	Multisystem inflammatory syndrome	52.00	Female	Unknown			Unknown			[redacted]
[redacted]	[redacted]	Literature-Non-Study	Multisystem inflammatory syndrome in children	Serious	Multisystem inflammatory syndrome in children	12.00	Female	Recovered/Resolved	Thyroiditis(C)		Unknown			[redacted]
[redacted]	[redacted]	Literature-Non-Study	Multisystem inflammatory syndrome in children	Serious	Multisystem inflammatory syndrome in children	13.00	Male	Recovered/Resolved			Unknown			[redacted]
[redacted]	[redacted]	Regulatory Authority	Septic shock	Serious	Cough, Nausea, Pyrexia, Respiratory failure, Septic shock, Vomiting	18.00	Male	Not Recovered/Not Resolved		ACETAMINOPHEN; ACETYLSALICYLIC ACID; OLANZAPINE; RISPERIDONE	Unknown			[redacted]

Appendix 11.19f Multisystem Inflammatory Syndrome (MIS): Brighton Collaboration Summary Information Level 1 to 3 for the Reporting Period: Narratives

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
[redacted]	This literature-non-study case was reported in a literature article and describes the occurrence of MULTISYSTEM INFLAMMATORY SYNDROME IN ADULTS (Multisystem inflammatory syndrome), OEDEMA PERIPHERAL (Leg edema), CHEST PAIN (Chest pain), DYSPNOEA (Dyspnea), HYPERSENSITIVITY (Allergic reaction), VASOPLEGIA SYNDROME (vasoplegia), RESPIRATORY FAILURE (hypoxic respiratory failure), PERIPHERAL ARTERY OCCLUSION (right common femoral artery occlusion), CEREBELLAR STROKE (cerebellar stroke), INTENSIVE CARE UNIT ACQUIRED WEAKNESS (critical illness polyneuropathy), MUSCLE NECROSIS (Muscle necrosis), EMBOLIC STROKE (Cardioembolic stroke) and POLYNEUROPATHY (Bilateral Polyneuropathy) in a 21-year-old female patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for COVID-19 vaccination. LITERATURE REFERENCE: Lieu A, Mah J, Church D. A case of multisystem inflammatory syndrome in adults following natural infection and subsequent immunization. Int J Infect Dis. 2022;116:34-7 The patient's past medical history included SARS-CoV-2 infection (previously received positive test results, 6 weeks before this acute illness. Patient was asymptomatic at the time of testing. Notably, 27 days after the patient tested positive, received the first dose of the messenger RNA (mRNA) vaccine (Moderna) without immediate adverse reactions.) on 30-Apr-2021. On an unknown date, the patient received first dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 02-Nov-2021, the patient experienced MUSCLE NECROSIS (Muscle necrosis) (seriousness criterion medically significant), EMBOLIC STROKE (Cardioembolic stroke) (seriousness criterion medically significant) and POLYNEUROPATHY (Bilateral Polyneuropathy) (seriousness criterion medically significant). On an unknown date, after starting mRNA-1273 (Moderna CoviD-19 Vaccine), the patient experienced MULTISYSTEM INFLAMMATORY	Level 2b	Unlikely	This case concerns a 21-year-old female patient with medical history of SARS-CoV-2 infection 27 days before her 1st dose of Spikevax who experienced edema peripheral, chest pain, dyspnea, hypersensitivity, vasoplegia syndrome, respiratory failure, peripheral artery occlusion, intensive care unit acquired weakness, and multisystem inflammatory syndrome and cerebellar stroke, approximately in 10 days after receiving the first dose of mRNA-1273 Vaccine. The patient started headache, nausea, vomiting, diarrhea, followed by rash and fever. Her symptoms were later associated with progressive shortness of breath and chest pain, leading to her ED presentation. Patient received fluid resuscitation, broad-spectrum antibiotics, and was admitted to the ICU to initiate inotropes. The patient was started on intravenous glucocorticoids, intravenous immunoglobulins, and aspirin. Cardiogenic shock ensued over the next 48 hours, and the patient required intubation because of hypoxic respiratory failure. The patient had a precipitous decline in cardiac function, as documented on serial TTEs. Anakinra was initiated for the cytokine storm and MIS-A. The patient had persistent hypoxic failure and vasoplegia, which required venous-arterial extracorporeal membrane oxygenation (VA-ECMO). Her clinical status improved. It was reported that the outcome of the events was resolving. Relevant exams and tests included SARS-CoV-2 test positive by a PCR 6 weeks before this acute illness, Body temperature 38.0 degree, Blood pressure measurement 80/50 mm hg, left ventricular ejection function decreased, CRP, ALT, CK, troponin, NT-proBNP and ferritin increased. The case presented fever, clinical features, lab evidence of inflammation and measures of disease activity for MIS-A. however, due to insufficient information on the duration of fever, it is considered level 2b for MIS. The recent history of COVID-19 infection is an important risk factor that provides a more plausible explanation for the occurrence of the reported event of MIS-A. According to the WHO causality assessment this report is considered unlikely and more likely explained by MIS-A due to COVID-19.	[redacted]

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	SYNDROME IN ADULTS (Multisystem inflammatory syndrome) (seriousness criteria hospitalization, medically significant and life threatening), OEDEMA PERIPHERAL (Leg edema) (seriousness criterion hospitalization), CHEST PAIN (Chest pain) (seriousness criterion hospitalization), DYSPNOEA (Dyspnea) (seriousness criterion hospitalization), HYPERSENSITIVITY (Allergic reaction) (seriousness criterion hospitalization), VASOPLEGIA SYNDROME (vasoplegia) (seriousness criteria hospitalization and medically significant), RESPIRATORY FAILURE (hypoxic respiratory failure) (seriousness criteria hospitalization and medically significant), PERIPHERAL ARTERY OCCLUSION (right common femoral artery occlusion) (seriousness criteria hospitalization and medically significant), CEREBELLAR STROKE (cerebellar stroke) (seriousness criteria hospitalization and medically significant) and INTENSIVE CARE UNIT ACQUIRED WEAKNESS (critical illness polyneuropathy) (seriousness criterion hospitalization). The patient was treated with ASPIRIN [ACETYLSALICYLIC ACID] for Adverse event, at an unspecified dose and frequency; ANAKINRA (intravenous) from 15-Jun-2021 to 28-Jun-2021 for Adverse event, at a dose of 100 milligram every twelve hours; IMMUNOGLOBULINS NOS (intravenous) on 14-Jun-2021 for Adverse event, at a dose of 2 gram per kilogram; METHYLPREDNISOLONE (intravenous) on 14-Jun-2021 for Adverse event, at a dose of 1 gram once a day and PREDNISONE for Adverse event, at an unspecified dose and frequency. At the time of the report, MULTISYSTEM INFLAMMATORY SYNDROME IN ADULTS (Multisystem inflammatory syndrome) had resolved with sequelae, OEDEMA PERIPHERAL (Leg edema), CHEST PAIN (Chest pain), DYSPNOEA (Dyspnea), HYPERSENSITIVITY (Allergic reaction), VASOPLEGIA SYNDROME (vasoplegia), RESPIRATORY FAILURE (hypoxic respiratory failure), PERIPHERAL ARTERY OCCLUSION (right common femoral artery occlusion), CEREBELLAR STROKE (cerebellar stroke) and INTENSIVE CARE UNIT ACQUIRED WEAKNESS (critical illness polyneuropathy) was resolving and MUSCLE NECROSIS (Muscle necrosis), EMBOLIC STROKE (Cardioembolic stroke) and POLYNEUROPATHY (Bilateral Polyneuropathy) outcome was unknown.				

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 01-May-2021, SARS-CoV-2 test: positive (Positive) Positive. On 14-Jun-2021, Alanine aminotransferase: 74 u/l (High) On Day 0 ALT was 74 (U/L) Normal range less than 39 U/L. On 14-Jun-2021, Blood albumin (30-45): 29 g/l (normal) 29 g/L. On 14-Jun-2021, Blood creatinine (40-100): 89 µmol/l (normal) On Day 0 her Creatinine was 89 (µmol/L). On 14-Jun-2021, Blood fibrinogen (1.6-4.1): 7.3 g/l (normal) 7.3 g/L. On 14-Jun-2021, Brain natriuretic peptide: 1641 ng/l (High) 1641 Normal range less than 300 ng/L. On 14-Jun-2021, C-reactive protein (0.0-8.0): 315.0 mg/l (High) On Day 0 her C-reactive protein was 315.0 (mg/L). On 14-Jun-2021, Chest X-ray: normal (normal) Lungs are clear, heart size is normal. On 14-Jun-2021, Electrocardiogram: abnormal (abnormal) Sinus tachycardia, QTc 435ms otherwise normal. On 14-Jun-2021, Fibrin D dimer: 2.09 mg/l (High) 2.09 mg/L normal range less than or equal to 0.50 mg/L FEU. On 14-Jun-2021, Lymphocyte count (0.5-3.3): 0.8 10^9/l (Low) On Day 0 her Lymphocytes was 0.8 (10^9/L). On 14-Jun-2021, Neutrophil count (2-9): 15.7 10^9/l On Day 0 her Neutrophils-15.7 (10^9/L). On 14-Jun-2021, Platelet count (150-400): 186 10^9/l (normal) On Day 0 her Platelet count was 186 (10^9/L). On 14-Jun-2021, Prothrombin time (0.9-1.1): 1.6 (High) 1.6 INR. On 14-Jun-2021, Serology test: positive (Positive) IgG serological test for antibodies directed toward the SARS-CoV-2 nucleocapsid protein was positive.. On 14-Jun-2021, Serum ferritin (20-300): 668 ug/l (High) On Day 0 her Ferritin was 668 (ug/L). On 14-Jun-2021, Troponin (0-13): 808 ng/l (High) On Day 0, Troponin was 808 (ng/L). On 14-Jun-2021, White blood cell count (4-11): 17.7 10^9/l (High) On Day 0, Leucocytes was 17.7 (10^9/L). On 15-Jun-2021, Alanine aminotransferase: 51 u/l (High)				

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	On Day 1 her ALT 51 (U/L) Normal range less than 39 U/L. On 15-Jun-2021, Blood creatinine (40-100): 73 µmol/l (normal) On Day 1 her Creatinine was 73 (µmol/L). On 15-Jun-2021, Blood lactate dehydrogenase (100-235): 317 u/l (High) 317 U/L. On 15-Jun-2021, C-reactive protein (0.0-8.0): 292.5 mg/l (High) On Day 1 her C-reactive protein was 292.5 (mg/L). On 15-Jun-2021, Echocardiogram: abnormal (abnormal) LV EF 30-35%, R Vsignificantly imapired, severe TR, small percaridal effusion. On 15-Jun-2021, Lymphocyte count (0.5-3.3): 0.2 10^9/l (Low) Day 1 her Lymphocytes was 0.2 (10^9/L). On 15-Jun-2021, Neutrophil count (2-9): 19.2 10^9/l On Day 1 her Neutrophils - 19.2 (10^9/L). On 15-Jun-2021, Platelet count (150-400): 202 10^9/l (normal) On Day 0 her Platelet count was 202 (10^9/L). On 15-Jun-2021, Prothrombin time (0.9-1.1): 1.5 (High) 1.5 INR. On 15-Jun-2021, Troponin (0-13): 1306 ng/l (High) On Day 1, Troponin was 1306 (ng/L). On 15-Jun-2021, White blood cell count (4-11): 21.2 10^9/l (High) On Day 1, Leucocytes was 21.2 (10^9/L). On 16-Jun-2021, Activated partial thromboplastin time (28-38): 91.6 seconds (High) 91.6 seconds. On 16-Jun-2021, Alanine aminotransferase: 102 u/l (High) On Day 2 her ALT was 102 (U/L) Normal range less than 39 U/L. On 16-Jun-2021, Blood creatinine (40-100): 75 µmol/l (normal) On Day 2 her Creatinine was 75 (µmol/L). On 16-Jun-2021, Blood fibrinogen (1.6-4.1): 5.1 g/l (normal) 5.1 g/L. On 16-Jun-2021, Brain natriuretic peptide: 27699 ng/l (High) 27699 ng/L Normal range less than 300 ng/L. On 16-Jun-2021, C-reactive protein (0.0-8.0): 281.1 mg/l (High) On Day 2 her C-reactive protein was 281.1 (mg/L). On 16-Jun-2021, Chest X-ray: abnormal (abnormal) Findings consistent with congestive heart failure. On 16-Jun-2021, Lymphocyte count (0.5-3.3): 0.3 10^9/l (Low) On Day 2 her Lymphocytes was 0.3 (10^9/L). On 16-Jun-2021, Neutrophil count (2-9): 15.5 10^9/l On				

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	Day 2 her Neutrophils-15.5 (10⁹/L). On 16-Jun-2021, Platelet count (150-400): 251 10⁹/l (normal) Day 2 Platelet count 251 (10⁹/L). On 16-Jun-2021, Prothrombin time (0.9-1.1): 1.4 (High) 1.4 INR. On 16-Jun-2021, Serum ferritin (20-300): 1342 ug/l (High) On Day 2, Ferritin was 1342 (ug/L). On 16-Jun-2021, Troponin (0-13): 689 ng/l (High) On Day 2, Troponi				

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
[redacted]	This literature-non-study case was reported in a literature article and describes the occurrence of MULTISYSTEM INFLAMMATORY SYNDROME IN ADULTS (hyperinflammatory syndrome), COVID-19 (breakthrough COVID-19 infection) and ATRIAL FIBRILLATION (atrial fibrillation) in a 63-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. LITERATURE REFERENCE: Narvel H, Kaur A, Seo J, Kumar A. Multisystem inflammatory syndrome in adults or hemophagocytic lymphohistiocytosis: A clinical conundrum in fully vaccinated adults with breakthrough COVID-19 infections. Cureus. 2022;14(2):e22123 The patient's past medical history included Dialysis, Coronary artery bypass graft and Percutaneous coronary intervention. Concurrent medical conditions included Hypertension, Type 2 diabetes mellitus, End stage renal disease (end-stage renal disease on dialysis), Heart failure and Stroke. In 2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. In 2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. In 2021, the patient experienced MULTISYSTEM INFLAMMATORY SYNDROME IN ADULTS (hyperinflammatory syndrome) (seriousness criteria hospitalization and medically significant), COVID-19 (breakthrough COVID-19 infection) (seriousness criteria hospitalization and medically significant) and ATRIAL FIBRILLATION (atrial fibrillation) (seriousness criteria hospitalization and medically significant). The patient was hospitalized from sometime in 2021 to sometime in 2021 due to ATRIAL FIBRILLATION, COVID-19 and MULTISYSTEM INFLAMMATORY SYNDROME IN ADULTS. The patient was treated with CEFTRIAXONE in 2021 for Pneumonia, at an unspecified dose and frequency; AZITHROMYCIN in 2021 for Pneumonia, at an unspecified dose and frequency; DEXAMETHASONE on	level 1	unlikely	Based on information from the origianl article, a 63-year-old female presented in August 2021 with a two-day history of bilateral leg weakness and left facial droop. She also reported feeling fatigued with subjective fevers, dry cough, diarrhea, and shortness of breath for a week. Her past medical history was significant for hypertension, type 2 diabetes, end-stage renal disease on dialysis, heart failure, and stroke. Past surgical history was notable for coronary artery bypass graft and percutaneous coronary intervention. She got the SARS-CoV-2 infection from her daughter although she was fully vaccinated with two doses of mRNA-1273 four months ago. She was positive SARS-CoV-2 by PCR at the time. Her right-sided lung infiltrate was seen on chest Xray. A new-onset atrial fibrillation on ECG and echo showed decreased ejection fraction and left ventricular hypokinesis. Lab showed remarkably elevated troponin and pro-B-type natriuretic peptide, microcytic anemia and leucocytosis with lymphocytes, splenomegaly, and suspicion for lymphoproliferative disorder. Chronic Lymphocytic Leukemia was also suspected by lab testing. The authors discussed possible differential diagnosis for hyperinflammatory presentation included MIS-A, Hemophagocytic Lymphohistiocytosis (HLH), or macrophage activation syndrome (MAS). The case focused on discussion of differentiation of two inflammatory events following a breakthrough Covid 19 infection. The author considered that the patient met the level 1 case definition for MIS-A. However, it is unlikely related to mRNA-1273 vaccination due to a TTO of 4 months, and an alternative recent Covid-19 infection.	[redacted]

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	25-Aug-2021 for Adverse event, at a dose of 20 milligram; DEXAMETHASONE on 07-Sep-2021 for Adverse event, at a dose of 10 milligram and APIXABAN in 2021 at an unspecified dose and frequency. At the time of the report, MULTISYSTEM INFLAMMATORY SYNDROME IN ADULTS (hyperinflammatory syndrome) was resolving and COVID-19 (breakthrough COVID-19 infection) and ATRIAL FIBRILLATION (atrial fibrillation) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Alanine aminotransferase: >700 u/l (High) >700 U/L. On an unknown date, Aspartate aminotransferase: 681 u/l (High) 681 U/L. On an unknown date, Blood culture: negative negative. On an unknown date, Blood fibrinogen: 446 mg/dl (normal) 446 mg/dL. On an unknown date, Blood pressure measurement: 118/67 mmhg 118/67 mmHg. On an unknown date, Blood smear test: abundant mature-appearing small lymphocytes A peripheral blood smear was reviewed, which showed abundant mature-appearing small lymphocytes and smudge cells raising concern for CLL. Several left-shifted polymorphonuclear leukocytes with toxic granules were noted, which would be consistent with acute infectious processes.. On an unknown date, Blood triglycerides: 166 mg/dl (normal) 166 mg/dL. On an unknown date, Body temperature: afebrile afebrile. On an unknown date, C-reactive protein: 183.5 mg/dl (High) 183.5 mg/dL (elevated). On an unknown date, Chemokine test: elevated elevated chemokine (C-X-C motif) ligand 9 (CXCL9) level at 6,000 pg/ml. On an unknown date, Chest X-ray: the right-sided infiltrate seen on the chest x-ray The right-sided infiltrate seen on the chest X-ray was not seen on the CT chest.. On an unknown date, Computerised tomogram: unremarkable Computed tomography (CT) scan of the head without contrast was done due to concern for neurologic deficits, which was unremarkable.. On an unknown date, Computerised tomogram thorax:				

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	revealed multiple bulky bilateral axillary, hilar CT pulmonary angiography with contrast showed no pulmonary embolism or focal consolidation but revealed multiple bulky bilateral axillary, hilar, and mediastinal lymph nodes raising suspicion for underlying hitherto undiagnosed lymphoproliferative disorder. On an unknown date, Echocardiogram: did not show any valvular vegetations did not show any valvular vegetations or cardiac thrombi but did note decreased ejection fraction of 40% and left ventricular hypokinesis.. On an unknown date, Electrocardiogram: abnormal patient was found to be in new-onset atrial fibrillation on ECG (sinus rhythm present on ECG done on day one), raising suspicion for a cardio-embolic event as a cause for TIA.. On an unknown date, Fibrin D dimer: 2,573 ng/ml 2,573 ng/mL. On an unknown date, Flow cytometry: suggestive of cd5+ lymphoproliferative disorder Flow cytometry showed aberrant B cells (79%), indeterminate for kappa and lambda, positive for CD19, CD23, CD5, and dim CD20, and negative for CD10, CD38, and FMC-7, which was suggestive of CD5+ lymphoproliferative disorder, likely CLL.. On an unknown date, HIV test: negative negative. On an unknown date, Haemoglobin: 9.6 g/dl Initial complete blood count showed hypochromic, microcytic anemia (hemoglobin: 9.6 g/dL). On an unknown date, Heart rate: 73 beats/min 73 beats/min. On an unknown date, Hepatitis viral test: negative negative. On an unknown date, Interleukin-2 receptor assay (175 pg/ml-858 pg/ml): 3,527 pg/ml elevated soluble interleukin-2 receptor level at 3,527 pg/ml. On an unknown date, Lymphocyte count: 86.8% lymphocytes 86.8% lymphocytes (36.15 lymphocytes/nL). On an unknown date, Neurological examination: abnormal remarkable for mild flattening of the nasolabial fold on the left side, intact sensory examination in all four extremities, and mild bilateral leg weakness on motor examination (strength ⅘).. On an unknown date, Oxygen saturation: normal maintaining normal oxygen saturation on room air. On an unknown date, Physical examination: decreased				

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	breath sounds Decreased breath sounds over the right lung field. On an unknown date, Procalcitonin: 5.32 ng/ml 5.32 ng/mL on day one. On an unknown date, Prohormone brain natriuretic peptide: elevated (High) Elevated. On an unknown date, Respiratory rate: 21 breaths/min 21 breaths/min. On an unknown date, SARS-CoV-2 antibody test: elevated (High) Patient also had significantly elevated titers of COVID-19 spike antibody (>2,500 U/ml) showing an appropriate response to vaccination. On an unknown date, SARS-CoV-2 test: positive (Positive) The patient completed eight weeks of steroid taper, however, did continue to have prolonged viral shedding with positive COVID-19 PCR test and positive found to have positive SARS-CoV-2 polymerase chain reaction (PCR) from nasopharyngeal swab and reactive total SARS-CoV-2 antibody. On an unknown date, Serum ferritin: 17,899 µg/l (High) 17,899 µg/L. On an unknown date, Troponin: 2.270 µg/l (High) 2.270 µg/L (elevated troponin). On an unknown date, Ultrasound abdomen: splenomegaly depicted splenomegaly with spleen size 14.1 cm. On an unknown date, White blood cell count: 41.66 white blood cells/nl 41.66 white blood cells/nL (leucocytosis). For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter considered MULTISYSTEM INFLAMMATORY SYNDROME IN ADULTS (hyperinflammatory syndrome), COVID-19 (breakthrough COVID-19 infection) and ATRIAL FIBRILLATION (atrial fibrillation) to be related. CC:This is a Literature-Non-Study case concerning a 63-year-old female patient, with medical history of Percutaneous coronary intervention, Coronary artery bypass graft and Stroke and concurrent condition of Hypertension, Type 2 diabetes mellitus, End stage renal disease, Dialysis and Heart failure and had no known diagnosis of an underlying rheumatologic condition; who experienced the serious unexpected AESIs of Multisystem				

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	inflammatory syndrome in adults, COVID-19 and Atrial fibrillation (serious criteria Medically Significant and Hospitalized); that occurred in an unknown date, approximately 4 months after the administration of the second dose of the mRNA-1273 vaccine. Relevant tests were performed that showed: Vital signs: normal range; normal oxygen saturat, decreased breath sounds over the right lung field; Xray: right-s				

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
[redacted]	This case was initially received via Takeda Pharmaceuticals (Reference number: [redacted] on 06-May-2022. The most recent information was received on 02-Jun-2022 and was forwarded to Moderna on 10-Jun-2022. This case, initially reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by a physician, was received via the PMDA (Ref, [redacted]. On 02-Jun-2022, follow-up information was received from a physician. On an unknown date, the patient received the 1st dose of a novel coronavirus vaccine (product name unknown). On an unknown date, the patient received the 2nd dose of a novel coronavirus vaccine (product name unknown). On 11-Apr-2022, the patient received the 3rd vaccination with this vaccine. On 12-Apr-2022, the patient experienced a pyrexia in the 38 degrees Celsius range. Around 13:00, due to the sudden onset of convulsions, the patient visited the emergency room of the reporting hospital by ambulance. The patient was status epilepticus at the time of the visit, and anticonvulsants were administered, which stopped the convulsions. Hypotension was observed, and vasoconstrictor was administered, and the patient was weaned from circulatory disorder. Due to persisting consciousness disturbed, endotracheal intubation was performed, and the patient was admitted to the intensive care unit for ventilatory management. The patient was hospitalized. On 13-Apr-2022, the patient developed acute liver disorder, acute kidney injury, and rhabdomyolysis, and was observed to have multi-organ failure. On 17-Apr-2022, hemodialysis was started. On 20-Apr-2022, a tracheostomy was performed. On 21-Apr-2022, the patient was in a state of multi-organ failure with disturbed consciousness with semi-comatose, acute kidney injury requiring dialysis, and persistent liver disorder when leaving the intensive care unit. On 06-May-2022, the patient experienced sepsis and entered the intensive care unit. On 13-May-2022, the patient left the intensive care unit. On 21-May-2022, the patient died. The cause of death was multi-organ failure. No autopsy was performed. The outcome of pyrexia was reported as ongoing and unchanged. The outcome of hypotension, consciousness disturbed, rhabdomyolysis, and semi-coma was unknown. The outcome of convulsion, status epilepticus, multi-organ failure, and sepsis was reported as fatal. No follow-up investigation will be made. Reporter comments	level 3a	conditiona l	This regulatory case reported by a physician was concerned a 63 years-old male patient who experienced altered state of consciousness, depressed level of consciousness, hypotension, multiple organ dysfunction syndrome, Pyrexia, Rhabdomyolysis, Seizure, Sepsis and Status epilepticus about 1 day after he received third dose of mRNA-1273. No information on medical history and co meds was available. He started to experience a pyrexia in the 38 degrees Celsius range first (ongoing during the disease process), status epilepticus and hypotension. He then developed acute liver disorder, acute kidney injury, and rhabdomyolysis, and multi-organ failure. He further experienced sepsis and died despite intensive medical attentions about 40 days after the vaccination. The cause of death was multi-organ failure. No autopsy was performed. The case did not report MIS-A. However, the patient had a fever > 3 consecutive days. His clinical features included hypotension and neurologic sign convulsion. The case lacked lab evidence of inflammation and measures of disease activity , such as elevated BNP or NT-proBNP or troponin, cardiac involvement by echocardiography or physical stigmata of heart failure, or EKG changes consistent with myocarditis or myo-pericarditis. in addition, it was heavily confounded by the diagnosis of sepsis, acute liver disorder, lack of information on medical history. It is considered conditional for MIS-A. . WHO causality is considered possible based on the time to onset for the events. Of note, no prior and concurrent medical conditions and co meds were provided for the case, confounding risks may not be fully assessed.	[redacted]

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	continuation: The relationship between the occurrence of adverse events and concomitant drugs is unknown. The relationship between the occurrence of adverse events and pathological factors of underlying diseases and complications is unknown. The relationship between the cause of death and adverse events is unknown because the patient died of multi-organ failure after convulsion. The patient with symptomatic epilepsy experienced pyrexia and convulsion and died of multi-organ failure probably due to status epilepticus after receiving this vaccine, although the relationship is unclear. Follow-up received on 02-JUN-2022 Updated: Patient Information, Other Relevant History, Lab Data, Product Information, Event Information, Narrative, Reporter Comments Company Comment: Status epilepticus developed after the administration of ELASOMERAN, factors such as concurrent conditions may have also had an influence. Pyrexia, seizure, hypotension, altered state of consciousness, rhabdomyolysis, multiple organ dysfunction syndrome, depressed level of consciousness, and sepsis developed after the administration of ELASOMERAN and there is temporal relationship.				

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
[redacted]	This case was received via Takeda Pharmaceuticals (Reference number: [redacted]) on 09-May-2022 and was forwarded to Moderna on 13-May-2022. CLARIFICATION REQUIRED: The product was autocoded as Spikevax with WORLD licence and did not stop for adjudication. This case was presented at "The 49th Annual Meeting of the [redacted]. Multisystem inflammatory syndrome was assessed as serious by the MAH. A 52-year-old woman presented to our hospital with fever, transient loss of consciousness and hypotension. Four days ago, she received second COVID-19 Moderna vaccination. At presentation to the hospital, troponin I, C-reactive protein, Neutrophil and NT-pro BNP were elevated, but electrocardiogram didnt show ST-segment change. Transthoracic echocardiography showed depression of cardiac function and cardiac magnetic resonance imaging demonstrated edema and inflammation of both ventricles. After administrating of antibiotics, cardiovascular agents and hydrocortisone intravenously, hemodynamic status and inflammation markers became improved. As diarrhea rash were presented during the clinical course, we diagnosed as MIS according to the case definition. Follow-up investigation will be made. Company Comment: The event developed after the administration of elasomeran and there is temporal relationship.	level 1	possible	No original article is available for the case. This meeting presentation case concerned a 52-year-old woman who experienced multisystem inflammatory syndrome four days after she received second COVID-19 Moderna vaccination. She presented fever (unspecified duration), transient loss of consciousness and hypotension. Troponin I, C-reactive protein, Neutrophil and NT-pro BNP were elevated. However, electrocardiogram did not show ST-segment change. Transthoracic echocardiography showed depression of cardiac function and cardiac magnetic resonance imaging demonstrated edema and inflammation of both ventricles. After administrating of antibiotics, cardiovascular agents and hydrocortisone intravenously, hemodynamic status and inflammation markers became improved. Diarrhea and rash were also presented during the clinical course. The case met MIS-A based on the clinical features of multiple organ involvement, lab evidence of inflammation with increased CRP, measures of disease activity of increased Troponin and NT-pro BNP, and evidence of heart function depression and myocarditis. Because the fever duration was unavailable, it may be considered either level 1 or 2 for MIS-A. It is conservatively classified as level 1. WHO causality is considered possible based on the temporal relation of 4 days.	[redacted]

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
[redacted]	This literature-non-study case was reported in a literature article and describes the occurrence of MULTISYSTEM INFLAMMATORY SYNDROME IN CHILDREN (Multisystem inflammatory syndrome in children) in a 12-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. LITERATURE REFERENCE: Ouldali N, Bagheri H, Salvo F, Antona D, Pariente A, Leblanc C, et al. Hyper inflammatory syndrome following COVID-19 mRNA vaccine in children: A national post-authorization pharmacovigilance study. Lancet Reg Health Eur. 2022;00:100393 Concurrent medical conditions included Thyroiditis. On an unknown date, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On an unknown date, received first dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. In October 2021, after starting mRNA-1273 (Spikevax), the patient experienced MULTISYSTEM INFLAMMATORY SYNDROME IN CHILDREN (Multisystem inflammatory syndrome in children) (seriousness criteria hospitalization and medically significant). The patient was hospitalized for 5 days due to MULTISYSTEM INFLAMMATORY SYNDROME IN CHILDREN. The patient was treated with IMMUNOGLOBULINS NOS (IMMUNOGLOBULIN I.V) ongoing since an unknown date for MIS-C, at an unspecified dose and frequency. At the time of the report, MULTISYSTEM INFLAMMATORY SYNDROME IN CHILDREN (Multisystem inflammatory syndrome in children) had resolved. Related DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, C-reactive protein: 150 mg/l 150 mg/L. On an unknown date, Ejection fraction: yes (50%) Yes (50%). On an unknown date, Haemoglobin: 11.8 g/dl 11.8 g/dL. On an unknown date, Lymphocyte count: 580/mm3 580/mm3.	level 1	possible	This literature non-study case concerns a 12-year-old female patient, who experienced Multisystem inflammatory syndrome in children (MIS-C) 24 days after receiving the 2nd dose of mRNA-1273 vaccine. Her medical history included transit thyroiditis. According to the authors, she had fever > 3 days, mucocutaneous involvement, shock, cardiac involvement, coagulopathy, acute gastrointestinal symptoms, elevated markers of inflammation after vaccination with no other obvious microbial cause. Other manifestations were cytolytic hepatitis, hepato-splenomegaly and lymphopenia. The abnormal lab tests included CRP 150 mg/L. No history of SARS-CoV-2 infection was reported. SARS-CoV-2 test was negative. Considering > 3 days fever, additional clinical features, lab evidence of inflammation and measures of disease activity, the case is considered level 1 for MIS-C. based on the TTO of 24 days in the absence of covid 19 infection, it is considered possible for WHO causality. As the authors stated: “A causal association between COVID-19 mRNA vaccines and hyper-inflammatory syndrome could not be asserted. Indeed, despite extensive investigation for previous SARS-CoV-2 infection in all cases, pauci or asymptomatic SARS-CoV-2 infections are frequent in children, and may not have been documented. Furthermore, false negatives can be observed for anti-Nucleocapsid serology. Thus, we cannot exclude that some of the cases reported here could be related to undiagnosed SARS-CoV-2 infections.”	[redacted]

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	On an unknown date, Neutrophil count: 9,560 /mm3 9,560 /mm3. On an unknown date, Platelet count: 2,20,000/mm3 2,20,000/mm3. On an unknown date, SARS-CoV-2 antibody test: negative (Negative) Anti-N: negative. On an unknown date, SARS-CoV-2 test: negative (Negative) Negative. On an unknown date, White blood cell count: 10,400 /mm3 10,400 /mm3. For mRNA-1273 (Spikevax) (Unknown), the reporter considered MULTISYSTEM INFLAMMATORY SYNDROME IN CHILDREN (Multisystem inflammatory syndrome in children) to be related. Concomitant medication was not reported. PICU transfer was reported as no. Delay from first vaccine injection to SARS-CoV-2 antibody testing was 50 days. The impressive number of suspected adverse drug reaction reports (>80,000 between January 2021 and January 2022 in [redacted] suggest that underreporting may have been very rare, especially for serious adverse drug reactions. Company Comment: This literature non-study case concerns a 12-year-old female patient, with medical history of thyroiditis, overweight, who experienced the unexpected serious medically significant AESI Multisystem inflammatory syndrome in children that occurred 24 days (48 days from first injection) after receiving the 2nd dose of mRNA-1273 vaccine. Patient had fever > 3 days, mucocutaneous involvement, shock, cardiac involvement, coagulopathy, acute gastrointestinal symptoms, elevated markers of inflammation, and no other obvious microbial cause. Other manifestations reported were cytolytic hepatitis, hepato-splenomegaly and lymphopenia. The following lab tests were performed: CRP 150 mg/L, hemoglobin 11.8 g/dl, leucocytes 10400 / mm3, neutrophils 9560 / mm3, lymphocytes 580 / mm3, platelets 220000 / mm3, and LVEF 50%. Patient has no past history of SARS-CoV-2 infection. SARS-CoV-2 test was negative. SARS-CoV-2 antibody Anti-Spike reported positive and Anti-N				

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	negative. Patient did not require intensive care nor hemodynamic support. Patient was started on intravenous immunoglobulins plus steroids therapy with favorable outcome and was discharged fully recovered after 5 days of hospitalization. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Event's seriousness assessed based on medical judgement. This case was linked to [redacted] (E2B Linked Report).				

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
[redacted]	This literature-non-study case was reported in a literature article and describes the occurrence of MULTISYSTEM INFLAMMATORY SYNDROME IN CHILDREN (Multisystem inflammatory syndrome in children) in a 13-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. LITERATURE REFERENCE: Ouldali N, Bagheri H, Salvo F, Antona D, Pariente A, Belot A, et al. Hyper inflammatory syndrome following COVID-19 mRNA vaccine in children: A national post-authorization pharmacovigilance study. Lancet Public Health. 2022;00 No Medical History information was reported. On an unknown date, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On an unknown date, received first dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. On an unknown date, the patient experienced MULTISYSTEM INFLAMMATORY SYNDROME IN CHILDREN (Multisystem inflammatory syndrome in children) (seriousness criteria hospitalization and medically significant). The patient was hospitalized for 5 days due to MULTISYSTEM INFLAMMATORY SYNDROME IN CHILDREN. At the time of the report, MULTISYSTEM INFLAMMATORY SYNDROME IN CHILDREN (Multisystem inflammatory syndrome in children) had resolved. Related DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, C-reactive protein: 109 mg/l CRP was 109 mg/L. On an unknown date, Eosinophil count: 320 mm3 Eosinophils was 320 mm3. On an unknown date, Haemoglobin: 13.4 g/dl Hemoglobin was 13.4 g/dL. On an unknown date, Lymphocyte count: 510 mm3 Lymphocytes was 510 mm3. On an unknown date, Neutrophil count: 6730 mm3 Neutrophils was 6730 mm3. On an unknown date, Platelet count: 192000 mm3	level 3a	possible	This literature non-study case concerns a 13-year-old male patient who experienced Multisystem inflammatory syndrome in children (MIS-C) 1 day after receiving the 2nd dose of mRNA-1273 vaccine. No medical history was reported. The patient presented with fever > 3 days, mucocutaneous involvement, coagulopathy, acute gastrointestinal symptoms, neurological involvement and elevated markers of inflammation following vaccination with no other obvious microbial cause. Other manifestations were cytolytic hepatitis, lymphopenia, poly-arthralgia, and myalgia. The abnormal lab tests included CRP 109 mg/L. SARS-CoV-2 test was negative. In consideration of > 3 days fever, additional clinical features, lab evidence of inflammation but with no information on measures of disease activity, the case is considered level 3a for MIS-C. based on the TTO of 1 day in the absence of covid 19 infection, it is considered possible for WHO causality. As the authors stated: "A causal association between COVID-19 mRNA vaccines and hyper-inflammatory syndrome could not be asserted. Indeed, despite extensive investigation for previous SARS-CoV-2 infection in all cases, pauci or asymptomatic SARS-CoV-2 infections are frequent in children, and may not have been documented. Furthermore, false negatives can be observed for anti-Nucleocapsid serology. Thus, we cannot exclude that some of the cases reported here could be related to undiagnosed SARS-CoV-2 infections."	[redacted]

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	Platelets was 192000 mm3. On an unknown date, SARS-CoV-2 antibody test: negative (Negative) Negative. On an unknown date, SARS-CoV-2 test: negative (Negative) Nasopharyngeal SARS-CoV-2 PCR was negative. On an unknown date, White blood cell count: 8000 mm3 Leucocytes was 8 000 mm3. For mRNA-1273 (Spikevax) (Unknown), the reporter considered MULTISYSTEM INFLAMMATORY SYNDROME IN CHILDREN (Multisystem inflammatory syndrome in children) to be related. No concomitant product reported. Patient reported specific therapy as steroids. Patient had no past history of SARS-CoV-2 infection. It was reported that patient did not required PICU transfer Hemodynamic support.Patient was not overweight and also did not have any comorbidity condition. Cytolytic hepatitis, lymphopenia, myalgia and arthralgia all were manifestation reported. Symptoms onset date was reported as Oct-2021. Delay from COVID-19 mRNA last injection to symptoms onset was 1 days from first injection. Details of MIS-C WHO criteria were Fever > 3 days, Mucocutaneous involvement, Coagulopathy, Acute gastrointestinal symptoms, Elevated markers of inflammation, No other obvious microbial cause. Delay from first vaccine injection to SARS-CoV-2 antibody testing was of 24 days. Company Comment: This literature non-study case concerns a 13-year-old male patient, with no reported medical history, who experienced the unexpected serious medically significant AESI Multisystem inflammatory syndrome in children that occurred 1 day (21 days from first injection) after receiving the 2nd dose of mRNA-1273 vaccine. Patient				

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	presented with fever > 3 days, mucocutaneous involvement, coagulopathy, acute gastrointestinal symptoms, elevated markers of inflammation. No other obvious microbial cause. Other manifestations were cytolytic hepatitis, lymphopenia, poly-arthralgia neurological involvement, and myalgia. The following lab tests were performed: CRP 109mg/L, hemoglobin 13.4g/dl, leucocytes 8000/ mm3, neutrophils 6730/ mm3, lymphocytes 510 mm3, eosinophils 320/ mm3, and platelets 192000/ mm3. SARS-CoV-2 test was negative. SARS-CoV-2 antibody (Anti-N) negative. Patient did not require intensive care nor hemodynamic support. Patient was started on steroids therapy with favorable outcome and was discharged fully recovered after 5 days of hospitalization. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. This case was linked to [redacted] (E2B Linked Report).				

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
[redacted]	This regulatory authority case was reported by a physician and describes the occurrence of SEPTIC SHOCK (Septic shock//Fever//Nausea//Vomiting//Cough//Respiratory insufficiency), PYREXIA (Septic shock//Fever//Nausea//Vomiting//Cough//Respiratory insufficiency), NAUSEA (Septic shock//Fever//Nausea//Vomiting//Cough//Respiratory insufficiency), VOMITING (Septic shock//Fever//Nausea//Vomiting//Cough//Respiratory insufficiency), COUGH (Septic shock//Fever//Nausea//Vomiting//Cough//Respiratory insufficiency) and RESPIRATORY FAILURE (Septic shock//Fever//Nausea//Vomiting//Cough//Respiratory insufficiency) in an 18-year-old male patient who received mRNA-1273 (COVID 19 Vaccine Moderna) for COVID-19 prophylaxis. Concomitant products included ACETAMINOPHEN, ACETYLSALICYLIC ACID, OLANZAPINE and RISPERIDONE for an unknown indication. On an unknown date, the patient received dose of mRNA-1273 (COVID 19 Vaccine Moderna) (unknown route) 1 dosage form. On an unknown date, the patient experienced SEPTIC SHOCK (Septic shock//Fever//Nausea//Vomiting//Cough//Respiratory insufficiency) (seriousness criterion medically significant), PYREXIA (Septic shock//Fever//Nausea//Vomiting//Cough//Respiratory insufficiency) (seriousness criterion medically significant), NAUSEA (Septic shock//Fever//Nausea//Vomiting//Cough//Respiratory insufficiency) (seriousness criterion medically significant), VOMITING (Septic shock//Fever//Nausea//Vomiting//Cough//Respiratory insufficiency) (seriousness criterion medically significant), COUGH (Septic shock//Fever//Nausea//Vomiting//Cough//Respiratory insufficiency) (seriousness criterion medically significant) and RESPIRATORY FAILURE (Septic shock//Fever//Nausea//Vomiting//Cough//Respiratory insufficiency) (seriousness criterion medically significant). At the time of the report, SEPTIC SHOCK (Septic shock//Fever//Nausea//Vomiting//Cough//Respiratory	level 3b	possible	This regulatory authority case reported by a physician concerned an 18-year-old male who experienced septic shock, pyrexia, nausea, vomiting, cough, and respiratory failure on an unknown date after he received mRNA-1273 vaccine on an unknown date. No medical history was provided. Co meds included acetaminophen, acetylsalicylic acid, olanzapine, and risperidone. No treatment medications were reported. The case is considered level 3b for MIS-C, as the case is medically confirmed, the patient had fever of unknown period, and clinical presentations showed GI and circulation involvement, but no Laboratory evidence of inflammation and measures of disease activity are available. The respiratory failure could be the outcome of shock. However, the WHO is considered unassessable due to lack of sufficient information, including TTO for events.	[redacted]

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	insufficiency), PYREXIA (Septic shock//Fever//Nausea//Vomiting//Cough//Respiratory insufficiency), NAUSEA (Septic shock//Fever//Nausea//Vomiting//Cough//Respiratory insufficiency), VOMITING (Septic shock//Fever//Nausea//Vomiting//Cough//Respiratory insufficiency), COUGH (Septic shock//Fever//Nausea//Vomiting//Cough//Respiratory insufficiency) and RESPIRATORY FAILURE (Septic shock//Fever//Nausea//Vomiting//Cough//Respiratory insufficiency) had not resolved. 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. No treatment medications were reported. Company comment: This regulatory authority case concerns an 18-year-old male patient with no reported medical history, who experienced the unexpected serious (medically significant) events of Septic shock, Pyrexia, Nausea, Vomiting, Cough, and Respiratory failure which occurred unknown days after administration of an unspecified dose of mRNA-1273 vaccine. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Events' seriousness assessed as per Regulatory Authority's report.				

Appendix 11.19g Multisystem Inflammatory Syndrome (MIS): Summary Information for all MIS-C/A related cases for the reporting period: Case Listings

Case ID	Country	Report Type	PT	Event Seriousness	ALL PTs	Patient Age (Years)	Patient Gender	Event Outcome	Medical History	Concomitant Medications	Dose #	TTO All Doses	Primary Cause of Death	WW Identifier
		Regulatory Authority	Haemophagocytic lymphohistiocytosis	Serious	Haemophagocytic lymphohistiocytosis	66.00	Male	Recovering/Resolving	Hairy cell leukaemia(H); Autoimmune haemolytic anaemia(C)		Unknown			
		Regulatory Authority	Multiple organ dysfunction syndrome	Serious	Multiple organ dysfunction syndrome, Septic shock	59.00	Male	Unknown	Hypertension(C); Aortic aneurysm repair		Dose 1	0		
		Spontaneous	Multisystem inflammatory syndrome	Serious	Multisystem inflammatory syndrome	74.00	Male	Unknown			Dose 2	0		
		Literature-Non-Study	Multisystem inflammatory syndrome	Serious	Multisystem inflammatory syndrome	33.00	Female	Recovering/Resolving	Tobacco user(C)		Unknown			
	TAIWAN, PROVINCE OF CHINA	Regulatory Authority	Haemophagocytic lymphohistiocytosis	Serious	Haemophagocytic lymphohistiocytosis, Stevens-Johnson syndrome, Toxic epidermal necrolysis	77.00	Female	Fatal	Mouth ulceration(H); Perineal ulceration(H)		Dose 2	11	Hemophagocytosis syndrome	
		Spontaneous	Multiple organ dysfunction syndrome	Serious	Abdominal discomfort, Coma, Communication disorder, Dysuria, Face oedema, Gait disturbance, Multiple organ dysfunction syndrome, Myelosuppression, Nephritis, Renal failure, Sepsis, Thrombocytopenia	64.00	Female	Unknown	Dialysis; Haemodialysis		Dose 3	8		
		Literature-Non-Study	Multisystem inflammatory syndrome in adults	Serious	Cerebellar stroke, Chest pain, Dyspnoea, Embolic stroke, Hypersensitivity, Intensive care mnt acquired weakness, Multisystem inflammatory syndrome in adults, Muscle necrosis, Oedema peripheral, Peripheral artery occlusion, Polyneuropathy Respiratory failure, Vasoplegia syndrome	21.00	Female	Recovered/Resolved with Sequelae	COVID-19(H)		Unknown			
	GERMANY	Regulatory Authority	Multiple organ dysfunction syndrome	Serious	Coagulopathy, COVID-19, Hepatic failure, Multiple organ dysfunction syndrome, Shock haemorrhagic, Thrombocytopenia	69.00	Female	Fatal	COVID-19(C); VAXZEVRIA; COMIRNATY		Unknown		Multiorgan failure	
	SINGAPORE	Literature-Non-Study	Multiple organ dysfunction syndrome	Serious	Cardiac arrest, Multiple organ dysfunction syndrome, Sepsis	33.00	Male	Fatal			Unknown		Consistent with multi organ failure following cardiac arrest	
		Regulatory Authority	Septic shock	Serious	Septic shock, Vaccination site pain	77.00	Female	Unknown	Hypertension(C); Hypercholesterolaemia(H); Obesity(H); Spinal osteoarthritis(C); CLARITHROMYCIN(H); VAXZEVRIA	LORAZEPAM; FUROSEMIDA LAM; DAFLONEX XL; CYAMEMAZINE; FLUOXETINA GI; STUGERON; INDERAL; LEVODOPA	Dose 3	2		
		Regulatory Authority	Systemic inflammatory response syndrome	Non Serious	Chest pain, Dyspnoea, Pyrexia, Systemic inflammatory response syndrome, Thrombocytopenia	42.00	Female	Recovered/Resolved			Dose 1	2		
		Regulatory Authority	Systemic inflammatory response syndrome	Serious	Balance disorder, Body temperature increased, Confusional state, Lethargy, Sepsis, Systemic inflammatory response syndrome		Female	Recovering/Resolving	Bipolar disorder(C); Sjogren's syndrome(C); Hypothyroidism(C)		Dose 3	1		
		Regulatory Authority	Cytokine storm	Serious	Cytokine storm, Hypotension, Renal failure, Respiratory failure, Shock, Thrombocytopenia	83.00	Male	Recovering/Resolving			Dose 3	2		
		Regulatory Authority	Multiple organ dysfunction syndrome	Serious	Hyperthermia, Multiple organ dysfunction syndrome, Status epilepticus	35.00	Female	Not Recovered/Not Resolved	Cognitive disorder(H); Optic neuritis(H); Generalised tonic-clonic seizure(H); Status epilepticus(H); Multiple sclerosis(H); Humerus fracture(H); Vitamin B complex deficiency(H)	COMIRNATY	Unknown			
		Regulatory Authority	Systemic inflammatory response syndrome	Serious	Diarrhoea, Dyspnoea, Pneumonia, Systemic inflammatory response syndrome	57.00	Male	Recovered/Resolved			Unknown			
		Regulatory Authority	Multiple organ dysfunction syndrome	Serious	Cardiac failure, Cyanosis, Dyspnoea, Multiple organ dysfunction syndrome, Necrosis, Peripheral embolism, Pulmonary embolism, Respiratory failure, Sepsis, Superficial vein thrombosis	59.00	Male	Recovering/Resolving	Ischaemic stroke(H); Tobacco user(C); Depression(H); Paraesthesia(H); Craniocerebral injury(H); Atrial septal defect(H); Metabolic syndrome(C); ZOLOFT(H); [redacted]H); TORVAST(H); SPIKEVAX	CARDIOASPIRINE	Unknown			
		Literature-Non-Study	Septic shock	Serious	Acute respiratory distress syndrome, Encephalopathy, Pneumonia aspiration, Respiratory failure, Septic shock	67.00	Female	Unknown	Rheumatoid arthritis(C); Sjogren's syndrome(C); Chronic obstructive pulmonary disease(C); COVID-19(H)		Unknown			
		Regulatory Authority	Vaccine associated enhanced respiratory disease	Serious	Dyspnoea, Rash morbilliform, Skin reaction, Vaccine associated enhanced respiratory disease	49.00	Female	Recovered/Resolved	Asthma(H)	[redacted]	Unknown			
	ITALY	Regulatory Authority	Septic shock	Serious	Acute kidney injury, Aphasia, Bladder sphincter atony, Cerebrovascular accident, Coma, Pneumonia, Respiratory failure, Septic shock	87.00	Male	Fatal	Chronic obstructive pulmonary disease(C); Hypertension(C); Cognitive disorder(H); Chronic kidney disease(C); COMIRNATY; COMIRNATY	NORVASC; KANRENOL; TRITTICO; QUETIAPINE; FOSTER [PIROXICAM]	Unknown		Shock septic	
	[redacted]	Regulatory Authority	Multiple organ dysfunction syndrome	Serious	Acute kidney injury, Multiple organ dysfunction syndrome, Myocardial ischaemia, Oliguria, Pyrexia, Septic shock	73.00	Female	Recovering/Resolving	Obesity(H); Cholecystectomy; COVID-19(H); Ex-tobacco user(H); Dyslipidaemia(H); Hypertension(C); COMIRNATY		Unknown			
	CYPRUS	Spontaneous	Septic shock	Serious	Contusion, Cyanosis, Erythema, Headache, Nausea, Oedema peripheral, Pain, Pain in extremity, Peripheral swelling, Roseola, Septic shock, Thrombosis	33.00	Female	Unknown	Hypercoagulation(C); Pyrexia(H)		Dose 1	34	Thrombosis/thrombosis in her abdominal/pelvic area, in her stomach and intestine	
	[redacted]	Regulatory Authority	Septic shock	Serious	Catarrh, COVID-19, Deafness, Dizziness, Headache, Pyrexia, Septic shock, Status epilepticus, Vaccination failure	59.00	Female	Recovered/Resolved	Hydrocephalus(H); Ventriculo-peritoneal shunt; Epilepsy(C)	COMIRNATY	Unknown			
	JAPAN	Spontaneous	Multiple organ dysfunction syndrome	Serious	Altered state of consciousness, Cerebral infarction, Heat illness, Movement disorder, Multiple organ dysfunction syndrome, Shock	76.00	Male	Fatal	COMIRNATY; COMIRNATY; Diabetes mellitus(C); Atrial fibrillation(C)		Unknown		Multiple cerebral infarction	
	ITALY	Regulatory Authority	Septic shock	Serious	Anuria, Multiple organ dysfunction syndrome, Septic shock	74.00	Male	Fatal	Respiratory failure(H); Amnestic disorder(H); Ex-tobacco user(H); Diabetic retinopathy(C); Sepsis(H); Diaphragmatic hernia(H); Peripheral arterial occlusive disease(H); Aortic valve replacement(H); Lactic acidosis(H); Hypertensive heart disease(H); Anaemia(H); Insulin-requiring type 2 diabetes mellitus(C); Hypertension(C); Hyperuricaemia(H); Atrial fibrillation(C); Hepatic steatosis(H); Acute pulmonary oedema(H); Cerebral infarction(H); Femur fracture(H); COMIRNATY; COMIRNATY	TOUJEO; TORVAST; CARDIOASPIRIN; LANOXIN; ELIQUIS; LASIX P; SERTRALINE; KANRENOL; SEQUACOR; LANSOX; NOVORAPID	Unknown		Shock septic	
	[redacted]	Regulatory Authority	Septic shock	Serious	Aortic thrombosis, Microembolism, Septic shock	71.00	Male	Recovered/Resolved	Bowen's disease(H); Benign prostatic hyperplasia(H); Nasal polyps(H); Obstructive airways disorder(H); Bronchitis(H); Blindness traumatic(H); Hypertension(H); Hiatus hernia(H); Gout(H); Gilbert's syndrome(H)		Dose 2	79		

Case ID	Country	Report Type	PT	Event Seriousness	ALL PTs	Patient Age (Years)	Patient Gender	Event Outcome	Medical History	Concomitant Medications	Dose #	TTO All Doses	Primary Cause of Death	WW Identifier
[redacted]	[redacted]	Literature-Non-Study	Multiple organ dysfunction syndrome	Serious	Cerebral haemorrhage, Circulatory collapse, Hepatic function abnormal, Multiple organ dysfunction syndrome, Pancytopenia, Pneumonia, Pyrexia, Renal impairment, Septic shock, Urinary tract infection	79.00	Female	Unknown	Cerebral haemorrhage(H); Subdural haemorrhage(H)		Unknown		Cerebral haemorrhage	[redacted]
	GERMANY	Regulatory Authority	Multiple organ dysfunction syndrome	Serious	Meningitis, Multiple organ dysfunction syndrome	69.00	Male	Fatal	COVID-19 VACCINE ASTRAZENECA; COMIRNATY		Dose 3	0	Multiple organ failure	
	[redacted]	Literature-Non-Study	Multisystem inflammatory syndrome in adults	Serious	Multisystem inflammatory syndrome in adults	73.00	Male	Unknown	Diabetes mellitus(C); Atrial fibrillation(C); Hypertension(C); Hyperlipidaemia(C)		Unknown			
		Spontaneous	Multiple organ dysfunction syndrome	Serious	Circulatory collapse, Coagulopathy, Dehydration, Fall, Hepatic function abnormal, Hypoglycaemia, Intestinal ischaemia, Metabolic acidosis, Multiple organ dysfunction syndrome, Muscle spasms, Pain, Renal impairment, Shock, Thrombosis	62.00	Male	Unknown	COMIRNATY; COMIRNATY		Dose 3	3		
		Regulatory Authority	Multisystem inflammatory syndrome in adults	Serious	Multisystem inflammatory syndrome in adults, Myositis	51.00	Male	Recovering/Resolving			Dose 3	2		
		Regulatory Authority	Haemophagocytic lymphohistiocytosis	Serious	Acute hepatic failure, Autoinflammatory disease, Haemophagocytic lymphohistiocytosis		Male	Unknown			Dose 2	0		
		Regulatory Authority	Septic shock	Serious	Cholecystitis acute, Septic shock	88.00	Male	Unknown			Unknown			
		Literature-Non-Study	Haemophagocytic lymphohistiocytosis	Serious	Haemophagocytic lymphohistiocytosis, Inappropriate schedule of product administration, Systemic lupus erythematosus	41.00	Female	Recovered/Resolved	Systemic lupus erythematosus(C); Erythema(C); PREDNISOLONE(H)	HYDROXYCHLOROQUINE ACTAVIS	Dose 1	17		
		Literature-Non-Study	Multiple organ dysfunction syndrome	Serious	Cardiogenic shock, Malaise, Multiple organ dysfunction syndrome, Myocarditis	47.00	Female	Recovered/Resolved	Lung assist device therapy; Intra-aortic balloon placement; Rehabilitation therapy; Temporary mechanical circulatory support; Postmenopause(C)		Unknown			
		Regulatory Authority	Vaccine associated enhanced respiratory disease	Non Serious	Vaccine associated enhanced respiratory disease	68.00	Female	Recovering/Resolving	Chronic respiratory failure(C); Asthma(C); Hypersensitivity		Unknown			
		Regulatory Authority	Systemic inflammatory response syndrome	Serious	Chest pain, Injection site erythema, Lymphadenopathy, Systemic inflammatory response syndrome	29.00	Female	Recovered/Resolved with Sequelae	COVID-19(H)	ENANTYUM	Dose 1	15		
		Literature-Non-Study	Multiple organ dysfunction syndrome	Serious	Capillary leak syndrome, Condition aggravated, Hypovolaemic shock, Multiple organ dysfunction syndrome	37.00	Female	Unknown	Monoclonal gammopathy(C); Capillary leak syndrome(C)	IMMUNOGLOBULIN I.V	Unknown			
		Spontaneous	Multisystem inflammatory syndrome	Serious	Multisystem inflammatory syndrome	30.00	Unknown	Unknown			Unknown			
		Literature-Non-Study	Multisystem inflammatory syndrome in adults	Serious	Atrial fibrillation, COVID-19, Multisystem inflammatory syndrome in adults	63.00	Female	Recovering/Resolving	Hypertension(C); Type 2 diabetes mellitus(C); End stage renal disease(C); Dialysis; Cardiac failure(C); Cerebrovascular accident(C); Coronary artery bypass; Percutaneous coronary intervention		Unknown			
		Regulatory Authority	Septic shock	Serious	Bacteraemia, Liver abscess, Sepsis, Septic shock	65.00	Male	Recovering/Resolving			Dose 1	10		
	UNITED STATES	Literature-Non-Study	Septic shock	Serious	Aplastic anaemia, Cardiac arrest, Clostridium difficile infection, Enterococcal infection, Febrile neutropenia, Pneumonia, Septic shock	60.00	Male	Fatal	Alcohol use(H); Nasal cavity packing; Clostridial infection(C)		Unknown		Cardiac arrest	
		Regulatory Authority	Multisystem inflammatory syndrome	Serious	Atrial fibrillation, Multisystem inflammatory syndrome, Type 1 diabetes mellitus	77.00	Female	Unknown			Dose 1	4		
		Regulatory Authority	Cytokine storm	Serious	Cytokine storm, Pyrexia	74.00	Male	Recovering/Resolving	Lung neoplasm malignant(C); Hypertension(C)		Dose 1	18		
		Regulatory Authority	Multisystem inflammatory syndrome	Non Serious	Insomnia, Multisystem inflammatory syndrome, Muscle contractions involuntary	62.00	Male	Not Recovered/Not Resolved			Unknown			
		Spontaneous	Septic shock	Serious	Arthralgia, Disseminated intravascular coagulation, Joint abscess, Psoas abscess, Septic shock, Stsphylococcal sepsis	57.00	Female	Unknown	Arthralgia(C); Comirnaty; Comirnaty; Dental caries(C); Deafness(H); Hypertension(H); Tazopipe(H); Cefazolin sodium(H)		Unknown			
		Regulatory Authority	Systemic inflammatory response syndrome	Serious	Arrhythmia, Fatigue, Hypertension, Systemic inflammatory response syndrome	61.00	Male	Not Recovered/Not Resolved	COVID-19 VACCINE JANSSEN		Unknown			
	SWEDEN	Regulatory Authority	Multiple organ dysfunction syndrome	Serious	Cardiac arrest, COVID-19 immunisation, Decreased appetite, Fatigue, General physical health deterioration, Malnutrition, Mobility decreased, Multiple organ dysfunction syndrome, Personality change	94.00	Female	Fatal	Upper limb fracture(H); Drug hypersensitivity; Colon cancer(H); Angina pectoris(C); Diarrhoea(H)		Unknown		Unspecified nutritional deficiency	
	[redacted]	Regulatory Authority	Systemic inflammatory response syndrome	Serious	Dyspnoea, Pericarditis, Pleural effusion, Systemic inflammatory response syndrome	57.00	Male	Recovering/Resolving		COVID-19 VACCINE JANSSEN	Dose 2	96		
	JAPAN	Spontaneous	Multiple organ dysfunction syndrome	Serious	Altered state of consciousness, Depressed level of consciousness, Hypotension, Multiple organ dysfunction syndrome, Pyrexia, Rhabdomyolysis, Seizure, Sepsis, Status epilepticus	63.00	Male	Fatal	Epilepsy(C); Head injury(H)	ALEVIATIN MINO; LAMICTAL	Unknown		Convulsion	
	[redacted]	Literature-Non-Study	Multisystem inflammatory syndrome	Serious	Multisystem inflammatory syndrome	52.00	Female	Unknown			Unknown			
		Regulatory Authority	Hypotensive crisis	Serious	Hypotension, Hypotensive crisis, Palpitations, Tachycardia	64.00	Male	Recovered/Resolved with Sequelae	Hypertension(C); Arrhythmia(C)		Dose 2	20		
		Literature-Non-Study	Multisystem inflammatory syndrome in children	Serious	Multisystem inflammatory syndrome in children	12.00	Female	Recovered/Resolved	Thyroiditis(C)		Unknown			
		Literature-Non-Study	Multisystem inflammatory syndrome in children	Serious	Multisystem inflammatory syndrome in children	13.00	Male	Recovered/Resolved			Unknown			
	GERMANY	Regulatory Authority	Autoinflammatory disease	Serious	Autoantibody positive, Autoimmune disorder, Autoinflammatory disease, Chills, Chronic fatigue syndrome, Dizziness, Fatigue, Feeling hot, Headache, Influenza, Myalgia, Paraesthesia, Post vaccination syndrome, Postural orthostatic tachycardia syndrome	30.00	Female	Not Recovered/Not Resolved	Migraine(C)		Dose 1	15		
	JAPAN	Spontaneous	Multiple organ dysfunction syndrome	Serious	Bacterial infection, Multiple organ dysfunction syndrome, Pneumonia, Pulmonary alveolar haemorrhage, Respiratory failure, Vasculitis	84.00	Female	Fatal	Back pain(C); Hypertension(C); Dementia(C); COMIRNATY; COMIRNATY		Unknown		Diffuse alveolar hemorrhage	
	SPAIN	Regulatory Authority	Vaccine associated enhanced respiratory disease	Serious	Atrial fibrillation, COVID-19 pneumonia, Pneumothorax, Vaccination failure, Vaccine associated enhanced respiratory disease	64.00	Male	Fatal	Peripheral venous disease(H); Mixed anxiety and depressive disorder(H)		Dose 2	227	COVID-19 pneumonia (10084380)	
	[redacted]	Regulatory Authority	Vaccine associated enhanced respirstory disease	Serious	Cerebral venous sinus thrombosis, Vaccination failure, Vaccine associated enhanced respiratory disease	47.00	Female	Recovering/Resolving	COVID-19(H); Microalbuminuria(H); Brucellosis(H); Sacroiliitis(H); Hypothyroidism(H); ENALAPRIL(H)		Dose 2	222		
		Literature-Non-Study	Multisystem inflammatory syndrome	Serious	Multisystem inflammatory syndrome		Male	Recovered/Resolved			Unknown			

Case ID	Country	Report Type	PT	Event Seriousness	ALL PTs	Patient Age (Years)	Patient Gender	Event Outcome	Medical History	Concomitant Medications	Dose #	TTO All Doses	Primary Cause of Death	WW Identifier
[redacted]	[redacted]	Literature-Non-Study	Multisystem inflammatory syndrome	Serious	Multisystem inflammatory syndrome		Male	Recovered/Resolved			Unknown			[redacted]
	[redacted]	Literature-Non-Study	Multisystem inflammatory syndrome	Serious	Multisystem inflammatory syndrome		Female	Recovered/Resolved			Unknown			
	JAPAN	Literature-Non-Study	Multisystem inflammatory syndrome	Serious	Multisystem inflammatory syndrome		Female	Recovered/Resolved			Unknown			
	JAPAN	Spontaneous	Multiple organ dysfunction syndrome	Serious	Cerebral infarction, Diarrhoea, Herpes virus infection, Lung abscess, Multiple organ dysfunction syndrome, Pneumonia, Pyrexia, Respiratory failure	40.00	Male	Fatal			Unknown		Pneumonia	
	[redacted]	Regulatory Authority	Septic shock	Serious	Cough, Nausea, Pyrexia, Respiratory failure, Septic shock, Vomiting	18.00	Male	Not Recovered/Not Resolved		ACETAMINOPHEN; ACETYLSALICYLIC ACID; OLANZAPINE; RISPERIDONE	Unknown			

Appendix 11.19h Multisystem Inflammatory Syndrome (MIS): Summary Information for all MIS-C/A related cases for the reporting period: Narratives

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
[redacted]	This case was received via European Medicines Agency (Reference number: [redacted] on 05-Jan-2022 and was forwarded to Moderna on 05-Jan-2022. This regulatory authority case was reported by a physician and describes the occurrence of HAEMOPHAGOCYTIC LYMPHOHISTIOCYTOSIS (Reactive hemophagocytic syndrome) in a 66-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The patient's past medical history included Hairy cell leukaemia. Concurrent medical conditions included Anaemia haemolytic autoimmune. In November 2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. In December 2021, the patient experienced HAEMOPHAGOCYTIC LYMPHOHISTIOCYTOSIS (Reactive hemophagocytic syndrome) (seriousness criteria hospitalization and medically significant). At the time of the report, HAEMOPHAGOCYTIC LYMPHOHISTIOCYTOSIS (Reactive hemophagocytic syndrome) was resolving. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No relevant concomitant medications were reported. No treatment information was provided.	level 5	Unlikely	This regulatory authority case concerned 66-year-old male patient with a history of hairy cell leukemia and concurrent condition of anaemia haemolytic autoimmune and without co meds reported, who experienced haemophagocytic lymphohistiocytosis reported by a physician. The event occurrence about 1 month after receiving Spikevax for COVID-19 vaccination. No additional information is provided. The case is considered level 4 for MIC-C/A, and unlikely for WHO causality assessment, and more likely explained by the pateitn's medical history. Of note, there is a case report for Hemophagocytic Lymphohistiocytosis Triggered by Disseminated Tuberculosis and Hairy Cell Leukaemia after SARS-CoV2 Infection. Moreover, a case also reports an association between hemophagocytic lymphohistiocytosis, mixed connective tissue disease, and autoimmune hemolytic anemia.This cases is classified as level 5 given the differential diagnosis of HLH. Hyperinflammatory states as HLH has a similar disease presentation to that observed in MIS-C/A.. This case is considered unlikely. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5515764/ file:///C:/Users[redacted]/Downloads/applsci-12-00564.pdf	[redacted]
[redacted]	This regulatory authority case was reported by a pharmacist and describes the occurrence of SEPTIC SHOCK (Septic shock) and MULTIPLE ORGAN DYSFUNCTION SYNDROME (multiorgan failure) in a 59-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine (mRNA-1273 Vaccine)) (batch no. 3004668) for an unknown indication. The patient's past medical history included Aortic aneurysm repair (Previous AAA repair). Concurrent medical conditions included Hypertension.	level 4	unassessable	This case reported by a pharmacist concerned a 59 years old male with a history of aortic aneurysm repair and concurrent hypertension and no co meds reported, who experienced septic shock and multiple organ dysfunction syndrome (multiorgan failure) one day after receiving the first dose of mrna-1273 vaccine. No additional information is provided for a medical assessment. Of note, multiple organ dysfunction syndrome is different from the MIS, and may be the outcome of the septic shock. Due to insufficient information, the case is considered level 4 for MIC-C/A, and unassessable for	[redacted]

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	On 17-Jul-2021 at 8:57 AM, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine (mRNA-1273 Vaccine)) (Intramuscular) 1 dosage form. On 18-Jul-2021, the patient experienced SEPTIC SHOCK (Septic shock) (seriousness criteria hospitalization and life threatening) and MULTIPLE ORGAN DYSFUNCTION SYNDROME (multiorgan failure) (seriousness criteria hospitalization and life threatening). At the time of the report, SEPTIC SHOCK (Septic shock) and MULTIPLE ORGAN DYSFUNCTION SYNDROME (multiorgan failure) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine (mRNA-1273 Vaccine)) (Intramuscular) was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine (mRNA-1273 Vaccine)) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medications were reported. No treatment information was reported. This is a regulatory authority case concerning a 59-year-old, male patient with past medical history of Aortic aneurysm repair and Concurrent medical conditions of Hypertension, who experienced the unexpected serious events of septic shock and multiorgan failure. The events occurred approximately 1 day after the first dose of mRNA-1273 COVID 19 Vaccine. The rechallenge was not applicable, as the event happened after the first dose. The events outcome was unknown. The past medical history of Aortic aneurysm repair and Concurrent medical conditions of Hypertension remains a confounder. The benefit-risk relationship of mRNA-1273 COVID 19 Vaccine, is not affected by this report.			WHO causality assessment.	
[redacted]	This spontaneous case was reported by a consumer and describes the occurrence of MULTISYSTEM INFLAMMATORY SYNDROME (Multi-system inflammatory syndrome) in a 74-year-old male patient who	level 4	conditional	This consumer reported case concerns a 74-year-old male patient with no medical history or co meds reported, who experienced multisystem inflammatory syndrome, the same day after the second dose of mRNA-1273, with a	[redacted]

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	received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 011A21A and 032L20A) for COVID-19 vaccination. No Medical History information was reported. On 22-Jan-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 27-Feb-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 27-Feb-2021, the patient experienced MULTISYSTEM INFLAMMATORY SYNDROME (Multi-system inflammatory syndrome) (seriousness criterion medically significant). The patient was treated with PREDNISONE for Adverse event, at an unspecified dose and frequency. At the time of the report, MULTISYSTEM INFLAMMATORY SYNDROME (Multi-system inflammatory syndrome) outcome was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Prednisone which he had on and off for 6 months. Concomitant medication were not reported. The patient did not experience any symptoms with the first dose of the vaccine. Within hours after the second dose he had swelling in the injection site on the left arm. The patient's swelling increased to the size of a golf ball, hard ball, and then soft ball. This swelling then spread down entire left arm and by the end of second day his hand was swollen. The patient could not recognize his own knuckles, and could not grasp a cup. The swollen areas were also very hot, but not red. This then went across his shoulders into his right arm , wrist, and hand. The patient watch was next to impossible to put on. By the 3rd day he was swollen from his neck to the bottom of his feet. The patient was hunched over, and could not move, and could not straighten up. The patient also had lower back pain, and it was extremely			presentation of swelling in the injection site on the left arm and spreading down entire left arm, hand, neck and to the bottom of his feet in 2 days after the vaccination. His doctor diagnosed him with multi-system inflammatory syndrome. He was treated with prednisone on and off for 6 months with an unknown outcome. No additional information is provided. The swelling in the case seemed to start from the injection site and spread to other parts of the body. However, no involvement in other systems other than cutaneious skin was reported. No information is provided on fever, lab evidence of inflammation, disease activity measures either. The case is considered level 4 for MIC. Although the case may clinically present a systemic allergic reaction based on the same day event TTO, more information is needed for an appropriate assessment. It is considered conditional for the WHO categories.	

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	difficult to walk. The patient then went to his doctor on 4-5 days after who stated he was "part of the 1 percent," and diagnosed him with Multi-system inflammatory syndrome, explaining the second shot was attacked by the first shot. Company comment: This case concerns a 74-year-old, male patient with no medical history reported, who experienced the unexpected event of multisystem inflammatory syndrome. The event occurred on the same day after the second dose of mRNA-1273. As reported, within hours after the second dose patient had swelling in the injection site on the left arm. The patient's swelling increased to the size of a golf ball, hard ball, and then soft ball. This swelling then spread down entire left arm and by the end of second day his hand was swollen. By the 3rd day patient was swollen from his neck to the bottom of his feet and went to his doctor 4-5 days after vaccination, who diagnosed him with Multi-system inflammatory syndrome. The benefit-risk relationship of mRNA-1273 is not affected by this report.				
[redacted]	This literature-non-study case was reported in a literature article and describes the occurrence of MULTISYSTEM INFLAMMATORY SYNDROME (MIS) in a 33-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. LITERATURE REFERENCE: Boira I, Torba A, Castello C, Esteban V, Vanes S, Chiner E. Pleuropericardial effusion and systemic inflammatory syndrome secondary to the administration of the mRNA-1273 vaccine for SARS-coV-2. Arch Bronconeumol. 2022 Concurrent medical conditions included Smoker (5 packages per year.). On an unknown date, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On an unknown date, the patient experienced MULTISYSTEM INFLAMMATORY SYNDROME (MIS) (seriousness criteria hospitalization and medically significant). The patient was treated with AZITHROMYCIN for Adverse event, at a dose of 500	level 4	conditional	This is a literature case concerning a 33-year-old female patient with no relevant medical history who experienced multisystem inflammatory syndrome, 5 days after she received the second dose of the mRNA-1273 vaccine. The patient reported moderate effort dyspnea, febricula, and arthralgias, without cough or any other symptoms. Bilateral pleural and pericardial effusion were identified by imaging tests, which was thought compatible with clinical picture of multisystem inflammatory syndrome. She was treated with azithromycin and methylprednisolone with favorable clinical and radiological progression. The Reporter assessed the event as related to the suspect product. SARS-CoV-2 test was negative. On an unknown date, her C-reactive protein was high, 4.03 mg/dl. No additional information is provided, such as the fever duration, clinical features of mucocutaneous, GI, neurologic system or shock/hypotension, and measures of disease activity. Her increased CRP could also be related to other etiologies including infections, eg, pulmonary and pericardiac infections which led to dyspnea. The case is considered level 4 for MIS. The case seemed to have a five-day vaccine/event TTO, but the patient did receive treatment before improvement. The case is considered conditional	[redacted]

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	milligram once a day; AZITHROMYCIN for Adverse event, at a dose of 500 milligram once a day; METHYLPREDNISOLONE for Adverse event, at a dose of 40 milligram twice a day and PREDNISONE for Adverse event, at a dose of 30 milligram on a tapering dose. At the time of the report, MULTISYSTEM INFLAMMATORY SYNDROME (MIS) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Antinuclear antibody: normal (normal) 23 days after discharge normal antinuclear antibody. On an unknown date, Aspiration pleural cavity: abnormal (abnormal) exudate (proteins 4.25 g/dL and LDH 191 U/L) with predominance of polymorphonuclear cells (73.2%), normal ADA (6.7 U/L), cholesterol of 75 mg/dL, CEA <1.7 ng/mL, and negative antinuclear antibodies. Cytology was negative for malignancy, culture showed no microorganisms, and Zhiel-Neelsen and culture using Lówenstein-Jensen media were negative.. On an unknown date, Auscultation: normal (normal) Heart auscultation was normal and abnormal (abnormal) Pulmonary auscultation showed decreased vesicular murmur in the lower third of both hemithorax, with decreased vocal vibration transmission, dullness to percussion, and semiology of pleural effusion.. On an unknown date, Blood lactate dehydrogenase: 257 u/l (normal) 257 U/L. On an unknown date, Blood pressure measurement: 101/70 mmhg (normal) 101/70 mmHg. On an unknown date, C-reactive protein: 4.03 mg/dl 4.03 mg/dL. On an unknown date, Carcinoembryonic antigen: less than ng/ml (normal) Less than ng/mL. On an unknown date, Chest X-ray: abnormal (abnormal) A chest x-ray performed in the emergency room showed blunting of the costophrenic angles compatible with bilateral pleural effusion.. On an unknown date, Computerised tomogram: abnormal (abnormal) A computed tomography angiography (CTA) of the chest performed to rule out pulmonary thromboembolism confirmed moderate bilateral pleural			for WHO causality.	

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	effusion with posterior basal and middle lobe atelectasis. and decrease in pleural and pericardial effusion. The thoracic control CT performed after 15 days showed a marked decrease in pleural and pericardial effusion.. On an unknown date, Echocardiogram: abnormal (abnormal) Echocardiography showed mild pericardial effusion with no compromise of cavity filling.. On an unknown date, Fibrin D dimer: 2656 ng/ml (High) 2656 ng/mL. On an unknown date, Full blood count: inconclusive (Inconclusive) 10.1x109/leukocytes with 5.9% eosinophils (600 eosinophils), haemoglobin of 14.2 g/dL. On an unknown date, Heart rate: 74 bpm (normal) 74 bpm. On an unknown date, Oxygen saturation: 98% (normal) 98%. On an unknown date, Physical examination: normal (normal) A good general condition, normocolored, normohydrated, and eupneic at rest. No upraclavicular adenopathy or acropaquia.. On an unknown date, Protein total: 6.69 g/dl (normal) 6.69 g/dL. On an unknown date, Respiratory rate: 12 vents/m (normal) 12 vents/m. On an unknown date, SARS-CoV-2 antibody test: positive (Positive) SARS-CoV-2 serology was positive for IGG.. On an unknown date, SARS-CoV-2 test: negative (Negative) Negative antigen and polymerase chain reaction (PCR) to COVID-19.. On an unknown date, Ultrasound abdomen: normal (normal) normal. For mRNA-1273 (Spikevax) (Unknown), the reporter considered MULTISYSTEM INFLAMMATORY SYNDROME (MIS) to be related. Patient visited the emergency room due to a sternal pain which had developed over 3 weeks that worsens with postural changes after administration of the second Moderna dose, 5 days prior to the onset of the clinical picture. She reported moderate effort dyspnea, febricula, and arthralgias, without cough or any other symptoms.				

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	Company comment: This is a literature case concerning a 33-year-old female patient with no relevant medical history who experienced serious unexpected event of Multisystem inflammatory syndrome. It was reported that the patient received the second dose of the mRNA-1273 vaccine 5 days prior to the onset of the clinical picture. The patient reported moderate effort dyspnea,febricula, and arthralgias, without cough or any other symptoms. It was also reported that the patient developed bilateral pleural and pericardial effusion excluding other causes, so the clinical picture was compatible with Multisystem inflammatory syndrome. Azithromycin 500 mg/24 h and methylprednisolone 40 mg/12h were administered for 6 days with favorable clinical and radiological progression, proceeding to discharge with prednisone 30 mg on a tapering dose and azithromycin 500/24 h for 4 additional days and outpatient clinic control. The Reporter assessed the event as related to the suspect product. The benefit-risk relationship of mRNA-1273 is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 25-Jan-2022: Follow up received by safety 26-Jan-2021 has Email with FTA received from SARA team and contains new information. Reporter information, Literature information, Relevant history, Lab data, product data and event data were updated.				
[redacted]	This regulatory authority case was reported by an other health care professional and describes the occurrence of STEVENS-JOHNSON SYNDROME (Stevens-Johnson syndrome (SJS)), TOXIC EPIDERMAL NECROLYSIS (Toxic epidermal necrolysis (TEN)) and HAEMOPHAGOCYTIC LYMPHOHISTIOCYTOSIS (Macrophage activating syndrome) in a 77-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The patient's past medical history included Oral ulceration (presented with EM like lesion with oral/perineal ulcers, diagnosed at Tungs' Taichung MetroHarbor Hospital) on 04-Oct-2021 and Perineal ulceration (presented with EM like lesion with oral/perineal ulcers, diagnosed at Tungs' Taichung MetroHarbor Hospital) on 04-Oct-2021.	level 5	Unlikely	This healthcare professional reported case concerns a 77-year-old female patient with no medical history reported, who experienced Stevens-Johnson syndrome, Toxic epidermal necrolysis, and Haemophagocytic lymphohistiocytosis, 12 days after the second dose of mRNA-1273 vaccine with a fatal outcome. It reported that patient presented with erythema multiforme like lesion with oral/perineal ulcers diagnosed at hospital. The cause of death was reported as hemophagocytic syndrome, acute cholecystitis, and suspected vaccine adverse reaction. No information about MIS is provided although some clinical signs and symptoms may overlap reported hemophagocytic lymphohistocytosis. In addition, SJS/TEN seemed to be diagnosed at a hospital. This case is classified as level 5 given the differential diagnosis of HLH. Hyperinflammatory states as HLH has	[redacted]

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	On 04-Jul-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 23-Sep-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 04-Oct-2021, the patient experienced STEVENS-JOHNSON SYNDROME (Stevens-Johnson syndrome (SJS)) (seriousness criteria death and hospitalization prolonged), TOXIC EPIDERMAL NECROLYSIS (Toxic epidermal necrolysis (TEN)) (seriousness criteria death and hospitalization prolonged) and HAEMOPHAGOCYTIC LYMPHOHISTIOCYTOSIS (Macrophage activating syndrome) (seriousness criteria death and hospitalization). The patient died on 05-Dec-2021. The reported cause of death was hemophagocytosis syndrome, Acute cholecystitis and suspected vaccine adverse reactions. It is unknown if an autopsy was performed. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Concomitant medication of the patient was not reported. No treatment information was provided by the reporter. It was reported that on January 7, 2022, Wuqi Health Center assisted in handling the application for relief for harm from of vaccination and an application was made to close the case. Company Comment: This is a RA case concerning a 77-year-old female patient, with no medical history reported, who experienced the unexpected events of Stevens-Johnson syndrome (AESI), Toxic epidermal necrolysis (AESI), and Haemophagocytic lymphohistiocytosis. The patient completed primary vaccination for COVID-19 with mRNA-1273 vaccine, with an interval between doses of 81 days (Inappropriate schedule of vaccine administered). The events occurred 12 days after the second dose of mRNA-1273 vaccine, and had a fatal outcome, with death occurring 13 days after second dose of mRNA-1273			a similar disease presentation to that observed in MIS-C/A.. This case is considered unlikely.	

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	vaccine. It is unknown if an autopsy was performed. Cause of death was reported as hemophagocytic syndrome, acute cholecystitis, and suspected vaccine adverse reaction. The benefit-risk relationship of mRNA-1273 is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 25-Apr-2022: Follow up document received, contains no new information (NNI).				
[redacted]	This spontaneous case was reported by a consumer and describes the occurrence of SEPSIS (Sepsis/lungs are undergoing sepsis), COMA (coma), THROMBOCYTOPENIA (Platelet count decreased), MYELOSUPPRESSION (poor hematopoiesis), MULTIPLE ORGAN DYSFUNCTION SYNDROME (multiple organ failures (liver, lung, kidney, heart).), RENAL FAILURE (Renal Failure/ kidney damage), NEPHRITIS (Acute nephritis), FACE OEDEMA (Face edema/the patient's face was severely swollen), GAIT DISTURBANCE (Walking difficulty/unable to walk well), DYSURIA (Urination is difficult) and COMMUNICATION DISORDER (unable to communicate) in a 64-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Renal dialysis (there was no improvement) on 12-Jan-2022 and Hemodialysis (due to the poor hematopoiesis) on 12-Jan-2022. On 04-Jan-2022, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 07-Jan-2022, the patient experienced ABDOMINAL DISCOMFORT (Abdominal discomfort). On 11-Jan-2022, the patient experienced FACE OEDEMA (Face edema/the patient's face was severely swollen) (seriousness criterion hospitalization prolonged), GAIT DISTURBANCE (Walking difficulty/unable to walk well) (seriousness criterion hospitalization prolonged) and COMMUNICATION DISORDER (unable to	level 5	unlikely	This case concerns a 64-year-old female patient with a history of renal dialysis and hemodialysis, who experienced sepsis, coma, thrombocytopenia, myelosuppression, renal failure, acute nephritis along with other clinical presentations. She experienced abdominal discomfort 3 days after her 3rd dose of vaccine, then face edema, gait disturbance, communication disorder 4 days later; another day later, she suffered sepsis, coma, thrombocytopenia, myelosuppression renal failure, nephritis, dysuria and multiple organ dysfunction syndrome. Covid-19 test was negative. C-reactive protein was high, and platelet count was decreased. The case provided insufficient information for the MIS and medical review. However, with her medical history and reported events which may be presentation and outcomes of her underlying conditions, eg, renal failure led to sepsis to multiple organ dysfunction syndrome, it is considered level 5 for MIS, and unlikely for WHO causality assessment due to the alternative etiology.	[redacted]

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	communicate) (seriousness criterion hospitalization prolonged). On 12-Jan-2022, the patient experienced SEPSIS (Sepsis/lungs are undergoing sepsis) (seriousness criteria hospitalization prolonged and medically significant), COMA (coma) (seriousness criteria hospitalization prolonged and medically significant), THROMBOCYTOPENIA (Platelet count decreased) (seriousness criteria hospitalization prolonged and medically significant), MYELOSUPPRESSION (poor hematopoiesis) (seriousness criteria hospitalization prolonged and medically significant), MULTIPLE ORGAN DYSFUNCTION SYNDROME (multiple organ failures (liver, lung, kidney, heart).) (seriousness criteria hospitalization prolonged and medically significant), RENAL FAILURE (Renal Failure/ kidney damage) (seriousness criteria hospitalization prolonged and medically significant), NEPHRITIS (Acute nephritis) (seriousness criteria hospitalization prolonged and medically significant) and DYSURIA (Urination is difficult) (seriousness criterion hospitalization prolonged). The patient was hospitalized on 12-Jan-2022 due to COMA, COMMUNICATION DISORDER, DYSURIA, FACE OEDEMA, GAIT DISTURBANCE, MULTIPLE ORGAN DYSFUNCTION SYNDROME, MYELOSUPPRESSION, NEPHRITIS, RENAL FAILURE, SEPSIS and THROMBOCYTOPENIA. At the time of the report, SEPSIS (Sepsis/lungs are undergoing sepsis), COMA (coma), THROMBOCYTOPENIA (Platelet count decreased) and NEPHRITIS (Acute nephritis) had not resolved and MYELOSUPPRESSION (poor hematopoiesis), MULTIPLE ORGAN DYSFUNCTION SYNDROME (multiple organ failures (liver, lung, kidney, heart).), RENAL FAILURE (Renal Failure/ kidney damage), FACE OEDEMA (Face edema/the patient's face was severely swollen), GAIT DISTURBANCE (Walking difficulty/unable to walk well), DYSURIA (Urination is difficult), COMMUNICATION DISORDER (unable to communicate) and ABDOMINAL DISCOMFORT (Abdominal discomfort) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 11-Jan-2022, SARS-CoV-2 test: negative (Negative) the result came out negative at around 10 PM.				

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	On 12-Jan-2022, C-reactive protein: high (High) Inflammatory level was too high, levels did not decrease. On 12-Jan-2022, Platelet count: decreased (Low) Decreased. Until 10-Jan-2022, the patients condition was not bad enough to communicate. But on 11-Jan-2022, the patient unable to communicated. On same day, patient rushed to the emergency room, but could not be admitted to the hospital until having the COVID-19 test. About 6 AM on 12-Jan-2022, the patient went to the emergency room again. Subsequently, patient performed several examinations and was hospitalized in the ICU(intensive care unit). At the time of reporting, the patient was still admitted to the ICU. The family had reported the event as an adverse reaction to the corona vaccine to the public health center, and were told that an epidemiological investigation will be carried out. The lungs were undergoing sepsis, but not being treated. The doctor of the nephrology department said that this was acute nephritis, and there was no causal relationship with the corona vaccine. The doctor did not mention any damage to organs other than the kidney. The patient experienced abdominal discomfort, so she took digestive medicine during the weekend. Concomitant product use was not provided by reporter. Company comment: This case concerns a 64-year-old, female patient with no relevant medical history, who experienced the unexpected serious events of Sepsis, Coma, Thrombocytopenia, Myelosupression, Renal Failure, Acute Nephritis, Face Edema, Gait Disturbance, Dysuria, Communication Disorder, and Multiorgan Dysfunction Syndrome; and unexpected non-serious event of Abdominal Discomfort. On the 4th day after the administration of the				

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	booster dose of mRNA-1273 (Moderna covid-19 vaccine), the patient experienced abdominal discomfort. 8 days post vaccination with the booster dose of mRNA-1273, the patient's face became severely swollen, unable to communicate, and unable to walk well. The patient was in the hospital, Covid-19 test was performed, which came out negative. It was reported that 9 days post vaccination with the booster dose of mRNA-1273, patient experienced se				
[redacted]	This literature-non-study case was reported in a literature article and describes the occurrence of MULTISYSTEM INFLAMMATORY SYNDROME IN ADULTS (Multisystem inflammatory syndrome), OEDEMA PERIPHERAL (Leg edema), CHEST PAIN (Chest pain), DYSPNOEA (Dyspnea), HYPERSENSITIVITY (Allergic reaction), VASOPLEGIA SYNDROME (vasoplegia), RESPIRATORY FAILURE (hypoxic respiratory failure), PERIPHERAL ARTERY OCCLUSION (right common femoral artery occlusion), CEREBELLAR STROKE (cerebellar stroke), INTENSIVE CARE UNIT ACQUIRED WEAKNESS (critical illness polyneuropathy), MUSCLE NECROSIS (Muscle necrosis), EMBOLIC STROKE (Cardioembolic stroke) and POLYNEUROPATHY (Bilateral Polyneuropathy) in a 21-year-old female patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for COVID-19 vaccination. LITERATURE REFERENCE: Lieu A, Mah J, Church D. A case of multisystem inflammatory syndrome in adults following natural infection and subsequent immunization. Int J Infect Dis. 2022;116:34-7 The patient's past medical history included SARS-CoV-2 infection (previously received positive test results, 6 weeks before this acute illness. Patient was asymptomatic at the time of testing. Notably, 27 days after the patient tested positive, received the first dose of the messenger RNA (mRNA) vaccine (Moderna) without immediate adverse reactions.) on 30-Apr-2021. On an unknown date, the patient received first dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 02-Nov-2021, the patient	Level 2b	Unlikely	This case concerns a 21-year-old female patient with medical history of SARS-CoV-2 infection 27 days before her 1st dose of Spikevax who experienced edema peripheral, chest pain, dyspnea, hypersensitivity, vasoplegia syndrome, respiratory failure, peripheral artery occlusion, intensive care unit acquired weakness, and multisystem inflammatory syndrome and cerebellar stroke, approximately in 10 days after receiving the first dose of mRNA-1273 Vaccine. The patient started headache, nausea, vomiting, diarrhea, followed by rash and fever. Her symptoms were later associated with progressive shortness of breath and chest pain, leading to her ED presentation. Patient received fluid resuscitation, broad-spectrum antibiotics, and was admitted to the ICU to initiate inotropes. The patient was started on intravenous glucocorticoids, intravenous immunoglobulins, and aspirin. Cardiogenic shock ensued over the next 48 hours, and the patient required intubation because of hypoxic respiratory failure. The patient had a precipitous decline in cardiac function, as documented on serial TTEs. Anakinra was initiated for the cytokine storm and MIS-A. The patient had persistent hypoxic failure and vasoplegia, which required venous-arterial extracorporeal membrane oxygenation (VA-ECMO). Her clinical status improved. It was reported that the outcome of the events was resolving. Relevant exams and tests included SARS-CoV-2 test positive by a PCR 6 weeks before this acute illness, Body temperature 38.0	[redacted]

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	experienced MUSCLE NECROSIS (Muscle necrosis) (seriousness criterion medically significant), EMBOLIC STROKE (Cardioembolic stroke) (seriousness criterion medically significant) and POLYNEUROPATHY (Bilateral Polyneuropathy) (seriousness criterion medically significant). On an unknown date, after starting mRNA-1273 (Moderna CoviD-19 Vaccine), the patient experienced MULTISYSTEM INFLAMMATORY SYNDROME IN ADULTS (Multisystem inflammatory syndrome) (seriousness criteria hospitalization, medically significant and life threatening), OEDEMA PERIPHERAL (Leg edema) (seriousness criterion hospitalization), CHEST PAIN (Chest pain) (seriousness criterion hospitalization), DYSPNOEA (Dyspnea) (seriousness criterion hospitalization), HYPERSENSITIVITY (Allergic reaction) (seriousness criterion hospitalization), VASOPLEGIA SYNDROME (vasoplegia) (seriousness criteria hospitalization and medically significant), RESPIRATORY FAILURE (hypoxic respiratory failure) (seriousness criteria hospitalization and medically significant), PERIPHERAL ARTERY OCCLUSION (right common femoral artery occlusion) (seriousness criteria hospitalization and medically significant), CEREBELLAR STROKE (cerebellar stroke) (seriousness criteria hospitalization and medically significant) and INTENSIVE CARE UNIT ACQUIRED WEAKNESS (critical illness polyneuropathy) (seriousness criterion hospitalization). The patient was treated with ASPIRIN [ACETYLSALICYLIC ACID] for Adverse event, at an unspecified dose and frequency; ANAKINRA (intravenous) from 15-Jun-2021 to 28-Jun-2021 for Adverse event, at a dose of 100 milligram every twelve hours; IMMUNOGLOBULINS NOS (intravenous) on 14-Jun-2021 for Adverse event, at a dose of 2 gram per kilogram; METHYLPREDNISOLONE (intravenous) on 14-Jun-2021 for Adverse event, at a dose of 1 gram once a day and PREDNISONE for Adverse event, at an unspecified dose and frequency. At the time of the report, MULTISYSTEM INFLAMMATORY SYNDROME IN ADULTS (Multisystem inflammatory syndrome) had resolved with sequelae, OEDEMA PERIPHERAL (Leg edema), CHEST PAIN (Chest pain), DYSPNOEA (Dyspnea), HYPERSENSITIVITY (Allergic reaction), VASOPLEGIA SYNDROME (vasoplegia), RESPIRATORY FAILURE (hypoxic respiratory failure),			degree, Blood pressure measurement 80/50 mm hg, left ventricular ejection function decreased, CRP, ALT, CK, troponin, NT-proBNP and ferritin increased. The case presented fever, clinical features, lab evidence of inflammation and measures of disease activity for MIS-A. however, due to insufficient information on the duration of fever, it is considered level 2b for MIS. The recent history of COVID-19 infection is an important risk factor that provides a more plausible explanation for the occurrence of the reported event of MIS-A. According to the WHO causality assessment this report is considered unlikely and more likely explained by MIS-A due to COVID-19.	

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	PERIPHERAL ARTERY OCCLUSION (right common femoral artery occlusion), CEREBELLAR STROKE (cerebellar stroke) and INTENSIVE CARE UNIT ACQUIRED WEAKNESS (critical illness polyneuropathy) was resolving and MUSCLE NECROSIS (Muscle necrosis), EMBOLIC STROKE (Cardioembolic stroke) and POLYNEUROPATHY (Bilateral Polyneuropathy) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 01-May-2021, SARS-CoV-2 test: positive (Positive) Positive. On 14-Jun-2021, Alanine aminotransferase: 74 u/l (High) On Day 0 ALT was 74 (U/L) Normal range less than 39 U/L. On 14-Jun-2021, Blood albumin (30-45): 29 g/l (normal) 29 g/L. On 14-Jun-2021, Blood creatinine (40-100): 89 µmol/l (normal) On Day 0 her Creatinine was 89 (µmol/L). On 14-Jun-2021, Blood fibrinogen (1.6-4.1): 7.3 g/l (normal) 7.3 g/L. On 14-Jun-2021, Brain natriuretic peptide: 1641 ng/l (High) 1641 Normal range less than 300 ng/L. On 14-Jun-2021, C-reactive protein (0.0-8.0): 315.0 mg/l (High) On Day 0 her C-reactive protein was 315.0 (mg/L). On 14-Jun-2021, Chest X-ray: normal (normal) Lungs are clear, heart size is normal. On 14-Jun-2021, Electrocardiogram: abnormal (abnormal) Sinus tachycardia, QTc 435ms otherwise normal. On 14-Jun-2021, Fibrin D dimer: 2.09 mg/l (High) 2.09 mg/L normal range less than or equal to 0.50 mg/L FEU. On 14-Jun-2021, Lymphocyte count (0.5-3.3): 0.8 10^9/l (Low) On Day 0 her Lymphocytes was 0.8 (10^9/L). On 14-Jun-2021, Neutrophil count (2-9): 15.7 10^9/l On Day 0 her Neutrophils-15.7 (10^9/L). On 14-Jun-2021, Platelet count (150-400): 186 10^9/l (normal) On Day 0 her Platelet count was 186 (10^9/L). On 14-Jun-2021, Prothrombin time (0.9-1.1): 1.6 (High) 1.6 INR. On 14-Jun-2021, Serology test: positive (Positive) IgG serological test for antibodies directed toward the SARS-CoV-2 nucleocapsid protein was positive..				

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	On 14-Jun-2021, Serum ferritin (20-300): 668 ug/l (High) On Day 0 her Ferritin was 668 (ug/L). On 14-Jun-2021, Troponin (0-13): 808 ng/l (High) On Day 0, Troponin was 808 (ng/L). On 14-Jun-2021, White blood cell count (4-11): 17.7 10⁹/l (High) On Day 0, Leucocytes was 17.7 (10⁹/L). On 15-Jun-2021, Alanine aminotransferase: 51 u/l (High) On Day 1 her ALT 51 (U/L) Normal range less than 39 U/L. On 15-Jun-2021, Blood creatinine (40-100): 73 µmol/l (normal) On Day 1 her Creatinine was 73 (µmol/L). On 15-Jun-2021, Blood lactate dehydrogenase (100-235): 317 u/l (High) 317 U/L. On 15-Jun-2021, C-reactive protein (0.0-8.0): 292.5 mg/l (High) On Day 1 her C-reactive protein was 292.5 (mg/L). On 15-Jun-2021, Echocardiogram: abnormal (abnormal) LV EF 30-35%, R Vsignificantly imapired, severe TR, small percaridal effusion. On 15-Jun-2021, Lymphocyte count (0.5-3.3): 0.2 10⁹/l (Low) Day 1 her Lymphocytes was 0.2 (10⁹/L). On 15-Jun-2021, Neutrophil count (2-9): 19.2 10⁹/l On Day 1 her Neutrophils - 19.2 (10⁹/L). On 15-Jun-2021, Platelet count (150-400): 202 10⁹/l (normal) On Day 0 her Platelet count was 202 (10⁹/L). On 15-Jun-2021, Prothrombin time (0.9-1.1): 1.5 (High) 1.5 INR. On 15-Jun-2021, Troponin (0-13): 1306 ng/l (High) On Day 1, Troponin was 1306 (ng/L). On 15-Jun-2021, White blood cell count (4-11): 21.2 10⁹/l (High) On Day 1, Leucocytes was 21.2 (10⁹/L). On 16-Jun-2021, Activated partial thromboplastin time (28-38): 91.6 seconds (High) 91.6 seconds. On 16-Jun-2021, Alanine aminotransferase: 102 u/l (High) On Day 2 her ALT was 102 (U/L) Normal range less than 39 U/L. On 16-Jun-2021, Blood creatinine (40-100): 75 µmol/l (normal) On Day 2 her Creatinine was 75 (µmol/L). On 16-Jun-2021, Blood fibrinogen (1.6-4.1): 5.1 g/l (normal) 5.1 g/L. On 16-Jun-2021, Brain natriuretic peptide: 27699 ng/l (High) 27699 ng/L Normal range less than 300 ng/L. On 16-Jun-2021, C-reactive protein (0.0-8.0): 281.1 mg/l (High) On Day 2 her C-reactive protein was 281.1 (mg/L).				

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	On 16-Jun-2021, Chest X-ray: abnormal (abnormal) Findings consistent with congestive heart failure. On 16-Jun-2021, Lymphocyte count (0.5-3.3): 0.3 10^9/l (Low) On Day 2 her Lymphocytes was 0.3 (10^9/L). On 16-Jun-2021, Neutrophil count (2-9): 15.5 10^9/l On Day 2 her Neutrophils-15.5 (10^9/L). On 16-Jun-2021, Platelet count (150-400): 251 10^9/l (normal) Day 2 Platelet count 251 (10^9/L). On 16-Jun-2021, Prothrombin time (0.9-1.1): 1.4 (High) 1.4 INR. On 16-Jun-2021, Serum ferritin (20-300): 1342 ug/l (High) On Day 2, Ferritin was 1342 (ug/L). On 16-Jun-2021, Troponin (0-13): 689 ng/l (High) On Day 2, Troponi				
[redacted]	This case was received via European Medicines Agency (Reference number: [redacted], on 01-Feb-2022 and was forwarded to Moderna on 01-Feb-2022. This regulatory authority case was reported by a physician and describes the occurrence of SHOCK HAEMORRHAGIC (Hemorrhagic shock), COAGULOPATHY (Clotting disorder), MULTIPLE ORGAN DYSFUNCTION SYNDROME (Multiple organ failure), HEPATIC FAILURE (Hepatic failure), COVID-19 (SARS-CoV-2 infection) and THROMBOCYTOPENIA (Thrombopenia) in a 69-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 000105A) for COVID-19 vaccination. Previously administered products included for COVID-19 vaccination: Vaxzevria COVID-19 Vaccine (ChAdOx1-S [recombinant])COVID-19 Vaccine AstraZeneca suspension for injectionCOVID-19 Vaccine AstraZeneca on 10-May-2021 and Comirnaty BNT162b2 on 02-Aug-2021. Past adverse reactions to the above products included No adverse event with Comirnaty BNT162b2 and Vaxzevria COVID-19 Vaccine (ChAdOx1-S [recombinant])COVID-19 Vaccine AstraZeneca suspension for injectionCOVID-19 Vaccine AstraZeneca. Concurrent medical conditions included SARS-CoV-2 infection. On 07-Jan-2022, the patient received dose of mRNA-1273	level 5	unlikely	This case concerns a 69-year-old female patient with a history of Covid 19 infection, a previous vaccination with Vaxzevria recombinant COVID-19 Vaccine on 10-May-2021 and Comirnaty BNT162b2 on 02-Aug-2021 and no co meds reported, who experienced Shock Hemorrhagic, Coagulopathy, Multiple organ dysfunction syndrome, Hepatic failure and Thrombocytopenia, approximately 2 days after receiving a dose of mRNA-1273 Vaccine on 07-Jan-2022 and resulted in a fatal outcome. The reported cause of death was Multiorgan failure. An autopsy was not performed. No additional information is provided for an appropriate assessment. However, based on the limited information, it is likely that thrombocytopenia and coagulopathy led to hemorrhagic shock and multiple organ dysfunction, including liver failure. This case is considered level 5 according to the Brighton Collaboration case definition for MIS due to the alternative diagnosis reported of multiple organ dysfunction syndrome in the setting of coagulopathy and hemorrhagic shock. Although the events occurred within 2 days of receiving Spikevax, concurrent COVID-19 infection and past vaccinations with Vaxzevria and Comirnaty COVID-19 vaccines are significant confounders. The WHO causality assessment for this case is considered unlikely, as COVID-19 infection is a more plausible alternate etiology for these events.	[redacted]

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	(Spikevax) (unknown route) 1 dosage form. On 09-Jan-2022, the patient experienced SHOCK HAEMORRHAGIC (Hemorrhagic shock) (seriousness criteria death, hospitalization and life threatening), COAGULOPATHY (Clotting disorder) (seriousness criteria death, hospitalization and life threatening), MULTIPLE ORGAN DYSFUNCTION SYNDROME (Multiple organ failure) (seriousness criteria death, hospitalization and life threatening), HEPATIC FAILURE (Hepatic failure) (seriousness criteria death, hospitalization and life threatening) and THROMBOCYTOPENIA (Thrombopenia) (seriousness criteria death, hospitalization and life threatening). On an unknown date, the patient experienced COVID-19 (SARS-CoV-2 infection) (seriousness criteria death, hospitalization and life threatening). The patient died on 09-Jan-2022. The reported cause of death was Multiorgan failure. An autopsy was not performed. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. Concomitant medication was not provided. Treatment information was not provided. Company Comment: This case concerns a 69-year-old female patient, with relevant medical history of previous vaccination with Vaxzevria COVID-19 Vaccine and Comirnaty BNT162b2, who experienced the unexpected serious events of Shock Hemorrhagic, Coagulopathy, Multiple organ dysfunction syndrome, Hepatic failure and Thrombocytopenia. The events occurred approximately 2 days after receiving a dose of mRNA-1273 Vaccine and resulted in a fatal outcome. The unexpected serious AESI event of COVID-19 occurred on an unknown date. The reported cause of death was Multiorgan failure. An autopsy was not performed. The patient's medical history of previous vaccination with Vaxzevria COVID-19 Vaccine and Comirnaty BNT162b2, remain as confounders for the occurrence of the events. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report.				

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
[redacted]	This literature-non-study case was reported in a literature article and describes the occurrence of MULTIPLE ORGAN DYSFUNCTION SYNDROME (Consistent with multi organ failure following cardiac arrest), CARDIAC ARREST (cardiac arrest due to right ventricular dysplasia) and SEPSIS (sepsis) in a 33-year-old male patient who received mRNA-1273 (COVID 19 Vaccine Moderna) for COVID-19 vaccination. LITERATURE REFERENCE: Yeo A,Kuek B, Lau M, Tan SR, Chan S. Post COVID-19 vaccine deaths - Singapore's early experience. Forensic Sci Int. 2022;332:111199 No Medical History information was reported. In 2021, the patient received second dose of mRNA-1273 (COVID 19 Vaccine Moderna) (unknown route) 1 dosage form. In 2021, the patient experienced MULTIPLE ORGAN DYSFUNCTION SYNDROME (Consistent with multi organ failure following cardiac arrest) (seriousness criteria death, hospitalization and medically significant) and CARDIAC ARREST (cardiac arrest due to right ventricular dysplasia) (seriousness criteria death, hospitalization and medically significant). 2021, the patient experienced SEPSIS (sepsis) (seriousness criteria death, hospitalization and medically significant). The patient died in 2021. The reported cause of death was consistent with multi organ failure following cardiac arrest, cardiac arrest due to right ventricular dysplasia and Sepsis. An autopsy was performed. Related DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Blood immunoglobulin E: 243 iu/ml 243 IU/mL. On an unknown date, C-reactive protein: 155 mg/l 155 mg/L. On an unknown date, Tryptase: 10.3 ug/l 10.3 ug/l. For mRNA-1273 (COVID 19 Vaccine Moderna)	level 5	Unlikely	This is a literature case that concerns a 33-year-old male patient with no medical history and no co meds reported, who experienced cardiac arrest due to right ventricular dysplasia one day after receiving the second dose of Spikevax. Lab tests included C-reactive protein high 155 mg/l. The autopsy-determined cause of death was multi organ failure (multiple organ dysfunction syndrome) with evidence of sepsis following cardiac arrest due to right ventricular dysplasia. There was no evidence of eosinophilic infiltration, myocarditis, or thrombosis and no signs of anaphylaxis, such as facial (including periorbital, lips etc.) or airway edema, skin changes (e.g. rash, urticaria). This case is considered level 5 according to the Brighton Collaboration case definition for MIS because of the alternative diagnosis of multiple organ dysfunction syndrome following cardiac arrest. The WHO causality assessment for this case is considered unlikely, as right ventricular dysplasia is a more plausible alternate etiology for these events.	[redacted]

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	(Unknown), the reporter considered MULTIPLE ORGAN DYSFUNCTION SYNDROME (Consistent with multi organ failure following cardiac arrest), CARDIAC ARREST (cardiac arrest due to right ventricular dysplasia) and SEPSIS (sepsis) to be related. No concomitant medication were provided. No treatment information were reported. A total of 34 deaths that occurred within 72 h of the deceased receiving their COVID-19 vaccination and autopsies, histological sampling and ancillary investigations consisting of total tryptase level, Immunoglobulin E (IgE), and C-reactive Protein (CRP), were performed on 29 of these cases. This case is related to patient number 27 as per article. It was reported that the patient in this case sustained neurological or cardiovascular compromise requiring medical resuscitation within 72 h of receiving the vaccine and subsequently demised after a period of hospitalization. There was no sign of Anaphylaxis such as facial (including periorbital, lips etc.) or airway edema, skin changes (e.g. rash, urticaria). And also no sign of Histological Features including the presence of eosinophilic infiltration, the presence of myocarditis and/or thrombosis. Company comment: This is a literature case that concerns a 33-year-old male patient with no medical history, who experienced the unexpected serious events of Multiple Organ Dysfunction Syndrome, Cardiac Arrest, and Sepsis. The events were medically significant, led to the hospitalization, and eventual demise of the patient. The events occurred on an unknown interval after receiving the second dose of mRNA-1273 Vaccine. The patient died on an unknown date. The reported cause of death was consistent with multi organ failure following cardiac arrest, cardiac arrest due to right ventricular dysplasia and Sepsis. An autopsy was performed, but no results were provided. No clinical or treatment details were given. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report.				

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	This case was linked to [redacted] (Patient Link). Most recent FOLLOW-UP information incorporated above includes: On 03-Feb-2022: Follow up received by safety on 03-Feb-2022 has Email with FTA received from SARA team and contains significant information. Authors, lab data, Hospitalization details, events and autopsy were added.				
[redacted]	This case was initially received via European Medicines Agency (Reference number: [redacted] on 02-Feb-2022. The most recent information was received on 21-Mar-2022 and was forwarded to Moderna on 21-Mar-2022. This regulatory authority case was reported by a consumer and describes the occurrence of SEPTIC SHOCK (Septic shock (BP=66/22 mmHg + body temperature =38.1°C; oliguria hyperkalemia); AKI; Rhabdomyolysis) in a 77-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 017G21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Hypercholesteremia and Obesity. Previously administered products included for Product used for unknown indication: CLARITHROMYCIN; for COVID-19 immunization: VAXZEVRIA. Past adverse reactions to the above products included Headache with VAXZEVRIA; and Vomiting with CLARITHROMYCIN. Concurrent medical conditions included Arterial hypertension and Lumbar spine degeneration (laminectomy 3 years ago and L1/L2 hernia extraction 4 months ago). Concomitant products included LORAZEPAM, FUROSEMIDE (FUROSEMIDA LAM), DIOSMIN, HESPERIDIN (DAFLONEX XL), CYAMEMAZINE from an unknown date to 11-Dec-2021, FLUOXETINE HYDROCHLORIDE (FLUOXETINA GI), CINNARIZINE (STUGERON) from an unknown date to 11-Dec-2021, PROPRANOLOL HYDROCHLORIDE (INDERAL) and LEVODOPA for an unknown indication.	level 4	unassessable	This case concerns a 77-year-old female patient with no relevant medical history reported and use of concomitant medications for anti-seizure, anti-depression, anti-psychotic drug, cardiovascular including anti hypertension drug and multiple vitamins, who experienced septic shock, approximately 4 days after the third dose of mRNA-1273. Lab tests included body temperature 38,1 degree and blood pressure measurement 66/22 mm hg. SARS-CoV-2 test was negative. No additional information was provided. The case is considered level 4 for MIS due to lack of sufficient information. It is also considered unassessable because of limited information regarding the events. Of note, septic shock may be the source of fever and blood pressure low as the outcomes.	[redacted]

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	On 09-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (Intramuscular) .5 milliliter. On 09-Dec-2021, after starting mRNA-1273 (Spikevax), the patient experienced VACCINATION SITE PAIN (Pain at the administration site and in the shoulder on the same side of the body.). On 11-Dec-2021, the patient experienced SEPTIC SHOCK (Septic shock (BP=66/22 mmHg + body temperature =38.1°C; oliguria hyperkalemia); AKI; Rhabdomyolysis) (seriousness criteria hospitalization and life threatening). At the time of the report, SEPTIC SHOCK (Septic shock (BP=66/22 mmHg + body temperature =38.1°C; oliguria hyperkalemia); AKI; Rhabdomyolysis) outcome was unknown and VACCINATION SITE PAIN (Pain at the administration site and in the shoulder on the same side of the body.) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 10-Dec-2021, Blood creatinine: 0.9 0.9 mg/dL. On 10-Dec-2021, Blood urea: 44 44 mg/dL. On 10-Dec-2021, Fibrin D dimer: 2882 2882 ng/mL. On 10-Dec-2021, Lymphocyte count: 10.9 / 0.6% 10.9 / 0.6%. On 10-Dec-2021, Monocyte count: 3.8 / 0.2% 3.8 / 0.2%. On 10-Dec-2021, Neutrophil count: 84.6 / 4.4 84.6 / 4.4 %. On 10-Dec-2021, Platelet count: 216 x 109 216 x 109/L. On 11-Dec-2021, Blood potassium: 6.26 6.26 mmol/L. On 11-Dec-2021, Blood pressure measurement: 66/22 66/22 mmHg Iu international unit(s). On 11-Dec-2021, Body temperature: 38.1 38.1°C. On 11-Dec-2021, Computerised tomogram: significant perirectal fat densification TC-TAP with IV contrast which showed “significant perirectal fat densification throughout its length with some sheets of free fluid in the vicinity, with the rectal wall having a slight uptake thickening that in the context of via removal of fecalomas, assuming that there was a large distension of the rectum, it may be related to proctolite stercolaris, and there is currently no pneumoperitoneum. There is colitis and not only proctitis because the entire sigmoid colon, descending colon and part of the transverse colon also show a slight thickening of its				

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	wall in addition to abundant liquid content and some dispersed fecal content, without signs of parietal ischemia.. On 11-Dec-2021, SARS-CoV-2 test: positive (Positive) Positive. Concomitant medications included Sinemet ,Fluoxetine, Inderal SOS , Lasix, Daflon, Lorazepan 2.5 mg, cyamemazine, stugeron and Lisinopril. It was reported that no medication error occurred. Patient had a no clinical changes and Immediately after the vaccine patient had only complained of pain at the injection site and in the shoulder on the same side of the body. Patient consulted the privacy hospital and seek the doctor who did not know how to interpret the analyses at the time of the first admission to the health unit. Treatment medications were not reported. Company comment: This regulatory case concerns a 77-year-old, female patient with medical history of Arterial hypertension, Hypercholesterolemia and Obesity, who experienced the unexpected, serious (Life threatening and Hospitalization) event of Septic shock. The event occurred 2 days after administration of third dose of mRNA-1273. It was reported that the patient was previously administered with Vaxzevria, however no further details were specified regarding the first two doses. On the day of the event, blood pressure and blood potassium were measured, computerised tomogram with IV contrast was done which revealed no signs of pneumoperitoneum or ischemia. SARS-CoV-2 test was done which revealed a positive result. The patient's medical history of Arterial hypertension, Hypercholesterolemia and Obesity could be contributing factors to the event Septic shock. The benefit-risk relationship of mRNA-1273 is not affected by this report. Most recent FOLLOW-UP information incorporated above				

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	includes: On 21-Mar-2022: Follow up received included new event, other relevant history, concomitant medication and laboratory data was updated. On 21-Mar-2022: Translated received on 25-Mar-2022 included translated verbatim for relevant past drug and event, concomitant medication information and laboratory results was updated.				
[redacted]	This case was received via European Medicines Agency (Reference number: [redacted]on 03-Feb-2022 and was forwarded to Moderna on 03-Feb-2022. This regulatory authority case was reported by an other health care professional and describes the occurrence of SYSTEMIC INFLAMMATORY RESPONSE SYNDROME (Systemic inflammatory response syndrome), DYSPNOEA (Dyspnea), CHEST PAIN (Chest pain), PYREXIA (Fever) and THROMBOCYTOPENIA (Thrombopenia) in a 42-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. No Medical History information was reported. On 14-Dec-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 16-Dec-2021, the patient experienced SYSTEMIC INFLAMMATORY RESPONSE SYNDROME (Systemic inflammatory response syndrome), DYSPNOEA (Dyspnea), CHEST PAIN (Chest pain), PYREXIA (Fever) and THROMBOCYTOPENIA (Thrombopenia). At the time of the report, SYSTEMIC INFLAMMATORY RESPONSE SYNDROME (Systemic inflammatory response syndrome), DYSPNOEA (Dyspnea), CHEST PAIN (Chest pain), PYREXIA (Fever) and THROMBOCYTOPENIA (Thrombopenia) had resolved. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medication information was mentioned by reporter	level 4	unassessable	This case concerns a 42-years-old female patient with no clinical history, no co meds and no treatment reported, who experienced systemic inflammatory response syndrome, dyspnoea, chest pain, pyrexia and thrombocytopenia, approximately 2 days after 1st dose of mRNA-1273. No additional information was provided for the case on fever, clinical features, lab evidence of inflammation and measures of disease activity, although systemic inflammatory response syndrome was reported. It is considered level 4 for MIS due to lack of evidence. It is also considered unassessable for WHO categories because of insufficient information to evaluate a vaccine/event causal relation.	[redacted]

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	No treatment medication information was mentioned by reporter COMPANY COMMENT: This is a Regulatory case concerning 42-years-old female patient with no clinical history who experienced the expected events of SYSTEMIC INFLAMMATORY RESPONSE SYNDROME, DYSPNOEA, CHEST PAIN, PYREXIA and THROMBOCYTOPENIA (AESI) approximately 2 days after 1st dose of mRNA-1273. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Terms and onset dates were captured as provided				
[redacted]	This case was received via [redacted] (Reference number: [redacted] on 03-Feb-2022 and was forwarded to Moderna on 03-Feb-2022. This regulatory authority case was reported by a physician and describes the occurrence of LETHARGY (lethargic), SEPSIS (Sepsis), BALANCE DISORDER (unsteadiness), CONFUSIONAL STATE (confusion), BODY TEMPERATURE INCREASED (grade temperature) and SYSTEMIC INFLAMMATORY RESPONSE SYNDROME (Systemic inflammatory response syndrome) in a female patient of an unknown age who received mRNA-1273 (Moderna CoviD-19 Vaccine) for an unknown indication. Concurrent medical conditions included Bipolar affective disorder, Sjogren's syndrome and Hypothyroidism. On 05-Dec-2021, the patient received third dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 06-Dec-2021, the patient experienced SYSTEMIC INFLAMMATORY RESPONSE SYNDROME (Systemic inflammatory response syndrome) (seriousness criteria hospitalization, disability and life threatening). On an unknown date, the patient experienced LETHARGY (lethargic) (seriousness criteria hospitalization, disability and life threatening), SEPSIS (Sepsis) (seriousness criteria hospitalization, disability and life threatening), BALANCE DISORDER (unsteadiness) (seriousness criteria hospitalization, disability and life threatening), CONFUSIONAL STATE (confusion)	level 4	unassessable	This case concerns a female patient of unknown age with concurrent conditions of Bipolar affective disorder, Sjogren's syndrome and Hypothyroidism, who experienced systemic inflammatory response syndrome and Lethargy, Sepsis, Balance disorder, Confusional state and Body temperature increased, 1 day after the third dose of mRNA- 1273 vaccine. Based on the report, she started having a high-grade temperature, felt unwell with unsteadiness, confusion and generally weak. She was admitted to the ITU for high flow nasal oxygen and CPAP. Initially treated as sepsis of unknown source but no source of infection identified. Her symptoms are improving now as well as inflammatory markers but still feels weak, lethargic and exhausted. It was reported she had positive ANA, RO and LA antibody consistent with her underlying autoimmune Sjogren's syndrome. Her Covid 19 test was negative. No co meds and no treatment info were provided. furthermore, the report did not provide additional details for an appropriate evaluation on MIS. Of note, her preexisting autoimmune condition may be a confounding risk for the event development. The case is considered level 4 for MIS, and unassessable for WHO categories because of insufficient information supplied. Also, the clinical presentation of fever, felt unwell with unsteadiness, confusion and general weakness may all be the results of the sepsis with an unknown origin.	[redacted]

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	(seriousness criteria hospitalization, disability and life threatening) and BODY TEMPERATURE INCREASED (grade temperature) (seriousness criteria hospitalization, disability and life threatening). At the time of the report, LETHARGY (lethargic), SEPSIS (Sepsis), BALANCE DISORDER (unsteadiness), CONFUSIONAL STATE (confusion), BODY TEMPERATURE INCREASED (grade temperature) and SYSTEMIC INFLAMMATORY RESPONSE SYNDROME (Systemic inflammatory response syndrome) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, SARS-CoV-2 test: negative (Negative) No - Negative COVID-19 test. The action taken with mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown) was unknown. For mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Relevant concomitant medications were not provided. Treatment information was not provided. Patient has not tested positive for COVID-19 since having the vaccineShe was investigated with lumper puncture, CT thorax , abdomen and pelvis , transoesophageal echo and CT PET scan which showed uptake at the pericardium but no evidence of malignancy or vasculitis . She was strongly ANA positive with positive RO and LA antibody on the background of known Sjogren's syndrome. Company Comment: This regulatory authority case concerns a female patient (age not specified) with Concurrent medical conditions of Bipolar affective disorder, Sjogren's syndrome and Hypothyroidism, who experienced the unexpected serious AESI event of Systemic inflammatory response syndrome and unexpected serious events of Lethargy, Sepsis, Balance disorder, Confusional state and Body temperature increased. The event Systemic inflammatory response syndrome occurred 1 day after and				

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	the events Lethargy, Sepsis, Balance disorder, Confusional state and Body temperature increased occurred on an unknown day after the third dose of mRNA- 1273 vaccine. Patient started having high grade temperature, felt unwell with unsteadiness, confusion and generally weak. She was admitted to the ITU for high flow nasal oxygen and CPAP. Initially treated as sepsis of unknown source but no source of infection identified. Her symptoms are improving now as well as inflammatory markers but still feels weak, lethargic and exhausted. Patients Concurrent medical conditions of Bipolar affective disorder, Sjogren's syndrome and Hypothyroidism remains as a confounder. 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 hospitalization, disability and life threatening.				
[redacted]	This regulatory authority case was reported by an other health care professional and describes the occurrence of THROMBOCYTOPENIA (Thrombocytopenia), CYTOKINE STORM (Cytokine storm, hypotension and shock, respiratory failure, renal failure), HYPOTENSION (Cytokine storm, hypotension and shock, respiratory failure, renal failure), SHOCK (Cytokine storm, hypotension and shock, respiratory failure, renal failure), RESPIRATORY FAILURE (Cytokine storm, hypotension and shock, respiratory failure, renal failure) and RENAL FAILURE (Cytokine storm, hypotension and shock, respiratory failure, renal failure) in an 83-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. On 17-Jan-2022, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 19-Jan-2022, the patient experienced THROMBOCYTOPENIA (Thrombocytopenia) (seriousness criterion life threatening), CYTOKINE STORM (Cytokine storm, hypotension and shock, respiratory failure, renal failure) (seriousness criterion life threatening), HYPOTENSION (Cytokine storm, hypotension and shock, respiratory failure, renal failure) (seriousness criterion life threatening), SHOCK (Cytokine	level 5	unassessable	This case concerns an 83-year-old male patient with no medical history reported, who experienced thrombocytopenia, cytokine storm and renal failure, hypotension, shock and respiratory failure, 2 days after administration of the third dose of mRNA-1273 (Spikevax). One day after vaccination, he started to experience general discomfort, loss of appetite and fever, then developed hypotension, oliguria, and dyspnea. Two days after vaccination, he continued to have severe chest pain, dyspnea, hypotension, shock, respiratory failure, renal failure and other symptoms. No co meds, no treatment info and no lab results were provided. Although there was limited information available, the clinical presentation could be explained as cytokine storm led to shock/hypotension and renal and respiratory failure and thrombocytopenia along with signs and symptoms of fever, general discomfort, dyspnea and oliguria. Therefore, the case is considered level 5 for MIS as alternative etiology was present. In addition, as limited information is available, the case is considered unassessable for WHO categories.	[redacted]

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	storm, hypotension and shock, respiratory failure, renal failure) (seriousness criterion life threatening), RESPIRATORY FAILURE (Cytokine storm, hypotension and shock, respiratory failure, renal failure) (seriousness criterion life threatening) and RENAL FAILURE (Cytokine storm, hypotension and shock, respiratory failure, renal failure) (seriousness criterion life threatening). At the time of the report, THROMBOCYTOPENIA (Thrombocytopenia), CYTOKINE STORM (Cytokine storm, hypotension and shock, respiratory failure, renal failure), HYPOTENSION (Cytokine storm, hypotension and shock, respiratory failure, renal failure), SHOCK (Cytokine storm, hypotension and shock, respiratory failure, renal failure), RESPIRATORY FAILURE (Cytokine storm, hypotension and shock, respiratory failure, renal failure) and RENAL FAILURE (Cytokine storm, hypotension and shock, respiratory failure, renal failure) was resolving. Not Provided For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medication were reported. No treatment information were reported. The patient age was reported as 83.3 . On 18-Jan-2022, the patient went to hospital for medical treatment due to general discomfort, loss of appetite and fever, and was admitted to hospital after the condition was evaluated by an outpatient physician. After admission, the patient had symptoms like hypotension, oliguria, and dyspnea. On 19-Jan-2022, the patient continued to have severe chest pain, dyspnea, hypotension, shock, respiratory failure, renal failure and other symptoms, and was transferred to the ICU. On 20-Jan-2022, the attending physician reported a suspected adverse event after COVID-19 vaccination. The lab test was reported as Anti-Platelet Factor 4 Antibody test with unknown results.				

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	Most recent FOLLOW-UP information incorporated above includes: On 25-Apr-2022: Non-significant follow up appended				
[redacted]	This case was received via European Medicines Agency (Reference number: [redacted]) on 09-Feb-2022 and was forwarded to Moderna on 09-Feb-2022. This regulatory authority case was reported by a physician and describes the occurrence of MULTIPLE ORGAN DYSFUNCTION SYNDROME (multivisceral failure), STATUS EPILEPTICUS (state of epileptic disease) and HYPERTHERMIA (Hyperthermie) in a 35-year-old female patient who received mRNA-1273 (Spikevax) (batch no. UNK) for COVID-19 vaccination. The patient's past medical history included Neurocognitive deficit, Optic neuritis retrobulbar, Generalized tonic-clonic seizure, Status epilepticus, Multiple sclerosis, Fracture of humerus and Unspecified vitamin B deficiency. Concomitant products included TOZINAMERAN (COMIRNATY) from 30-Sep-2021 to an unknown date for COVID-19 vaccination. On 07-Jul-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 09-Jan-2022, received dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to 1 dosage form. On 10-Jan-2022, the patient experienced STATUS EPILEPTICUS (state of epileptic disease) (seriousness criterion hospitalization). On an unknown date, the patient experienced MULTIPLE ORGAN DYSFUNCTION SYNDROME (multivisceral failure) (seriousness criterion hospitalization) and HYPERTHERMIA (Hyperthermie) (seriousness criterion hospitalization). At the time of the report, MULTIPLE ORGAN DYSFUNCTION SYNDROME (multivisceral failure), STATUS EPILEPTICUS (state of epileptic disease) and HYPERTHERMIA (Hyperthermie) had not resolved. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Treatment information was not provided.	level 5	unassessable	This regulatory case concerns a 35-year-olf female patient with multiple history of generalized tonic-clonic seizure, optic neuritis retrobulbar and neurocognitive deficit, multiple sclerosis and unspecified vitamin B deficiency, who the next day after the 2nd dose of Spikevax (taken 6 months after the 1st dose) experienced multiple organ dysfunction syndrome, status epilepticus and hyperthermia. No additional detail information was provided for an appropriate evaluation for MIS as well as for WHO categories. The case is considered level 5 for MIS, and unassessable for WHO categories because of insufficient information available. However, the patient's underlying CNS conditions may contribute to some event development.	[redacted]

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	Company comment: This regulatory case concerns a 35-year-olf female patient with medical history of Generalized tonic-clonic seizure, Optic neuritis retrobulbar and neurocognitive deficit experienced the unexpected, serious events Multiple organ dysfunction syndrome, status epilepticus and hyperthermia, one day after second dose of mRNA-1273 taken six months after first dose. Treatment and outcome details not reported. At the time of reporting, the events had not resolved. Medical history of Generalized tonic-clonic seizure, Optic neuritis retrobulbar and neurocognitive deficit remain confounders. The benefit-risk relationship of mRNA-1273 is not affected by this report. Event seriousness assessed as per Regulatory Authority reporting.				
[redacted]	This case was received via European Medicines Agency (Reference number: [redacted] on 10-Feb-2022 and was forwarded to Moderna on 10-Feb-2022. This regulatory authority case was reported by a physician and describes the occurrence of PNEUMONIA (Pneumonia), DYSPNOEA (Dyspnoea), SYSTEMIC INFLAMMATORY RESPONSE SYNDROME (SIRS) and DIARRHOEA (Diarrhoea) in a 57-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 092F21A) for COVID-19 vaccination. No Medical History information was reported. On 22-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 24-Dec-2021, the patient experienced SYSTEMIC INFLAMMATORY RESPONSE SYNDROME (SIRS) (seriousness criteria hospitalization and life threatening). On 25-Dec-2021, the patient experienced PNEUMONIA (Pneumonia) (seriousness criteria hospitalization and life threatening) and DYSPNOEA (Dyspnoea) (seriousness criteria hospitalization and life threatening). On 30-Dec-2021, the patient experienced DIARRHOEA (Diarrhoea) (seriousness criteria hospitalization and life threatening). On 04-Jan-2022, PNEUMONIA (Pneumonia), DYSPNOEA (Dyspnoea) and DIARRHOEA (Diarrhoea) had resolved. At the time of the report, SYSTEMIC INFLAMMATORY RESPONSE SYNDROME (SIRS) had	level 4	unassessable	This case concerns a 57-year-old male patient with no medical history or co meds reported, who experienced systemic inflammatory response syndrome (3 days), pneumonia and dyspnoea (4 days) and diarrhoea 9 days after receiving the mRNA-1273 (Spikevax). No treatment info was supplied. Although the case reported the event of systemic inflammatory response syndrome, no additional details are provided for an appropriate evaluation on MIS, including fever, clinical features, lab evidence of inflammation and measures of disease activity. Information is also insufficient for a proper judgement for WHO categories. The case is considered level 4 for MIS, and unassessable for WHO categories.	[redacted]

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	resolved. The action taken with mRNA-1273 (Spikevax) (Unknown) was unknown. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. No concomitant medication was reported No treatment medications was reported. Company comment: This regulatory case concerns a 57-year-old male patient with no medical history reported, who experienced the unexpected serious event of systemic inflammatory response syndrome (3 days), unexpected serious events pneumonia and dyspnoea (4 days) and unexpected serious event of diarrhoea 9 days after receiving the mRNA-1273 (Spikevax). Dyspnea is a possible manifestation of pneumonia. Pneumonia can trigger systemic inflammatory response syndrome in susceptible patients. The event of diarrhea is unexpected as it is retained as serious per the source document authority reporting. Clinical, diagnostic and treatment details not reported. The benefit-risk relationship of mRNA-1273 (Spikevax) is not affected by this report.				
[redacted]	This case was initially received via European Medicines Agency (Reference number: [redacted] on 10-Feb-2022. The most recent information was received on 21-Feb-2022 and was forwarded to Moderna on 21-Feb-2022. This regulatory authority case was reported by a physician and describes the occurrence of DYSPNOEA (Dyspnoea, cyanosis Multiorgan insufficiency during sepsis heart failure pulmonary embolism peripheral embolis bilateral necrosis TVS GS type II respiratory failure), the first episode of RESPIRATORY FAILURE (Dyspnoea, cyanosis Multiorgan insufficiency during sepsis heart failure pulmonary embolism peripheral embolis bilateral necrosis TVS GS type II respiratory failure), PULMONARY EMBOLISM (Dyspnoea, cyanosis Multiorgan insufficiency during sepsis heart failure pulmonary embolism peripheral embolis bilateral necrosis	level 5	Unlikely	This case concerns a 59-year-old male patient with no medical history and no co meds reported, who experienced respiratory failure, pulmonary embolism, multi organ dysfunction syndrome, sepsis by cellulofacititis of lower extremities, cardiac failure, and peripheral embolism about 1 month 22 days after receiving a dose of mRNA-1273 Vaccine. No clinical or treatment details were given, and the outcome of the events was unknown. The case provided insufficient information for a proper evaluation for MIS including fever, clinical features, lab evidence of inflammation and measures of disease activities, and for WHO categories. However, based on the limited data, the reported events were believed to be most likely due to a bacterial infection led to cellulofacititis of lower extremities then sepsis, which further led to multi organ failure including respiratory and cardiac failure, and attribute to pulmonary	[redacted]

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	TVS GS type II respiratory failure), CARDIAC FAILURE (Dyspnoea, cyanosis Multiorgan insufficiency during sepsis heart failure pulmonary embolism peripheral embolis bilateral necrosis TVS GS type II respiratory failure), the second episode of RESPIRATORY FAILURE (Dyspnoea, cyanosis Multiorgan insufficiency during sepsis heart failure pulmonary embolism peripheral embolis bilateral necrosis TVS GS type II respiratory failure), MULTIPLE ORGAN DYSFUNCTION SYNDROME (Dyspnoea, cyanosis Multiorgan insufficiency during sepsis heart failure pulmonary embolism peripheral embolis bilateral necrosis TVS GS type II respiratory failure), PERIPHERAL EMBOLISM (Dyspnoea, cyanosis Multiorgan insufficiency during sepsis heart failure pulmonary embolism peripheral embolis bilateral necrosis TVS GS type II respiratory failure), NECROSIS (Dyspnoea, cyanosis Multiorgan insufficiency during sepsis heart failure pulmonary embolism peripheral embolis bilateral necrosis TVS GS type II respiratory failure), SEPSIS (Dyspnoea, cyanosis Multiorgan insufficiency during sepsis heart failure pulmonary embolism peripheral embolis bilateral necrosis TVS GS type II respiratory failure), CYANOSIS (Dyspnoea, cyanosis Multiorgan insufficiency during sepsis heart failure pulmonary embolism peripheral embolis bilateral necrosis TVS GS type II respiratory failure) and SUPERFICIAL VEIN THROMBOSIS (Dyspnoea, cyanosis Multiorgan insufficiency during sepsis heart failure pulmonary embolism peripheral embolis bilateral necrosis TVS GS type II respiratory failure) in a 59-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3006322) for COVID-19 vaccination. The patient's past medical history included Ischaemic stroke (right due to occlusion of the ipsilateral vertebral artery) on 01-Jan-2017, Depression, Paraesthesia on 01-Jan-2014, Intracranial injury NOS and Foramen ovale patent on 01-Jan-2017. Previously administered products included for SARS-CoV-2 immunisation: SPIKEVAX (EX COVID-19 VACCINE MODERNA) (MODERNA BIOTECH SPAIN and S.L.) (J07BX03) on 28-Oct-2021; for Product used for unknown indication: [redacted] (C03DA02), TORVAST [redacted]			and peripheral embolism development which in turn could further facilitate cardiac and respiratory failures. The case is considered level 5 for MIS as the alternative etiology may explain the clinical presentation, and unlikely for WHO	

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	(C10AA05) and ZOLOFT [redacted] (N06AB06). Past adverse reactions to the above products included No adverse event with [redacted] (C03DA02), SPIKEVAX (EX COVID-19 VACCINE MODERNA) (MODERNA BIOTECH SPAIN, S.L.) (J07BX03), TORVAST [redacted] (C10AA05) and ZOLOFT [redacted] (N06AB06). Concurrent medical conditions included Smoker and Metabolic syndrome (high blood pressure, dyslipidemia, obesity, B12 vit deficiency). Concomitant products included ACETYLSALICYLIC ACID (CARDIOASPIRINE) for an unknown indication. On 25-Nov-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) .5 milliliter. On 12-Jan-2022, the patient experienced DYSPNOEA (Dyspnoea, cyanosis Multiorgan insufficiency during sepsis heart failure pulmonary embolism peripheral embolis bilateral necrosis TVS GS type II respiratory failure) (seriousness criterion life threatening), the first episode of RESPIRATORY FAILURE (Dyspnoea, cyanosis Multiorgan insufficiency during sepsis heart failure pulmonary embolism peripheral embolis bilateral necrosis TVS GS type II respiratory failure) (seriousness criterion life threatening), PULMONARY EMBOLISM (Dyspnoea, cyanosis Multiorgan insufficiency during sepsis heart failure pulmonary embolism peripheral embolis bilateral necrosis TVS GS type II respiratory failure) (seriousness criterion life threatening), CARDIAC FAILURE (Dyspnoea, cyanosis Multiorgan insufficiency during sepsis heart failure pulmonary embolism peripheral embolis bilateral necrosis TVS GS type II respiratory failure) (seriousness criterion life threatening), the second episode of RESPIRATORY FAILURE (Dyspnoea, cyanosis Multiorgan insufficiency during sepsis heart failure pulmonary embolism peripheral embolis bilateral necrosis TVS GS type II respiratory failure) (seriousness criterion life threatening), MULTIPLE ORGAN DYSFUNCTION SYNDROME (Dyspnoea, cyanosis Multiorgan insufficiency during sepsis heart failure pulmonary embolism peripheral embolis bilateral necrosis TVS GS				

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	type II respiratory failure) (seriousness criterion life threatening), NECROSIS (Dyspnoea, cyanosis Multiorgan insufficiency during sepsis heart failure pulmonary embolism peripheral embolis bilateral necrosis TVS GS type II respiratory failure) (seriousness criterion life threatening), SEPSIS (Dyspnoea, cyanosis Multiorgan insufficiency during sepsis heart failure pulmonary embolism peripheral embolis bilateral necrosis TVS GS type II respiratory failure) (seriousness criterion life threatening), CYANOSIS (Dyspnoea, cyanosis Multiorgan insufficiency during sepsis heart failure pulmonary embolism peripheral embolis bilateral necrosis TVS GS type II respiratory failure) (seriousness criterion life threatening) and SUPERFICIAL VEIN THROMBOSIS (Dyspnoea, cyanosis Multiorgan insufficiency during sepsis heart failure pulmonary embolism peripheral embolis bilateral necrosis TVS GS type II respiratory failure) (seriousness criterion life threatening). 12-Jan-2022, the patient experienced PERIPHERAL EMBOLISM (Dyspnoea, cyanosis Multiorgan insufficiency during sepsis heart failure pulmonary embolism peripheral embolis bilateral necrosis TVS GS type II respiratory failure) (seriousness criterion life threatening). At the time of the report, DYSPNOEA (Dyspnoea, cyanosis Multiorgan insufficiency during sepsis heart failure pulmonary embolism peripheral embolis bilateral necrosis TVS GS type II respiratory failure), PULMONARY EMBOLISM (Dyspnoea, cyanosis Multiorgan insufficiency during sepsis heart failure pulmonary embolism peripheral embolis bilateral necrosis TVS GS type II respiratory failure), CARDIAC FAILURE (Dyspnoea, cyanosis Multiorgan insufficiency during sepsis heart failure pulmonary embolism peripheral embolis bilateral necrosis TVS GS type II respiratory failure), the last episode of RESPIRATORY FAILURE (Dyspnoea, cyanosis Multiorgan insufficiency during sepsis heart failure pulmonary embolism peripheral embolis bilateral necrosis TVS GS type II respiratory failure), MULTIPLE ORGAN DYSFUNCTION SYNDROME (Dyspnoea, cyanosis Multiorgan insufficiency during sepsis heart failure pulmonary embolism peripheral embolis bilateral necrosis TVS GS type II respiratory failure), PERIPHERAL EMBOLISM (Dyspnoea, cyanosis Multiorgan insufficiency during sepsis heart failure pulmonary embolism peripheral				

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	embolis bilateral necrosis TVS GS type II respiratory failure), NECROSIS (Dyspnoea, cyanosis Multiorgan insufficiency during sepsis heart failure pulmonary embolism peripheral embolis bilateral necrosis TVS GS type II respiratory failure), SEPSIS (Dyspnoea, cyanosis Multiorgan insufficiency during sepsis heart failure pulmonary embolism peripheral embolis bilateral necrosis TVS GS type II respiratory failure), CYANOSIS (Dyspnoea, cyanosis Multiorgan insufficiency during sepsis heart failure pulmonary embolism peripheral embolis bilateral necrosis TVS GS type II respiratory failure) and SUPERFICIAL VEIN THROMBOSIS (Dyspnoea, cyanosis Multiorgan insufficiency during sepsis heart failure pulmonary embolism peripheral embolis bilateral necrosis TVS GS type II respiratory failure) w				
[redacted]	This literature-non-study case was reported in a literature article and describes the occurrence of ENCEPHALOPATHY (Encephalopathy/progressive encephalopathy), RESPIRATORY FAILURE (respiratory failure), ACUTE RESPIRATORY DISTRESS SYNDROME (acute respiratory distress syndrome), PNEUMONIA ASPIRATION (aspiration pneumonia) and SEPTIC SHOCK (septic shock) in a 67-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. LITERATURE REFERENCE: Cepero GS, Freiberg MB, Mucha S. Encephalopathy after COVID-19 infection and vaccine in a patient with underlying autoimmune disease. Crit Care Med. 2022;50(1):82 The patient's past medical history included COVID-19 (resolved with immunosuppression). Concurrent medical conditions included Rheumatoid arthritis, Sjogren's syndrome and Chronic obstructive pulmonary disease. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On an unknown date, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage	level 5	Unlikely	This literature case concerns a 67-year-old female with a history of Rheumatoid arthritis, Sjogren's syndrome and Chronic obstructive pulmonary disease and covid-19 infection, who experienced encephalopathy 1 day after receiving her first COVID-19 vaccine, and again suffered similarly progressive encephalopathy complicated by respiratory failure, acute respiratory distress syndrome, and septic shock secondary to aspiration pneumonia, unresponsive and recurrent fevers. Laboratory tests included negative findings on repeat infectious, autoimmune, and paraneoplastic testing, other that inflammatory marker test was elevated on an unknown date. The encephalopathy resolved with the treatment of levetiracetam which is indicated for partial onset seizures and methylprednisolone for the second onset. No information regarding a MIS is provided. In addition to her encephalopathy after second vaccine administration, the clinical presentations may be supported by encephalopathy attributed aspiration pneumonia which led to septic shock, acute respiratory distress syndrome and respiratory failure. The case is considered level 5 for MIS as alternative etiology encephalopathy seemed ascertained. It is considered unlikely for WHO causality assessment. The recent history of COVID-19 infection is an important risk factor that provides a more plausible explanation for the occurrence of the reported events.	[redacted]

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	was changed to 1 dosage form. On an unknown date, the patient experienced ENCEPHALOPATHY (Encephalopathy/progressive encephalopathy) (seriousness criteria hospitalization, medically significant and life threatening), RESPIRATORY FAILURE (respiratory failure) (seriousness criteria hospitalization, medically significant and life threatening), ACUTE RESPIRATORY DISTRESS SYNDROME (acute respiratory distress syndrome) (seriousness criteria hospitalization, medically significant and life threatening), PNEUMONIA ASPIRATION (aspiration pneumonia) (seriousness criteria hospitalization, medically significant and life threatening) and SEPTIC SHOCK (septic shock) (seriousness criteria hospitalization, medically significant and life threatening). The patient was treated with LEVETIRACETAM for Encephalopathy, at an unspecified dose and frequency; METHYLPREDNISOLONE for Adverse event, at a dose of 1 gram; Rehabilitation therapy (Rehabilitation facility) for Encephalopathy; Rehabilitation therapy (Rehabilitation facility) for Respiratory failure; Rehabilitation therapy (Rehabilitation facility) for Acute respiratory distress syndrome; Rehabilitation therapy (Rehabilitation facility) for Pneumonia aspiration and Rehabilitation therapy (Rehabilitation facility) for Septic shock. At the time of the report, ENCEPHALOPATHY (Encephalopathy/progressive encephalopathy) had resolved and RESPIRATORY FAILURE (respiratory failure), ACUTE RESPIRATORY DISTRESS SYNDROME (acute respiratory distress syndrome), PNEUMONIA ASPIRATION (aspiration pneumonia) and SEPTIC SHOCK (septic shock) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, CSF test: negative (Negative) Negative. On an unknown date, Coma scale: 3 Patient was liberated from the ventilator after four days of antibiotics but remained encephalopathic with a Glasgow Coma Scale (GCS) of 3.. On an unknown date, Electroencephalogram: negative (Negative) Negative. On an unknown date, Inflammatory marker test: elevated elevated inflammatory markers.				

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	On an unknown date, Magnetic resonance imaging: negative (Negative) Negative. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter considered ENCEPHALOPATHY (Encephalopathy/progressive encephalopathy) to be related. No further causality assessments were provided for RESPIRATORY FAILURE (respiratory failure), ACUTE RESPIRATORY DISTRESS SYNDROME (acute respiratory distress syndrome), PNEUMONIA ASPIRATION (aspiration pneumonia) and SEPTIC SHOCK (septic shock). The patient was liberated from the ventilator after four days of antibiotics. Laboratory tests also included negative findings on repeat infectious, autoimmune, and paraneoplastic testing. The patient was unresponsive for 32 days and was transitioned to hospice. The patient had a dramatic improvement in the mental status within 24 hours and was subsequently discharged to an acute rehabilitation facility with resolution of encephalopathy. Company comment: This literature case concerns a 67-year-old female patient with relevant medical history of rheumatoid arthritis, Sjogren's syndrome, COVID-19 and chronic obstructive pulmonary disease, who experienced unexpected, serious events of encephalopathy the day after the first dose of mRNA-1273 vaccine. Cerebrospinal fluid analysis, MRI and electroencephalogram were negative, and the event resolved with levetiracetam. Six weeks later the day after received second dose of mRNA vaccine patient again presented unexpected serious life -threatening event of encephalopathy complicated with serious, unexpected life-threatening events of respiratory failure, pneumonia aspiration, septic shock and unexpected serious life-threatening AESI of acute respiratory distress syndrome. The course of reported events was characterized by recurrent fever and elevated inflammatory parameters. The patients remined unresponsive for 32 days. Treatment of reported events included antibiotics, mechanical ventilations, however patient improved only when prednisolone was initiated. Article author assessed the event				

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	as potential inflammatory encephalopathy in response to mRNA-1273 vaccine in patient with autoimmune disease. As the event of encephalopathy occurred after the first and the second dose rechallenge is positive. The medical history of rheumatoid arthritis, Sjogren's syndrome was considered as confounders for the event of encephalopathy and septic shock. The medical history of COPD and COVID-19 contributed to acute respiratory distress syndrome and respiratory failure after aspiration pneumonia. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 17-Feb-2022: Upon internal quality review performed by MSA on 07-MAR-2022, events, re-challenge and non-drug treatment/non-drug treatment notes were updated				
[redacted]	This case was initially received via European Medicines Agency (Reference number: [redacted] on 14-Feb-2022. The most recent information was received on 09-Mar-2022 and was forwarded to Moderna on 09-Mar-2022. This case was initially received via European Medicines Agency (Reference number: [redacted] on 14-Feb-2022. The most recent information was received on 09-Mar-2022 and was forwarded to Moderna on 09-Mar-2022. This case was initially received via European Medicines Agency (Reference number: [redacted] on 14-Feb-2022. The most recent information was received on 09-Mar-2022 and was forwarded to Moderna on 09-Mar-2022. This regulatory authority case was reported by a consumer and describes the occurrence of VACCINE ASSOCIATED ENHANCED RESPIRATORY DISEASE (respiratory distress, asthmatic patient. 3 days without breathing.), SKIN REACTION (respiratory distress, asthmatic patient. 3 days without breathing.), RASH MORBILLIFORM (respiratory distress, asthmatic patient. 3 days without breathing.) and DYSPNOEA (respiratory distress, asthmatic patient. 3 days without breathing.) in a 49-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 030G21A Scad 31/3/22) for COVID-19 vaccination.	level 5	conditional	This consumer reported case concerns a 49-year-old female patient with a history of asthma on fluticasone and salmeterol, who experienced vaccine associated enhanced respiratory disease and dyspnea, about 1 day after a dose of mRNA-1273 vaccine. Treatment information was not provided. No report on MIS and no detail information on fever, clinical features, lab evidence of inflammation and measures of disease activities were provided to indicate a potential MIS. The case is considered level 5 for MIS. Additionally, there is insufficient information for a proper vaccine/event causal relation though a reasonable TTO existed. Of note, the underlying allergic asthma would be a risk factor for the event development. It is considered comditional for WHO at present.	[redacted]

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	The patient's past medical history included Allergic asthma. Concomitant products included FLUTICASONE PROPIONATE, SALMETEROL XINAFOATE [redacted] for Asthma. On 01-Jan-2022, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 02-Jan-2022, the patient experienced VACCINE ASSOCIATED ENHANCED RESPIRATORY DISEASE (respiratory distress, asthmatic patient. 3 days without breathing.) (seriousness criterion medically significant). 02-Jan-2022, the patient experienced SKIN REACTION (respiratory distress, asthmatic patient. 3 days without breathing.) (seriousness criterion medically significant), RASH MORBILLIFORM (respiratory distress, asthmatic patient. 3 days without breathing.) (seriousness criterion medically significant) and DYSPNOEA (respiratory distress, asthmatic patient. 3 days without breathing.) (seriousness criterion medically significant). On 28-Jan-2022, VACCINE ASSOCIATED ENHANCED RESPIRATORY DISEASE (respiratory distress, asthmatic patient. 3 days without breathing.), SKIN REACTION (respiratory distress, asthmatic patient. 3 days without breathing.), RASH MORBILLIFORM (respiratory distress, asthmatic patient. 3 days without breathing.) and DYSPNOEA (respiratory distress, asthmatic patient. 3 days without breathing.) had resolved. It was reported that On 21 February 2022, contacted the patient by phone who reports that the ADR was completely resolved on 28 Jan 2022. Patient experienced after 4 days from the vaccination, for 4 days patient had a localized skin reaction on the temples and forehead (red measles-like pustules). the patient also received the 2nd dose with a different vaccine. 2nd dose with COMIRNATY on 29 Jan 2022 at 18:55, Lot No 33295TB EXP 31 May 2022, IM, LH shoulder (no ADR received). Treatment Medication use information was not provided by				

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	reporter. Company Comment - This regulatory authority case concerns a 49 year old female patient with medical history of asthma, who experienced the serious unexpected events of vaccine associated enhanced respiratory disease, skin reaction, rash morbilliform and dyspnoea. The events occurred 1 day after a dose of mRNA-1273 vaccine. Patient's medical history of asthma remains a confounder. All the events were reported as medically significant and after 26 days all have resolved. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 07-Mar-2022: Follow up received does not contain new information On 09-Mar-2022: Follow up received that contains significant information that includes Added event, Updated event verbatim, Updated event stop date and outcome, Updated sender comment, Updated Narrative.				
[redacted]	This case was initially received via European Medicines Agency (Reference number [redacted] on 14-Feb-2022. The most recent information was received on 22-Feb-2022 and was forwarded to Moderna on 22-Feb-2022. This regulatory authority case was reported by a physician and describes the occurrence of RESPIRATORY FAILURE (sphincter release, aphasic, septic shock, coma state, respiratory failure, bilateral pneumonitis, suspected stroke, IRA), PNEUMONIA (sphincter release, aphasic, septic shock, coma state, respiratory failure, bilateral pneumonitis, suspected stroke, IRA), CEREBROVASCULAR ACCIDENT (sphincter release, aphasic, septic shock, coma state, respiratory failure, bilateral pneumonitis, suspected stroke, IRA), COMA (sphincter release, aphasic, septic shock, coma state, respiratory failure, bilateral pneumonitis, suspected stroke, IRA), BLADDER SPHINCTER ATONY (sphincter release, aphasic, septic shock, coma state, respiratory failure, bilateral pneumonitis, suspected stroke, IRA), ACUTE KIDNEY INJURY (sphincter release, aphasic, septic shock, coma state, respiratory failure, bilateral	level 5	unlikely	This case concerns an 87-year-old male patient with a medical history of SARS-CoV-2 vaccination with Comirnaty and neurocognitive deficit and concurrent medical conditions of COPD, hypertension arterial and renal failure chronic, who experienced respiratory failure, pneumonia, cerebrovascular accident, aphasia, bladder sphincter atony, acute kidney injury, septic shock and coma with a fatal outcome, approximately 59 days after a dose of mRNA-1273 vaccine administration. Concomitant medications included anti-hypertensive and anti-depression and antipsychotic: Norvasc, Kanrenol, Trittico, fluoxetine hydrochloride, Fostera and Quetiapine. SARS-CoV-2 test negative. Other labs including blood test, angiogram cerebral, chest x-ray, CT head, echocardiogram, electrocardiogram, electroencephalogram, culture for blood, CSF and tracheal aspirate were all inconclusive. Treatment information was unavailable. No reported MIS or information on fever, details of clinical features, lab evidence of inflammation and measures of disease activities associated with MIS. In addition, the information is insufficient for the medical assessment.	[redacted]

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	pneumonitis, suspected stroke, IRA), SEPTIC SHOCK (sphincter release, aphasic, septic shock, coma state, respiratory failure, bilateral pneumonitis, suspected stroke, IRA) and APHASIA (sphincter release, aphasic, septic shock, coma state, respiratory failure, bilateral pneumonitis, suspected stroke, IRA) in an 87-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3006322) for COVID-19 vaccination. The patient's past medical history included Neurocognitive deficit (MMSE 13/30) on 01-Apr-2021. Previously administered products included for SARS-CoV-2 vaccination: COMIRNATY (BIONTECH MANUFACTURING GMBH) (J07BX03) on 02-Apr-2021 and COMIRNATY (BIONTECH MANUFACTURING GMBH) (J07BX03) on 23-Apr-2021. Past adverse reactions to the above products included No adverse event with COMIRNATY (BIONTECH MANUFACTURING GMBH) (J07BX03) and COMIRNATY (BIONTECH MANUFACTURING GMBH) (J07BX03). Concurrent medical conditions included COPD, Hypertension arterial and Renal failure chronic. Concomitant products included AMLODIPINE BESILATE (NORVASC), POTASSIUM CANRENOATE (KANRENOL), TRAZODONE HYDROCHLORIDE (TRITTICO), QUETIAPINE and PIROXICAM (FOSTER [PIROXICAM]) for an unknown indication. On 23-Nov-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) .25 milliliter. On 21-Jan-2022, the patient experienced RESPIRATORY FAILURE (sphincter release, aphasic, septic shock, coma state, respiratory failure, bilateral pneumonitis, suspected stroke, IRA) (seriousness criterion death), PNEUMONIA (sphincter release, aphasic, septic shock, coma state, respiratory failure, bilateral pneumonitis, suspected stroke, IRA) (seriousness criterion death), CEREBROVASCULAR ACCIDENT (sphincter release, aphasic, septic shock, coma state, respiratory failure, bilateral pneumonitis, suspected stroke, IRA) (seriousness criterion death), COMA (sphincter release, aphasic, septic shock, coma state, respiratory failure, bilateral pneumonitis, suspected stroke,			The clinical presentation may likely be infectious pneumonia led to respiratory failure, septic shock, acute kidney failure and death under the condition of the various basic conditions especially COPD, chronic renal failure and CNS deficit in this aged patient. The case is considered level 5 for MIS, and unlikely for WHO due to vaccine/event TTO of two months and underlying confounding risks.	

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	IRA) (seriousness criterion death), BLADDER SPHINCTER ATONY (sphincter release, aphasic, septic shock, coma state, respiratory failure, bilateral pneumonitis, suspected stroke, IRA) (seriousness criterion death), ACUTE KIDNEY INJURY (sphincter release, aphasic, septic shock, coma state, respiratory failure, bilateral pneumonitis, suspected stroke, IRA) (seriousness criterion death), SEPTIC SHOCK (sphincter release, aphasic, septic shock, coma state, respiratory failure, bilateral pneumonitis, suspected stroke, IRA) (seriousness criterion death) and APHASIA (sphincter release, aphasic, septic shock, coma state, respiratory failure, bilateral pneumonitis, suspected stroke, IRA) (seriousness criterion death). The patient died on 27-Jan-2022. The reported cause of death was Shock septic. An autopsy was not performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 21-Jan-2022, Angiogram cerebral: inconclusive (Inconclusive) Inconclusive. On 21-Jan-2022, Blood gases: inconclusive (Inconclusive) Inconclusive. On 21-Jan-2022, Blood test: inconclusive (Inconclusive) Inconclusive. On 21-Jan-2022, CSF culture: inconclusive (Inconclusive) Inconclusive. On 21-Jan-2022, Chest X-ray: inconclusive (Inconclusive) Inconclusive. On 21-Jan-2022, Computerised tomogram head: inconclusive (Inconclusive) Inconclusive. On 21-Jan-2022, Echocardiogram: inconclusive (Inconclusive) Inconclusive. On 21-Jan-2022, Electrocardiogram: inconclusive (Inconclusive) Inconclusive. On 21-Jan-2022, Electroencephalogram: inconclusive (Inconclusive) Inconclusive. On 21-Jan-2022, Physical examination: inconclusive (Inconclusive) Inconclusive. On 21-Jan-2022, SARS-CoV-2 test negative: inconclusive (Inconclusive) Inconclusive. On 22-Jan-2022, Blood culture: inconclusive (Inconclusive) Inconclusive. On 22-Jan-2022, Tracheal aspirate culture: inconclusive				

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	(Inconclusive) Inconclusive. On 25-Jan-2022, Specialist consultation: inconclusive (Inconclusive) Inconclusive. The action taken with mRNA-1273 (Spikevax) (Intramuscular) was unknown. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Treatment medication were not reported. Company comment: This regulatory case concerns an 87-year-old elderly male patient with medical history of COPD, hypertension arterial, renal failure chronic, neurocognitive deficit, and interchange of vaccine products (two doses of Comirnaty Covid19 vaccine), experienced the unexpected Fatal events Respiratory failure, Pneumonia, Cerebrovascular accident, Coma, bladder sphincter atony, Acute kidney injury, Septic shock, and Aphasia, one month twenty-nine days after a dose of mRNA-1273. The cause of death was reported as Septic shock. Autopsy was not performed. Advanced age of the patient could be a risk factor. Medical history of COPD, hypertension arterial, renal failure chronic could be confounding. 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 22-Feb-2022: Added patient's medical history, lab data, concomitant medications, events (bilateral pneumonia, stroke, coma, bladder sphincter atony, renal failure acute, aphasia), updated seriousness, verbatim for events (respiration failure, septic shock) and deleted event (sopor). On 07-Mar-2022: Non-significant follow up appended, Senders comment updated				
[redacted]	This case was initially received via European Medicines Agency (Reference number: [redacted] on 17-Feb-2022. The most recent information was received on 14-Mar-2022 and was forwarded to Moderna on 14-Mar-	level 4	unlikely	A physician reported case concerned a 73-year-old female patient who experienced acute kidney injury, pyrexia, oliguria, septic shock, multiple organ dysfunction syndrome and myocardial ischemia after she received	[redacted]

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	2022. This regulatory authority case was reported by a physician and describes the occurrence of ACUTE KIDNEY INJURY (fever, oliguria, IRA, multiorganic insufficiency, myocardial ischemia, septic shock), PYREXIA (fever, oliguria, IRA, multiorganic insufficiency, myocardial ischemia, septic shock), OLIGURIA (fever, oliguria, IRA, multiorganic insufficiency, myocardial ischemia, septic shock), SEPTIC SHOCK (fever, oliguria, IRA, multiorganic insufficiency, myocardial ischemia, septic shock), MULTIPLE ORGAN DYSFUNCTION SYNDROME (fever, oliguria, IRA, multiorganic insufficiency, myocardial ischemia, septic shock) and MYOCARDIAL ISCHAEMIA (fever, oliguria, IRA, multiorganic insufficiency, myocardial ischemia, septic shock) in a 73-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 000004A) for COVID-19 vaccination. The patient's past medical history included Obesity, COVID-19 (SARS-Cov2 PCR Buffer 25/02/2021: Positive) on 25-Feb-2021, Recovered smoker, Dyslipidemia and Cholecystectomy. Previously administered products included for SARS-CoV-2 immunisation: COMIRNATY (BIONTECH MANUFACTURING GMBH) (J07BX03) on 11-Jun-2021. Past adverse reactions to the above products included No adverse event with COMIRNATY (BIONTECH MANUFACTURING GMBH) (J07BX03). Concurrent medical conditions included Hypertension. On 15-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) .5 milliliter. On 24-Jan-2022, the patient experienced ACUTE KIDNEY INJURY (fever, oliguria, IRA, multiorganic insufficiency, myocardial ischemia, septic shock) (seriousness criterion life threatening), PYREXIA (fever, oliguria, IRA, multiorganic insufficiency, myocardial ischemia, septic shock) (seriousness criterion life threatening), OLIGURIA (fever, oliguria, IRA, multiorganic insufficiency, myocardial ischemia, septic shock) (seriousness criterion life threatening), SEPTIC SHOCK (fever, oliguria, IRA, multiorganic insufficiency, myocardial ischemia, septic			mRNA-1273. Past medical history included obesity, COVID-19 positive on 25-Feb-2021, recovered smoker, and dyslipidemia. Prior vaccination with COMIRNATY on 11-Jun-2021. Concurrent conditions included hypertension. Information on co-meds and treatments was unavailable. On 15-Dec-2021, she received a dose of mRNA-1273. About 40 days later, on 24-Jan-2022, she experienced the above events. At the time of the report, they were resolving. Results for Blood culture, Echocardiogram, Physical examination, Thrombocytopenia and Troponin were inconclusive. The case did not report a MIS-A, but reported fever and septic shock which may be clinical presentations for MIS-A. However, details were unavailable, including labs to indicate inflammatory status, as many other clinical conditions including concurrent infectious origin may overlap the presentation. The underlying obesity, smoking, dyslipidemia, and hypertension may confound myocardial ischemia and acute kidney injury. Multiple organ dysfunction syndrome may also be the outcome of septic shock. Of note, the patient was infected with Covid-19 but that was about a year earlier. The case is considered level 4 for MIS-A due to insufficient information. It is evaluated as unlikely based on the TTO of more than one month and multiple underlying diseases.	

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	shock) (seriousness criterion life threatening), MULTIPLE ORGAN DYSFUNCTION SYNDROME (fever, oliguria, IRA, multiorganic insufficiency, myocardial ischemia, septic shock) (seriousness criteria medically significant and life threatening) and MYOCARDIAL ISCHAEMIA (fever, oliguria, IRA, multiorganic insufficiency, myocardial ischemia, septic shock) (seriousness criteria medically significant and life threatening). At the time of the report, ACUTE KIDNEY INJURY (fever, oliguria, IRA, multiorganic insufficiency, myocardial ischemia, septic shock), PYREXIA (fever, oliguria, IRA, multiorganic insufficiency, myocardial ischemia, septic shock), OLIGURIA (fever, oliguria, IRA, multiorganic insufficiency, myocardial ischemia, septic shock), SEPTIC SHOCK (fever, oliguria, IRA, multiorganic insufficiency, myocardial ischemia, septic shock), MULTIPLE ORGAN DYSFUNCTION SYNDROME (fever, oliguria, IRA, multiorganic insufficiency, myocardial ischemia, septic shock) and MYOCARDIAL ISCHAEMIA (fever, oliguria, IRA, multiorganic insufficiency, myocardial ischemia, septic shock) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 29-Jan-2022, Blood culture positive: inconclusive (Inconclusive) Inconclusive. On 29-Jan-2022, Echocardiogram: inconclusive (Inconclusive) Inconclusive. On 29-Jan-2022, Physical examination: inconclusive (Inconclusive) Inconclusive. On 29-Jan-2022, Thrombocytopenia: inconclusive (Inconclusive) Inconclusive. On 29-Jan-2022, Troponin increased: inconclusive (Inconclusive) Inconclusive. The action taken with mRNA-1273 (Spikevax) (Intramuscular) was unknown. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Concomitant product use was not provided by the reporter.				

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	Treatment information was not provided. Company Comment: This regulatory authority case concerns a 73 year old female patient with relevant medical history of Obesity , Covid 19 , previous smoker , hypertension , dyslipidemia , initially vaccinated with COMIRNATY (BIONTECH MANUFACTURING GMBH) with no reported adverse reaction , who experienced Serious (Life threatening) , unexpected AESI events of Acute kidney injury, Myocardial ischemia and serious , unexpected events of pyrexia , oliguria , septic shock and multiple organ dysfunction syndrome . These events occurred one month 9 days post vaccination with an unknown dose number of mRNA-1273 vaccine. Diagnostic procedures reported were Physical examination , blood culture, Echocardiogram with inconclusive results and troponin increased and thrombocytopenia . Treatment details were not reported and other laboratories /diagnostic procedures like kidney functions test were not included in this report. The outcome of the events were reported as resolving. The above medical conditions mentioned : obesity , Covid 19 ,previous smoker, dyslipidemia , hypertension , vaccination with 1 dose of Comirnaty and the age of this patient are all considered as confounders for the case. The benefit -risk relationship of mRNA -1273 (Moderna Covid 19 Vaccine) is not affected by this report Most recent FOLLOW-UP information incorporated above includes: On 04-Mar-2022: Follow-up received contains No NewInformation. On 14-Mar-2022: Significant follow-up was received: Medical history, historical vaccine, lab tests and events were added. Event verbatim, start date and outcome were updated for the event septic shock.				
[redacted]	This spontaneous case was reported by an attorney and describes the occurrence of THROMBOSIS (Thrombosis/thrombosis in her abdominal/pelvic area, in her stomach and intestine), SEPTIC SHOCK (Septic shock/ shortness of breath/difficulties in breathing/Hypoxemia /Oxygen saturation 89 percent/Tachycardia/irregular heart rhythm/heart rhythm greater than 100 beats per minute/Use of accessory muscles of ventilation/high temperature/fever) and OEDEMA PERIPHERAL (Oedema lower limb) in a 33-year-old female patient who received mRNA-1273 (COVID 19 Vaccine Moderna) (batch no. 3005294) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Fever.				[redacted]

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	Family history included Thrombophilia (carried the gene of thrombophilia, patient was thrombophilia anaphylactic.) since an unknown date. On 04-Jan-2022 at 9:00 AM, the patient received first dose of mRNA-1273 (COVID 19 Vaccine Moderna) (unknown route) 1 dosage form. On 07-Jan-2022, after starting mRNA-1273 (COVID 19 Vaccine Moderna), the patient experienced CONTUSION (bruising appearing in one of her fingers/bruising). On 08-Feb-2022, the patient experienced SEPTIC SHOCK (Septic shock/ shortness of breath/difficulties in breathing/Hypoxemia /Oxygen saturation 89 percent/Tachycardia/irregular heart rhythm/heart rhythm greater than 100 beats per minute/Use of accessory muscles of ventilation/high temperature/fever) (seriousness criteria hospitalization, medically significant and life threatening). On 08-Feb-2022 at 8:05 AM, the patient experienced OEDEMA PERIPHERAL (Oedema lower limb) (seriousness criterion hospitalization). On an unknown date, the patient experienced THROMBOSIS (Thrombosis/thrombosis in her abdominal/pelvic area, in her stomach and intestine) (seriousness criteria death and medically significant), PAIN (pain/aches), PERIPHERAL SWELLING (swelling of her small finger/left foot was swelling), CYANOSIS (Cyanosis), ERYTHEMA (Erythema/Redness generalized/localized), ROSEOLA (Roseola generalized), HEADACHE (severe headache), NAUSEA (nausea) and PAIN IN EXTREMITY (Pain in left lower limb). The patient was hospitalized on 08-Feb-2022 due to OEDEMA PERIPHERAL and SEPTIC SHOCK. The patient was treated with HYDROCODONE at an unspecified dose and frequency; ENOXAPARIN SODIUM (CLEXANE) at an unspecified dose and frequency; PARACETAMOL (APOTEL) at an unspecified dose and frequency; ONDANSETRON (ZOFRAN 4 ZYDIS) at an unspecified dose and frequency; DEXAMETHASONE at an unspecified dose and frequency; SODIUM BICARBONATE at an unspecified dose and frequency; EPINEPHRINE (intravenous) on 08-Feb-2022 at an unspecified dose and frequency; PARACETAMOL (DEPON) at an unspecified dose and frequency and PARACETAMOL (PANADOL) at an unspecified dose and frequency. The patient died on 08-Feb-2022. The reported cause of death was thrombosis/thrombosis in her abdominal/pelvic area, in her stomach and intestine. It is unknown if an autopsy was performed. At the time of death, SEPTIC SHOCK (Septic shock/ shortness of breath/difficulties in breathing/Hypoxemia /Oxygen saturation 89 percent/Tachycardia/irregular heart rhythm/heart rhythm greater than 100 beats per minute/Use of accessory muscles of ventilation/high temperature/fever), OEDEMA PERIPHERAL (Oedema lower limb), PAIN (pain/aches), CONTUSION (bruising appearing in one of her fingers/bruising), PERIPHERAL SWELLING (swelling of her small finger/left foot was swelling), CYANOSIS (Cyanosis), ERYTHEMA (Erythema/Redness generalized/localized), ROSEOLA (Roseola generalized), HEADACHE (severe headache), NAUSEA (nausea) and PAIN IN EXTREMITY (Pain in left lower limb) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 08-Feb-2022, Blood creatine: 2.19 2.19. On 08-Feb-2022, Blood creatine phosphokinase: 18320 18320. On 08-Feb-2022, Blood lactate dehydrogenase: 1243 1243. On 08-Feb-2022, Blood lactic acid: 10 10. On 08-Feb-2022, Blood potassium: 3.45 3.45. On 08-Feb-2022, Blood pressure systolic: less than 90 mmhg Less than 90 mmHg and less than 100 mmhg Less than 100 mmHg. On 08-Feb-2022, Blood sodium: 130 130. On 08-Feb-2022, Blood urea: 48 48. On 08-Feb-2022, Body temperature: 36.2 36.2 Degree C. On 08-Feb-2022, Breath sounds: nb NB. On 08-Feb-2022, C-reactive protein: 297 297. On 08-Feb-2022, Ejection fraction: 65% without any visible segmental contractility 65% without any visible segmental contractility disorders. TR 1/4. Normal diameters R heart ventricle. AV of good systolic diameter index. Clear pericardium.. On 08-Feb-2022, Electrocardiogram: sr 135 bpm without acute ischemic changes SR 135 bpm without acute ischemic changes.. On 08-Feb-2022, Fibrin D dimer: 1462 1462. On 08-Feb-2022, Haemoglobin: 15.4 15.4.				

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	On 08-Feb-2022, Heart rate: greater than 100 beats per minute Greater than 100 beats per minute and 45 45. On 08-Feb-2022, Magnetic resonance imaging: thrombosis (abnormal) Had thrombosis in her abdominal area, in her intestine. On 08-Feb-2022, Oxygen saturation: 60% (Low) 60%, 80% (Low) 80% and 89% 89%. On 08-Feb-2022, PCO2: 36 36. On 08-Feb-2022, PO2: 42 42. On 08-Feb-2022, Platelet count: 224 224. On 08-Feb-2022, Polymerase chain reaction: negative (Negative) Negative. On 08-Feb-2022, Serum ferritin: 1300 1300. On 08-Feb-2022, Troponin: 0.28 0.28. On 08-Feb-2022, White blood cell count: 3.57 3.57. On 08-Feb-2022, pH body fluid: 6.99 6.99. On an unknown date, Blood lactic acid: 10.5 10.5. The patent did not have any allergy. No concomitant medication were reported. On 16 Jan 2022, the patient came in Emergency Department at 13.18 pm. She was checked in at 13.56 pm with normal vitals and severeness evaluation 4 due to bruised finger. The physician did not find any pathological findings and recommended patient to continue the anticoagulant and thrombosis protection treatment. The patient was discharged walking in a perfect general condition around 15.30 pm. On 08 Feb 2022, patient came second time in Emergency Department at 7.58 am. She was checked in at 8.05 am with pathological vitals while she had an oedema of lower left part and hard of breathing. She was admitted immediately in a COVID-19 suspicious cases room. She was given additional oxygen and was immediately evaluated by nurses and trainee doctor, supported her vital functions-stabilization (W/S 300 ml, N 40 mg, oxygen supply, IV hydration (2.5 L NS and 2.5 L HS), analgesia supply, anticoagulant treatment, corticoids) around 8.35 am. Around 8.45 am, patient stayed unstable as far as respiratory and circulation systems were concerned. An intubation was performed immediately, placing of central vein catheter, supply of vasoconstrictors and then imaging control. Then patient was transferred to ICU around 12.30 pm. She unfortunately died in the afternoon. Treatment medication mentioned as painkillers (aspirin she thought). Most recent FOLLOW-UP information incorporated above includes: On 21-Feb-2022: Medical history, lab data, product information and event updated. On 02-May-2022: Follow-up information received on 02 May 2022 included: Events added, Seriousness criteria (Hospitalization added), Medical reports received, Patient demographics updated, Medical history added, lab test added.				
[redacted]	This case was received via European Medicines Agency (Reference number: [redacted] on 17-Feb-2022 and was forwarded to Moderna on 17-Feb-2022. This regulatory authority case was reported by a physician and describes the occurrence of STATUS EPILEPTICUS (Status epilepticus), COVID-19 (COVID-19), SEPTIC SHOCK (Septic shock), DEAFNESS (Deafness),	level 4	unassessable	A physician reported case concerned a 59-year-old female patient who experienced status epilepticus, covid-19, septic shock, deafness, headache, vaccination failure, dizziness, pyrexia and catarrh after she received mRNA-1273. Past history included hydrocephalus and ventriculo-peritoneal shunt in 1990. Concurrent conditions included Epilepsy. Prior COVID-19	[redacted]

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	HEADACHE (Headache), VACCINATION FAILURE (Vaccination failure), DIZZINESS (Dizziness), PYREXIA (Fever) and CATARRH (Catarrh) in a 59-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 016G21A) for COVID-19 vaccination. The patient's past medical history included Hydrocephalus and Ventriculo-peritoneal shunt in 1990. Concurrent medical conditions included Epilepsy. Concomitant products included TOZINAMERAN (COMIRNATY) from 19-May-2021 to 09-Jun-2021 for COVID-19 vaccination. On 18-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (Intramuscular) .25 milliliter. On 21-Dec-2021, the patient experienced DIZZINESS (Dizziness) (seriousness criterion hospitalization) and CATARRH (Catarrh) (seriousness criterion hospitalization). On 07-Jan-2022, the patient experienced DEAFNESS (Deafness) (seriousness criterion hospitalization). On an unknown date, the patient experienced STATUS EPILEPTICUS (Status epilepticus) (seriousness criterion hospitalization), COVID-19 (COVID-19) (seriousness criterion hospitalization), SEPTIC SHOCK (Septic shock) (seriousness criterion hospitalization), HEADACHE (Headache) (seriousness criterion hospitalization), VACCINATION FAILURE (Vaccination failure) (seriousness criterion hospitalization) and PYREXIA (Fever) (seriousness criterion hospitalization). At the time of the report, STATUS EPILEPTICUS (Status epilepticus), COVID-19 (COVID-19), SEPTIC SHOCK (Septic shock), HEADACHE (Headache), VACCINATION FAILURE (Vaccination failure), PYREXIA (Fever) and CATARRH (Catarrh) had resolved and DEAFNESS (Deafness) and DIZZINESS (Dizziness) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 28-Dec-2021, SARS-CoV-2 test: positive (Positive) Positive. On 01-Jan-2022, SARS-CoV-2 test: negative (Negative) Negative.			vaccination included TOZINAMERAN (COMIRNATY) from 19-May-2021 to 09-Jun-2021. On 18-Dec-2021, she received third dose of mRNA-1273. Three days later on 21-Dec-2021, she experienced dizziness and catarrh. On an unknown date, she experienced other events above. At the time of the report, the events were not resolved. On 28-Dec-2021, SARS-CoV-2 test was positive. Two FU SARS-CoV-2 tests were both negative on 1 Jan and 4 Jan 22. The case did not report MIS-A. The clinical presentation of fever, catarrh, headache, and septic shock may be seen in MIS-A. however, details were unavailable, including period of fever and labs which indicated inflammatory status. Majority of events were present with an unknown TTO. In addition, her underlying hydrocephalus with ventriculo-peritoneal shunt and epilepsy could be confounding risks. Her Covid 19 and vaccination failure remained questionable as one test positive but two close FU tests were negative. The case is considered level 4 for MIS-A, and unassessable for WHO because of insufficient information provided for evaluation.	

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	On 04-Jan-2022, SARS-CoV-2 test: negative (Negative) Negative. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No Treatment information was provided. Company comment: This is a regulatory case concerning a 59 year-old, female patient with a history of Hydrocephalus, Ventriculo-peritoneal shunt in 1990 and Epilepsy, who experienced the serious (due to hospitalization) unexpected, events of COVID-19 (AESI), status epilepticus, septic shock, deafness, headache, dizziness, pyrexia and catarrh, approximately 4 to 21 days after the mRNA-1273 vaccine, received as the third dose of COVID-19 vaccination. A COVID-19 PCR test positive was reported 10 days after the vaccination. Additionally, vaccination failure was reported in this case, although the first two doses were Comirnaty (interchange of vaccine products is considered) and the COVID-19 was diagnosed 11 days after the mRNA-1273 vaccine. The mentioned medical history remain as confounders for the event status epilepticus. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.				
[redacted]	This case was initially received via Takeda Pharmaceuticals (Reference number: [redacted] on 16-Feb-2022. The most recent information was received on 16-Mar-2022 and was forwarded to Moderna on 24-Mar-2022. This case, initially reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by a physician, was received via the PMDA (Ref, [redacted]. On 16-Mar-2022, follow-up information was received from a physician. On an unknown date, the patient received the 1st dose of non-company coronavirus modified uridine RNA vaccine (SARS-CoV-2). On an unknown date, the patient received the 2nd dose of non-company coronavirus modified uridine RNA vaccine (SARS-CoV-2). On 12-Feb-2022, the patient received the 3rd vaccination with this vaccine. On 13-Feb-2022, around 16:00, consciousness disturbed developed. The patient was found collapsed and was transported by ambulance. The patient was suspected to have developed heat illness in a hot environment due to difficulty moving	level 5	unassessable	A physician reported case concerned a 76-year-old male who experienced Altered state of consciousness, Cerebral infarction, Heat illness, Movement disorder, Multiple organ dysfunction syndrome, and Shock on 13-Feb-2022, one day after he received the 3rd vaccination of mRNA-1273. He received two prior doses of non-company coronavirus modified uridine RNA vaccine on unknown dates. Medical history included diabetes mellitus and atrial fibrillation. The cause of the heat illness was said due to a fall in a bedrock bath facility. A CT showed the possibility of multiple cerebral infarctions but could not be confirmed. There was a suspected cerebral infarction due to chronic atrial fibrillation. He passed away on 14-Feb-2022 with the cause of death of heat illness. The case did not report a MIS-A, and no detail information to support a MIS-A. Based on the limited info provided, the clinical presentation may be that underlying atrial fibrillation led to suspected cerebral infarction led to	[redacted]

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	due to an unforeseen accident or a preceding disease. The patient was already in multi-organ failure, in shock, and difficult to save the patients life. CT showed the possibility of multiple cerebral infarctions but could not be confirmed. There was a suspected cerebral infarction due to chronic atrial fibrillation. On 14-Feb-2022, the patient was confirmed dead. The cause of death was heat illness. No autopsy was performed. The outcome of consciousness disturbed, possible multiple cerebral infarctions, difficulty in moving, suspected heat illness, multi-organ failure and shock was reported as fatal. No follow-up investigation will be made. Reporter's comment: The causal relationship between the progress and this vaccination is unknown. There is a possibility that cerebral infarction caused the difficulty in moving, resulting in heat illness, but the possibilities that the cause was atrial fibrillation, that the cerebral infarction was a result rather than a cause, and that the patient had no cerebral infarction from the beginning were also cannot be ruled out. Other factors include the possibility of suspected cerebral infarction due to chronic atrial fibrillation. The relationship between cause of death and adverse events is unknown. The cause of the heat illness was a fall in a bedrock bath facility, which may have been caused by cerebral infarction. Since it cannot be denied that cerebral infarction may be caused by thrombosis or chronic atrial fibrillation due to vaccination with this vaccine, it is unclear whether the occurrence of adverse events is temporally related to the timing of administration of this vaccine. The occurrence of adverse events may be associated with pathological factors of chronic atrial fibrillation. Neither the presence or absence of cerebral infarction nor the association of cerebral infarction with this vaccination, if any, can be determined. Follow-up received on 16-MAR-2022 Updated: Patient Information, Other Relevant History, Lab Data, Event Information, Narrative, Reporter Comments LP Company Comment: As for heat illness, the event developed after the administration of ELASOMERAN, but it could also be due to the patient's environment, or other influences. As for cerebral infarction, the event developed			altered consciousness and falling in a bedrock bath facility to cause heat illness, which led to shock, multiple organ dysfunction and death, in this elderly diabetic patient with atrial fibrillation. The case is considered level 5 for MIS-A due to an alternative etiology. It is thought to be unassessable because of the underlying risks, despite the TTO of 1 day.	

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	after the administration of ELASOMERAN, but it could also be due to the patient's medical history or concurrent events, or other influences. Company comment: This spontaneous case concerns a 76-year-old, male patient with medical history of Diabetes mellitus and Atrial fibrillation, who experienced unexpected serious events of Cerebral infarction (seriousness criterion: Fatal, Hospitalisation, Medically significant), Heat illness (seriousness criterion: Fatal, Hospitalisation, Medically significant), Multiple organ dysfunction syndrome (seriousness criterion: Fatal, Medically significant), Shock (seriousness criterion: Fatal, Medically significant), Movement disorder (seriousness criterion: Fatal, Hospitalization) and Altered state of consciousness (seriousness criterion: Fatal, Hospitalisation, Medically significant). It was reported that a day after receiving the mRNA-1273 vaccine (as third dose), the patient developed disturbed consciousness. The patient was found collapsed and was transported by ambulance. The patient was suspected to had developed heat illness in a hot environment due to difficulty moving due to an unforeseen accident or a preceding disease. The patient was already in multi-organ failure and shock. CT showed the possibility of multiple cerebral infarctions due to chronic atrial fibrillation, but it could not be confirmed. The cause of death was heat illness and no autopsy was performed. The outcome of consciousness disturbed, possible multiple cerebral infarctions, difficulty in moving, suspected heat illness, multi-organ failure and shock was reported as fatal. Underlying medical history of atrial fibrillation remains a major confounder for Cerebral infarction which could contribute to movement disorder and altered state of consciousness. The patient's elderly age remains an additional confounder. Having in mind that this patient received Comrinaty vaccine prior to vaccination with the company product, Interchange of vaccine products should have been considered in this specific case. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report.				
[redacted]	This case was initially received via European Medicines Agency (Reference number: [redacted] on 17-Feb-2022. The most recent information was received on	level 4	unassessable	A physician reported case concerned a 74-year-old male patient who experienced anuria, multiple organ dysfunction syndrome and septic shock on 30-Jan-2022, 8	[redacted]

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	07-Mar-2022 and was forwarded to Moderna on 07-Mar-2022. This regulatory authority case was reported by a physician and describes the occurrence of ANURIA (anuria, urinary septic shock with MOF, cardiopathic, diabetic, AOCP), MULTIPLE ORGAN DYSFUNCTION SYNDROME (anuria, urinary septic shock with MOF, cardiopathic, diabetic, AOCP) and SEPTIC SHOCK (anuria, urinary septic shock with MOF, cardiopathic, diabetic, AOCP) in a 74-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3005887) for COVID-19 vaccination. The patient's past medical history included Respiration failure on 01-Nov-2015, Amnestic disorder, Recovered smoker (end date- 01-Jan-1992), Septicaemia (01/10/2021: admitted again for septicemia) on 01-Jan-2020, Diaphragmatic hernia, Obstructive arteriosclerosis of lower extremities on 01-Sep-2021, Aortic valve replacement, Lactic acidosis (iatrogenic) on 01-Aug-2015, Hypertensive heart disease, Anemia (severe enteric loss anemia) on 01-Aug-2015, Hyperuricaemia, Hepatic steatosis on 01-Jan-2010, Acute pulmonary oedema on 01-Jan-2007, Cerebral infarct on 01-Jan-2007 and Femur fracture (dx) on 01-Jan-1972. Previously administered products included for SARS-CoV-2 immunisation: COMIRNATY (BIONTECH MANUFACTURING GMBH) (J07BX03) on 06-Apr-2021 and COMIRNATY (BIONTECH MANUFACTURING GMBH) (J07BX03) on 27-Apr-2021. Past adverse reactions to the above products included No adverse event with COMIRNATY (BIONTECH MANUFACTURING GMBH) (J07BX03) and COMIRNATY (BIONTECH MANUFACTURING GMBH) (J07BX03). Concurrent medical conditions included Diabetic retinopathy, Insulin-requiring type 2 diabetes mellitus on 01-Jan-2007, Hypertension arterial and Atrial fibrillation. Concomitant products included INSULIN GLARGINE (TOUJEO), ATORVASTATIN CALCIUM (TORVAST), ACETYLSALICYLIC ACID (CARDIOASPIRIN), DIGOXIN (LANOXIN), APIXABAN (ELIQUIS), FUROSEMIDE (LASIX P), SERTRALINE, POTASSIUM CANRENOATE (KANRENOL), BISOPROLOL FUMARATE (SEQUACOR), LANSOPRAZOLE			days after he received a dose of mRNA-1273. Medical history included respiration failure, amnestic disorder, previous smoker, septicemia, obstructive arteriosclerosis of lower extremities, aortic valve replacement, lactic acidosis (iatrogenic), hypertensive heart disease, hyperuricemia, hepatic steatosis, acute pulmonary oedema, cerebral infarct. Concurrent medical conditions included Insulin-requiring type 2 diabetes mellitus, hypertension arterial and atrial fibrillation. Previous SARS-CoV-2 immunization with COMIRNATY on 06-Apr-2021 and 27-Apr-2021. He died on 10-Feb-2022 with shock septic as a reported cause of death. Relevant and meaningful lab tests were unavailable. The case did not report a MIS-A. septic shock may be one of the clinical presentation of MIS-A. however, detail information of clinical features and labs were not provided for assessment of the MIS. The case is considered level 4 for MIS-A due to lack of information for evaluating or differentiating a diagnosis. A causal relation between vaccination and the events are thought to be unassessable because of the unclear clinical process in this elderly patient with multiple underlying diseases, despite a TTO of 8 days.	

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	(LANSOX) and INSULIN ASPART (NOVORAPID) for an unknown indication. On 22-Nov-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) .25 milliliter. On 30-Jan-2022, the patient experienced ANURIA (anuria, urinary septic shock with MOF, cardiopathic, diabetic, AOCP) (seriousness criterion death), MULTIPLE ORGAN DYSFUNCTION SYNDROME (anuria, urinary septic shock with MOF, cardiopathic, diabetic, AOCP) (seriousness criterion death) and SEPTIC SHOCK (anuria, urinary septic shock with MOF, cardiopathic, diabetic, AOCP) (seriousness criterion death). The patient died on 10-Feb-2022. The reported cause of death was Shock septic. An autopsy was not performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 30-Jan-2022, Blood test: inconclusive (Inconclusive) Inconclusive. On 30-Jan-2022, Chest X-ray: inconclusive (Inconclusive) Inconclusive. On 30-Jan-2022, SARS-CoV-2 test negative: inconclusive (Inconclusive) Inconclusive. On 30-Jan-2022, Vital signs measurement: inconclusive (Inconclusive) Inconclusive. On 31-Jan-2022, Blood gases: inconclusive (Inconclusive) Inconclusive. On an unknown date, Ultrasound scan: inconclusive (Inconclusive) Inconclusive. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Reporter states first dose on 06/04/2021 comirnaty vaccine lot: et7205 sc: 31/07/2021, the second dose on 27/04/2021 comirnaty vaccine lot: ex3599 sc: 31/08/2021. Concomitant pathologies includes diabetes mellitus, heart disease and aocp. Company Comment: This is a Regulatory case concerning a				

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	74-year-old male patient with interchange of vaccine administration (COVID-19 vaccine, 2 doses of Comirnaty 6-7 months (interval of 21 days) prior to mRNA-1273 dose and medical history of Septicaemia (recurrence: 2020 & Oct 2021), Obstructive arteriosclerosis of lower extremities (2021), Aortic valve replacement, Severe enteric loss anemia (2015), Hepatic steatosis (2010), Hyperuricaemia, Acute pulmonary oedema (2007), Cerebral infarct (2007), and concurrent Type 2 diabetes mellitus (15y), Diabetic retinopathy, Hypertension arterial, Atrial fibrillation, Heart disease and AOCP. The patient experienced the serious fatal unexpected events of Anuria (AESI), Multiple Organ Dysfunction Syndrome and Septic shock. The events occurred approximately 2 months 9 days after a dose of mRNA-1273 received as the third dose for COVID-19 Vaccination. The patient died on 10-Feb-2022 (11 days after events onset). The reported cause of death was Shock septic. An autopsy was not performed. Diagnostic workup (Blood test, Chest X-ray, Vital signs, blood gases) was reported with inconclusive results, however an urinary origin of the septic shock was described. Treatment information was not provided. The increased risk of developing infections and sepsis due to type 2 diabetes remains a confounder. Suggestive urinary tract infection could be contributory for septic shock. Septic shock is a contributing cause of MODS and anuria. Patient's advanced age, vast comorbidities and heart disease remain as confounders and increase risk for fatal outcome. Moreover case could be confounded by polypharmacy. The benefit-risk relationship of COVID-19 Vaccine Moderna (mRNA-1273) is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 04-Mar-2022: Follow Up received with Non-Significant information. On 07-Mar-2022: Follow up received contains medical history, concomitant medications and event details.				
[redacted]	This case was received via European Medicines Agency (Reference number: [redacted] on 23-Feb-2022 and was forwarded to Moderna on 23-Feb-2022. This regulatory authority case was reported by a physician and describes the occurrence of SEPTIC SHOCK (Septic shock), AORTIC THROMBOSIS (Thoracic aortic	level 4	unlikely	A physician reported case concerned a 71-year-old male patient who septic shock, aortic thrombosis and micro-embolism on 30-Sep-2021, about 79 days after he received second dose of mRNA-1273. Medical history included Bowen's disease, Obstruction lung disease, Bronchitis, Hypertension arterial, Gout flare and Gilbert's	[redacted]

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	thrombus) and MICROEMBOLISM (Embolic shower) in a 71-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 214009) for COVID-19 vaccination. The patient's past medical history included Bowen's disease, Benign prostatic hyperplasia, Nasal polyps, Obstruction lung disease, Bronchitis, Traumatic blindness, Hypertension arterial, Hernia hiatal, Gout flare and Gilbert's syndrome. On 13-Jul-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) .5 milliliter. On 30-Sep-2021, the patient experienced SEPTIC SHOCK (Septic shock) (seriousness criterion life threatening), AORTIC THROMBOSIS (Thoracic aortic thrombus) (seriousness criteria hospitalization and life threatening) and MICROEMBOLISM (Embolic shower) (seriousness criterion life threatening). At the time of the report, SEPTIC SHOCK (Septic shock) and AORTIC THROMBOSIS (Thoracic aortic thrombus) had resolved and MICROEMBOLISM (Embolic shower) had not resolved. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medication was reported. No treatment medication was reported. Company comment: This case concerns a 71-year-old male patient with no relevant medical history reported, who experienced the unexpected, serious (life-threatening and hospitalization) events of septic shock, aortic thrombosis (AESI) and microembolism (AESI) 79 days after the second dose of mRNA-1273. Information regarding clinical evaluation, diagnostic tests and treatment provided has not been disclosed. Seriousness assessment has been retained as per Regulatory Authority reporting. The benefit-risk relationship of mRNA-1273 is not affected by this report.			syndrome. No concomitant and treatment medication were reported. The case did not report a MIS-A, or provide details for evaluate a MIS-A. The limited information is insufficient to define or differentiate the case. It is considered level 4 for MIS-A, and unlikely for a vaccine and event causal relation due to an unknown nature and process of the conditions, in addition to the TTO of 79 days.	

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
[redacted]	This case was initially received via Takeda Pharmaceuticals (Reference number: [redacted]) on 21-Feb-2022. The most recent information was received on 25-Mar-2022 and was forwarded to Moderna on 30-Mar-2022. This case was presented in "The 673rd Kanto Regional Meeting of the Japanese Society of Internal Medicine". Since the proprietary name of the suspect drug was not specified, the drug is handled as a Takeda product in this case report. Pancytopenia, bilateral pneumonia, function kidney decreased, septic shock, multi-organ failure, and acute circulatory failure were assessed as serious by the MAH. Follow-up information revealed that ELASOMERAN (product name: "COMIRNATY intramuscular injection") was not a Takeda product. A 79-year-old female patient. [History of present illness] The patient visited with chief complaint of difficulty retention sitting to our reporting hospital. Since subcutaneous haemorrhage in right occipital lobe and bilateral subdural haemorrhage were noted, the patient was admitted to the brain surgery department of the hospital. [Clinical courses] Covid-19 vaccine (proprietary name unknown) was vaccinated 14 days after the hospitalization following the states were stabilized. The patient experienced pyrexia in the night of the same day. The patient had been on the treatments for urinary tract infection, but general condition was aggravated. Therefore, the patient was transferred to this department. Bilateral pneumonia on the imaging, decreased kidney and hepatic functions, pancytopenia, new cerebral haemorrhage were noted. Fourth day of the onset, the patient was monitored on ventilator. Although the patient had been on the treatments for multi-organ failure, acute circulatory failure caused by septic shock, she died on the same day. After obtaining the family's agreement, pathologic autopsy was performed. Direct cause of the death was cerebral haemorrhage, but pancytopenia caused by covid-19 vaccination adverse reaction was suggested in pathological findings. Follow-up investigation will be made. Follow-up received on 25-MAR-2022 Updated: Narrative Company Comment: The events developed after the administration of elasomeran and there is temporal relationship.	level 5	unassessable	This was a presentation in a Regional Medical meeting, in which the original info was included in the narrative. The case concerned a 79-year-old female who experienced pancytopenia, bilateral pneumonia, function kidney decreased, septic shock, multi-organ failure, and acute circulatory failure after she received ELASOMERAN. The patient was hospitalized initially for a chief complaint of difficulty retention sitting, with a subcutaneous hemorrhage in right occipital lobe and bilateral subdural hemorrhage. She was vaccinated 14 days after the hospitalization and experienced pyrexia in the night of the same day. The patient had been on the treatments for urinary tract infection, but general condition was aggravated. Bilateral pneumonia on the imaging, decreased kidney and hepatic functions, pancytopenia, and new cerebral hemorrhage were noted. Fourth day of the event onset, she was on ventilator, and passed away during the treatments for multi-organ failure, septic shock induced acute circulatory failure on the same day. An autopsy revealed that cerebral hemorrhage was the direct cause of death, and pancytopenia caused by covid-19 vaccination was suggested in pathological findings. The case did not report a MIS-A. based on the limited information, the patient was hospitalized due to cerebral and subdural hemorrhage before vaccination. She was also suffering urinary tract infection at the time. No information regarding MIS-A was available for evaluation especially the labs. Her fever may be associated with bilateral pneumonia and urinary tract infection. The infectious origin in this brain hemorrhaged elderly patient may lead to septic shock, pancytopenia and further to multi organ failure including kidney and liver. Therefore, the clinical picture was more likely confounded by the brain hemorrhage and infections. It may be challenging to know whether the vaccination could contribute to the event development at present, as the TTO of same day for the first event fever could well be due to concurrent lung and urinary infections. The case is considered level 5 for MIS-A, and considered conservatively unassessable for WHO categories.	[redacted]
[redacted]	This case was received via European Medicines Agency (Reference number: [redacted]) on 28-Feb-2022 and was forwarded to Moderna on 28-Feb-2022.	level 5	unassessable	A physician reported case concerned a 69-year-old male patient who experienced meningitis and multiple organ dysfunction syndrome with a fatal outcome above the	[redacted]

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	This regulatory authority case was reported by a physician and describes the occurrence of MENINGITIS (Meningitis) and MULTIPLE ORGAN DYSFUNCTION SYNDROME (Multiple organ failure) in a 69-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. Date of death not given. First result of the autopsy with proof unspec. Coatings on the meninges in the sense of meningitis. Previously administered products included for COVID-19 vaccination: COMIRNATY and COVID-19 VACCINE ASTRAZENECA (Vaxzevria). Past adverse reactions to the above products included No adverse event with COMIRNATY and COVID-19 VACCINE ASTRAZENECA. On 16-Jan-2022, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 16-Jan-2022, the patient experienced MENINGITIS (Meningitis) (seriousness criteria death, hospitalization and life threatening) and MULTIPLE ORGAN DYSFUNCTION SYNDROME (Multiple organ failure) (seriousness criteria death, hospitalization and life threatening). The reported cause of death was Multiple organ failure. An autopsy was performed. The autopsy-determined cause of death was Meningitis. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. Concomitant medications were not provided. Treatment information was not provided. Company comment: This is a regulatory case concerning a 69 year-old, male patient with no reported medical history, who experienced the fatal serious unexpected, events of meningitis (AESI) and Multiple organ dysfunction syndrome, the same day after the mRNA-1273 vaccine, received as the booster dose of the COVID-19 vaccination			same day after he received third dose of mRNA-1273. He previously received Covid 19 vaccine with COMIRNATY and Vaxzevria. Medical history, co-meds and treatment info were unavailable. Date of death was not provided. Autopsy reported an unspecific with meningitis as cause of death. The case did not report a MIS-A, and provide limited information relevant to MIS-A. The autopsy confirmed meningitis as the cause of death. No information on if autopsy included findings for multiple organ dysfunction. So, the clinical presentation was more likely a meningitis and not MIS-A. Because no information on prior and concurrent conditions was available, it may be hard to evaluate a causal relation between vaccine and event development, despite a TTO of the same day. The case is considered unassessable for WHO categories.	

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	schedule. Patient´s death date was not provided but the duration of both events was reported as 2 days. The autopsy determined cause of death was meningitis and an additional cause of death reported in the case was Multiple organ dysfunction syndrome. Additionally, Interchange of vaccine products was noted in the case, vaccination with a dose of COVID-19 vaccine Tozinameran and a dose of NRVV AD (CHADOX1 NCOV-19) no dates provided. No further clinical information was available for medical review. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.				
[redacted]	This literature-non-study case was reported in a literature article and describes the occurrence of MULTISYSTEM INFLAMMATORY SYNDROME IN ADULTS (multisystemic inflammatory syndrome (MIS-A)) in a 73-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. LITERATURE REFERENCE: Morataya C, Pertuz GDR, Parmar K, Pawar D, Nugent K. Post-immunization multisystemic inflammatory response in non-COVID patient. J Investig Med. 2022;70(2):695 Concurrent medical conditions included Diabetes, Atrial fibrillation, Hypertension and Hyperlipidemia. On an unknown date, the patient received dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On an unknown date, the patient experienced MULTISYSTEM INFLAMMATORY SYNDROME IN ADULTS (multisystemic inflammatory syndrome (MIS-A)) (seriousness criteria hospitalization and medically significant). The patient was treated with DESMOPRESSIN ACETATE (DESMOPRESSIN [DESMOPRESSIN ACETATE]) for Hyponatremia, at an unspecified dose and frequency. At the time of the report, MULTISYSTEM INFLAMMATORY SYNDROME IN ADULTS (multisystemic inflammatory syndrome (MIS-A)) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):	level 4	possible	This literature case report concerned a 73-year-old male with a past medical history of diabetes, atrial fibrillation, hypertension, and hyperlipidemia, started with weakness, low appetite, fever, chills, and headaches 2 days after receiving the Moderna vaccine. COVID-19 test was negative. Physicals revealed afebrile. Laboratories showed WBC of 35.16 K/µL, sodium of 120 mmol/L, alanine transaminase of 84 IU/L, and aspartate transaminase of 116 IU/L. The patient denied having unintentional weight loss, fever, adenopathy, rash, pruritus, new medications, or recent infection. Chest x-ray did not show pleural effusion, consolidation or pneumothorax. his hepatitis panel was negative. Peripheral blood smear showed normocytic anemia, neutrophilia, monocytosis, lymphopenia, and thrombocytosis. Workup for myeloproliferative process including Jak2, CALR, MPL, BCR -ABL, was negative. Blood and urine cultures were negative. The patient was briefly transferred to ICU secondary to worsening hyponatremia, decreased mental status, and acute kidney injury (AKI). He developed erythematous non-pruritic rash on his arms and upper chest on day 13 which resolved after oral antihistamines. Transaminitis, hyponatremia, and AKI resolved, and patient was discharged 18 days later with WBC of 14.42 K/µL. The case provided insufficient information, especially for fever, eg, reported fever but was afebrile. It did not show two or more clinical features for MIS-A, no lab evidence of inflammation and measures of disease activities such as elevated BNP, NT-proBNP or troponin, echocardiography of cardiac involvement or heart failure or EKG of myocarditis or myo-pericarditis were available. His thrombocytosis was also inconsistent with	[redacted]

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	On an unknown date, Alanine aminotransferase: 84 iu/l 84 IU/L. On an unknown date, Aspartate aminotransferase: 116 iu/l 116 IU/L. On an unknown date, Blood culture: negative (Negative) Negative. On an unknown date, Blood smear test: abnormal (abnormal) showed normocytic anemia, neutrophilia, monocytosis, lymphopenia,and thrombocytosis. On an unknown date, Blood sodium: 120 mmol/l 120 mmol/L. On an unknown date, Chest X-ray: normal (normal) Chest x-ray did not show pleural effusion, consolidation or pneumothorax. On an unknown date, Culture urine: negative (Negative) Negative. On an unknown date, SARS-CoV-2 test: negative (Negative) COVID-19 antigen was negative and negative (Negative) COVID-19 PCR Test was negative. On an unknown date, Ultrasound liver: ruled out cirrhosis Liver ultrasound ruled out cirrhosis. On an unknown date, White blood cell count: 35.16 k/mul 35.16 K/muL, elevated white blood cell count and 14.42 k/mul discharged 18 days later with WBC of 14.42 K/muL. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown) was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter considered MULTISYSTEM INFLAMMATORY SYNDROME IN ADULTS (multisystemic inflammatory syndrome (MIS-A)) to be related. Patient had no prior history of COVID infection. Patient presented to the Emergency Department secondary to an elevated white blood cell count. Patient started with weakness, low appetite, fever, chills, and headaches 2 days after receiving the Moderna vaccine and was hemodynamically stable and afebrile. Patient			thrombocytopenia for MIS-A. The case is considered level 4 for MIS-A. It is considered possible for WHO categories, because weakness, fever, chills, and headaches are all listed adverse reactions for Moderna vaccine in addition to a TTO of 2 days.	

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	denied having unintentional weight loss, fever, adenopathy, rash, pruritus, new medications, or recent infection. Patient was started on broad spectrum antibiotics, and on hypertonic saline, fluid restriction for severe hyponatremia. Laboratory tests included hepatitis panel test which was negative and workup for myeloproliferative process including Jak2, CALR, MPL, BCR -ABL, was also negative. Patient was briefly transferred to ICU secondary to worsening hyponatremia, decreased mental status, and acute kidney injury(AKI). Patient developed erythematous non-pruritic rash on his arms and upper chest on day 13 which resolved after oral antihistamines. Transaminitis, hyponatremia, and AKI resolved, and patient was discharged 18 days later. CC: This is a Literature-Non-Study case concerning a 73-year-old male patient, with no relevant medical history who experienced the serious (hospitalized and medically significant), unexpected AESI of Multisystem inflammatory syndrome in adults on an unknown date, approximately 2 days after the administration of a dose of the mRNA-1273 vaccine. Testing sowed neutropenia, monocytosis, leukopenia, thrombocytosis, hyponatremia, increased liver enzymes and elevated WBC along with normal hepatitis screen, CXR and ultrasound of the liver. Treatment was with desmopressin and antihistamines. The event is resolving. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 01-Mar-2022: Significant FU: Follow up received by safety on 02-Mar-2022 has Email from SARA team and contains significant information. Citation details updated (additional authors name and publication year) and onset latency added				
[redacted]	This case was initially received via Takeda Pharmaceuticals (Reference number: [redacted] on 28-Feb-2022. The most recent information was received on 22-	level 4	unassessable	A physician reported case concerned a 62-year-old male who experienced Circulatory collapse, Coagulopathy, Dehydration, Fall, Hepatic function abnormal,	[redacted]

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	Mar-2022 and was forwarded to Moderna on 29-Mar-2022. This case, reported to the [redacted] by a physician, was received via the [redacted] (Ref, [redacted]). On 22-Mar-2022, follow-up information was received from a physician. On an unknown date, the patient received the 1st dose of non-company coronavirus modified uridine RNA vaccine (SARS-CoV-2). On an unknown date, the patient received the 2nd dose of non-company coronavirus modified uridine RNA vaccine (SARS-CoV-2). On 18-Feb-2022, the patient received the 3rd vaccination with this vaccine to the left arm. After the administration, pain in the left arm developed. On 19-Feb-2022, pain in the left arm continued. Generalized pain developed. On 20-Feb-2022, the patient had an anemia-like symptom and fell down several times. In the early evening, the patient complained of muscle cramps in the extremities. On 21-Feb-2022, in the morning, the patient stood up but was unable to move. In the afternoon, a family member found the patient unable to move with fall at home. The patient was raced to the reporting hospital. The level of consciousness on arrival was JCS 10. The color of the trunk and extremities was suggestive of circulatory failure. Respiratory rate was 40 times with unmeasurable SpO2. Blood gases showed marked metabolic acidosis and hypoglycemia, and the patient was in a state of shock with blood pressure in the range of 70 mmHg. Blood samples showed marked intravascular dehydration, hepatic and renal function impairment, and coagulation abnormalities including high D-dimer levels, raising suspicion of thrombosis. Glucose was administered, and administration of extracellular fluid at the full rate was also performed. Whole body CT scan showed no obvious abnormality, but the patient was in a state of shock of unknown cause and also had multi-organ failure; therefore, the patient was transferred to an altitude emergency and critical care medical center. On an unknown date, a surgery was performed for non-occlusive mesenteric ischemia. The possibility of occurrence of systemic thrombosis of some kind was suspected. The outcome of generalized pain, collapsed, muscle cramps in the extremities, circulatory failure, metabolic acidosis, hypoglycemia, shock, intravascular dehydration, hepatic and renal impairment, coagulation abnormal, multi-organ failure, non-occlusive mesenteric ischemia, and possibility			Hypoglycemia, Intestinal ischemia, Metabolic acidosis, Multiple organ dysfunction syndrome, Muscle spasms, Pain, Renal impairment, Shock, Thrombosis after he received the 3rd vaccination with ELASOMERAN on 18-Feb-2022. He experienced pain in the injection arm on the same day, and a generalized pain next day. He fell down several times, complained of muscle cramps in the extremities, and was unable to move. The level of consciousness on arrival was JCS 10 (Arousable by being spoken to). The color of the trunk and extremities was suggestive of circulatory failure. Respiratory rate was 40 times with unmeasurable SpO2. Blood gases showed marked metabolic acidosis and hypoglycemia, and the patient was in a state of shock with blood pressure in the range of 70 mmHg. Blood samples showed marked intravascular dehydration, hepatic and renal function impairment, and coagulation abnormalities including high D-dimer levels, raising suspicion of thrombosis. Glucose was administered, and administration of extracellular fluid at the full rate was also performed. Whole body CT scan showed no obvious abnormality, but the patient was in a state of shock of unknown cause and also had multi-organ failure. On an unknown date, a surgery was performed for non-occlusive mesenteric ischemia. The possibility of occurrence of systemic thrombosis of some kind was suspected. The case did not report a MIS-A. A shock may present in MIS-A. however, based on the limited information, it was challenging for evaluation of the nature and progress for the clinical presentations. The patient provided no prior and concurrent medical history. He experienced hypoglycemia, marked metabolic acidosis, dehydration, liver and kidney injury, likely due to shock of unknown cause. A mesenteric surgery on unknown date may confound the conditions. Due to insufficient information provided, it may be unable to evaluate or differentiate a disease definition. The case is considered level 4 for MIS-A. because of limited information and unclear nature and progress of the clinical condition, a vaccine and event causal relation may be unassessable.	

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	of systemic thrombosis was unknown. The outcome of hepatic and renal impairment was unchanged and ongoing. No follow-up investigation will be made. Reporter comments continuation: It is unknown whether the occurrence of adverse events was related to concomitant drugs. It is unknown whether the occurrence of adverse events was related to pathological factors of underlying diseases and complications. The patient was in poor general condition and was urgently transferred to an altitude emergency and critical care medical center, so details of the clinical course was unable to be checked at the reporting hospital. As D-dimer level was high and it was reported that surgery was performed for non-occlusive mesenteric ischemia at the hospital where the patient was transferred, the possibility of systemic thrombosis of some kind was suspected. Follow-up received on 22-MAR-2022 Updated: Patient Information, Lab Data, Event Information, Narrative, Reporter Comments Company Comment: The events developed after the administration of ELASOMERAN and there is temporal relationship. Sender's comments: The events developed after the administration of ELASOMERAN and there is temporal relationship.				
[redacted]	This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOSITIS (1.Right hand interstitial myositis (M60.141) 2. Multisystem inflammatory syndrome may related to Moderna vaccination induced cytokine storm (M35.81) Multisystem inflammatory syndrome was caused by Moderna vaccination.) and MULTISYSTEM INFLAMMATORY SYNDROME IN ADULTS (1.Right hand interstitial myositis (M60.141) 2. Multisystem inflammatory syndrome may related to Moderna vaccination induced cytokine storm (M35.81) Multisystem inflammatory syndrome was caused by Moderna vaccination.) in a 51-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. On 15-Jan-2022, the patient received third dose of mRNA-	level 5	possible	A health care professional reported case concerned a 51-year-old male patient who experienced myositis and multisystem inflammatory syndrome in adults on 17-Jan-2022, about 2 days after he received third dose of mRNA-1273. No Medical History information was reported but has no allergy history. He received two prior Moderna vaccine on 06/10/2021 and 07/14/2021. Two days after the third dose, he developed right hand swelling and painful erythema which were also found over his bilateral thighs, right ankle and right foot dorsal part. Severe chills attacked intermittently, but no real fever was noted. He was on regular upadacitinib, apixaban, celebrex, acroxia, ultracept for 2 weeks. Although the case reported MIS-A, there was no fever, and no lab evidence of inflammation and measures of disease activity were provided. It did not provide the evidence to support diagnosis of myositis. The presence of selling and erythema could be related to allergic reaction, as allergic reactions even acute anaphylactic reaction was one of the warnings and precautions for mRNA-1273. The case was considered	[redacted]

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 17-Jan-2022, the patient experienced MYOSITIS (1.Right hand interstitial myositis (M60.141) 2. Multisystem inflammatory syndrome may related to Moderna vaccination induced cytokine storm (M35.81) Multisystem inflammatory syndrome was caused by Moderna vaccination.) (seriousness criterion hospitalization) and MULTISYSTEM INFLAMMATORY SYNDROME IN ADULTS (1.Right hand interstitial myositis (M60.141) 2. Multisystem inflammatory syndrome may related to Moderna vaccination induced cytokine storm (M35.81) Multisystem inflammatory syndrome was caused by Moderna vaccination.) (seriousness criterion hospitalization). At the time of the report, MYOSITIS (1.Right hand interstitial myositis (M60.141) 2. Multisystem inflammatory syndrome may related to Moderna vaccination induced cytokine storm (M35.81) Multisystem inflammatory syndrome was caused by Moderna vaccination.) and MULTISYSTEM INFLAMMATORY SYNDROME IN ADULTS (1.Right hand interstitial myositis (M60.141) 2. Multisystem inflammatory syndrome may related to Moderna vaccination induced cytokine storm (M35.81) Multisystem inflammatory syndrome was caused by Moderna vaccination.) was resolving. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. On 02/15/2022 Male patient was quite well; he has no allergy history. Patient received Moderna vaccine on 06/10/2021, 07/14/2021. After the half dose booster (third dose) Moderna COVID-19 vaccine on 01/15/2022, he had right hand swelling and painful erythema developed since 01/17/2022. Associated similar skin lesions were also found over his bilateral thighs, right ankle and right foot dorsal part. Severe chills attacked intermittently, especially soon after a painful episodic right hand swollen prodrome. Though no real fever was noted, extremity muscle painful weakness and painful paresthesia caused patient significant discomfort. Although with regular upadacitinib, apixaban, celebrex, acroxia, ultracept for 2 weeks,			level 5 for MIS-A due to an alternative etiology. There is a possible causal relation between vaccine and the events based on the TTO of 2 days.	

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	Company comment: This regulatory case concerns a 51-year-old male patient with no medical history reported, who experienced the unexpected serious (seriousness criterion-hospitalization) event Myositis and unexpected serious (seriousness criterion-Hospitalization) AESI event multisystem inflammation, two days after the third dose of mRNA-1273. It was reported that the patient Initially developed right hand swelling and painful erythema. Associated similar skin lesions were also found over his bilateral thighs, right ankle and right foot dorsal part. Had severe chills, especially soon after a painful episodic right hand swollen prodrome and had caused significant discomfort. The patient was treated with upadacitinib, apixaban, celebrex, acroxia, ultracept for 2 weeks, symptoms like abdominal discomfort, vomiting, exertional palpitation and dyspnea, skin rashes did not significantly go down. He was also administered with human immunoglobulin (IVIG) therapy. At the time of reporting, the events were resolving. The benefit-risk relationship of mRNA-1273 could be affected by this report. Event seriousness assessed as per Regulatory Authority reporting. Most recent FOLLOW-UP information incorporated above includes: On 25-Apr-2022: Follow up includes No new information.				
[redacted]	This case was received via European Medicines Agency (Reference number: [redacted]on 03-Mar-2022 and was forwarded to Moderna on 03-Mar-2022. This regulatory authority case was reported by a consumer and describes the occurrence of ACUTE HEPATIC FAILURE (Acute hepatic failure), AUTOINFLAMMATORY DISEASE (Autoinflammatory syndrome) and HAEMOPHAGOCYTIC LYMPHOHISTIOCYTOSIS (Macrophage activation syndrome) in an adult male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. Medical history was reported as nicotine abuse until 2019, bronchial asthma since 6 years of age and allergic to penicillin, house[redacted]	level 4	possible	A consumer reported case concerned an adult male patient of unknown age who experienced acute hepatic failure, autoinflammatory disease and hemophagocytic lymphohistiocytosis on 26-Jun-2021, same day after he received second dose of mRNA-1273. Medical history included nicotine abuse until 2019, bronchial asthma from 6 years of age and allergic to penicillin and house dust mite. Relevant concomitant medications were not reported. He started to feel discomfort on the vaccine day and had a fever up to 39.5 °C next day, which declined one day later after he took paracetamol. A general practitioner's performance showed increased liver tests. There was a slight right abdominal pressure, nausea without vomiting, light bowel movements and dark urine. Laboratory bilirubin and GPT increased. liver/spleen sonography showed splenomegaly, liver parenchyma damage and non-puncture 4 quadrant ascites. The case provided insufficient information to fit MIS-A criteria	[redacted]

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	On 26-Jun-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 26-Jun-2021, the patient experienced ACUTE HEPATIC FAILURE (Acute hepatic failure) (seriousness criteria hospitalization and life threatening), AUTOINFLAMMATORY DISEASE (Autoinflammatory syndrome) (seriousness criteria hospitalization and life threatening) and HAEMOPHAGOCYTIC LYMPHOHISTIOCYTOSIS (Macrophage activation syndrome) (seriousness criteria hospitalization and life threatening). At the time of the report, ACUTE HEPATIC FAILURE (Acute hepatic failure), AUTOINFLAMMATORY DISEASE (Autoinflammatory syndrome) and HAEMOPHAGOCYTIC LYMPHOHISTIOCYTOSIS (Macrophage activation syndrome) outcome was unknown. The action taken with mRNA-1273 (Spikevax) (Intramuscular) was unknown. Relevant concomitant medications were not reported. Acute liver failure, especially autoinflammatory syndrome, DD macrophage activation syndrome in z-n. The patient had begun with a feeling of discomfort on 26-Jun-2021. On that day, the 2nd COVID-19 vaccination took place at 4 pm. The following day there was a fever of up to 39.5 °C, so that the intake of 2-3 St. paracetamol (500 mg) took place. The next day, the fever had already declined. A general practitioner's performance showed increased liver tests. After a sonography at the family doctor, the hospital was then hospitalized. Afterwards, inpatient stay until 06-Aug-2021, in case of acute liver failure of unclear etiology. Initially, there was a slight right abdominal pressure, nausea without vomiting, light bowel movements and dark urine. Subjective freedom of complaints over the course. Laboratory values in domo (from 16-Jul-2021), initial was bilirubin max. 33.8 mg/dl, quick minimum 28.7%, got increased up to 2656 u/l, GPT up to 2848 u/l increases liver/spleen sonography from 19-Jul-2021, inconspicuous			other than a fever, which could be one of the known vaccine adverse reactions. A fever and splenomegaly may present in reported hemophagocytic lymphohistiocytosis. However, the information provided did not fit diagnosis criteria either. The case is considered level 4 for MIS-A due to limited information. A causal relation for WHO may be possible based on the TTO of about 1 day for fever which is a known reaction for mRNA-1273.	

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	liver perfusion, Splenomegaly, liver parenchyma damage with rounded liver edge, non-puncture 4 quadrant ascites anamnestic. Company comment-This regulatory authority case concerns a male patient with unknown age with no relevant medical history reported, who experienced Serious (life threatening , hospitalization) , AESI event of acute hepatic failure and Serious (life threatening , hospitalization) , unexpected events of autoinflammatory disease , and haemopahagocytic lymphohistiocytosis which occurred on the same day post vaccination with an unknown dose of mRNA-1273 vaccine (per narration it was mentioned as the 2nd dose) . This patient initially had a feeling of discomfort after the vaccination . The next day he had fever and self medicated with paracetamol which controlled the fever. He was seen by his physician which noted increased liver tests. An ultrasound was done and he was admitted as a case of acute liver failure with unclear etiology. Laboratory values initial was bilirubin max. 33.8 mg/dl, quick minimum 28.7%, got increased up to 2656 u/l, GPT up to 2848 u/l increased, Ultrasound was: inconspicuous liver perfusion, Splenomegaly, liver parenchyma damage with rounded liver edge, non-puncture 4 quadrant ascites. Treatment details were not included in this report. At the time of this report the events outcome were reported as unknown. The benefit -risk relationship of mRNA -1273 (Moderna Covid 19 Vaccine) is not affected by this report. Events seriousness assessed per regulatory report.				
[redacted]	This case was initially received via European Medicines Agency (Reference number: [redacted] on 10-Mar-2022. The most recent information was received on 30-Mar-2022 and was forwarded to Moderna on 30-Mar-2022. This regulatory authority case was reported by a physician and describes the occurrence of SEPTIC SHOCK (acute cholecystitis and septic shock) and CHOLECYSTITIS ACUTE (acute cholecystitis and septic shock) in an 88-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 000004A) for COVID-19 vaccination. No Medical History information was reported.	level 5	unlikely	A physician reported case concerned an 88-year-old male patient who experienced septic shock and cholecystitis acute about 29 days after he received a dose of mRNA-1273 on 22-Dec-2021. No Medical History, co-meds and treatment information were reported. SARS-CoV-2 test was inconclusive. No other information was available. The case did not report MIS-A. Although septic shock may be a clinical presentation for MIS-A, it was most likely associated with cholecystitis based on the limited information. The case is considered level 5 for MIS-A due to an alternative etiology, and unlikely for WHO based on the TTO of over 4 weeks.	[redacted]

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	On 22-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) .5 milliliter. On 20-Jan-2022, the patient experienced SEPTIC SHOCK (acute cholecystitis and septic shock) (seriousness criterion life threatening) and CHOLECYSTITIS ACUTE (acute cholecystitis and septic shock) (seriousness criterion life threatening). At the time of the report, SEPTIC SHOCK (acute cholecystitis and septic shock) and CHOLECYSTITIS ACUTE (acute cholecystitis and septic shock) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 04-Jan-2021, SARS-CoV-2 test: inconclusive (Inconclusive) Inconclusive. The action taken with mRNA-1273 (Spikevax) (Intramuscular) was unknown. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medications were reported. On 04-Jan-2021, the patient got positive result for Covid-19 infection. No treatment medications were reported. Company Comment: This regulatory authority case concerns an 88-year-old male patient, with unknown medical history, who experienced the unexpected serious (Life threatening) events of Acute cholecystitis and Septic shock. The events occurred 29 days after receiving a dose of mRNA-1273 vaccine, dose number not provided. There is no available information regarding clinical course and treatment medication. The patient's age remains a confounder for both events. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Company comment: This regulatory case concerns an 88-year-old, male patient with no reported medical history, who experienced the unexpected, serious (Life threatening) events of Septic shock and Cholecystitis acute. The events				

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	occurred 29 days after administration of a dose of mRNA-1273. There is no available information regarding clinical course and treatment medication. The benefit-risk relationship of mRNA-1273 is not affected by this report. Events' seriousness retained as per Regulatory Authority's report. Most recent FOLLOW-UP information incorporated above includes: On 30-Mar-2022: Significant follow-up added, lab data results updated				
[redacted]	This literature-non-study case was reported in a literature article and describes the occurrence of SYSTEMIC LUPUS ERYTHEMATOSUS (severe SLE exacerbation) in a 41-year-old female patient who received mRNA-1273 (COVID-19 Vaccine Moderna Intramuscular Injection) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. LITERATURE REFERENCE: Sugimoto T, Yorishima A, Oka N, Masuda S, Yoshida Y, Hirata S. Exacerbation of systemic lupus erythematosus after receiving mRNA-1273-based coronavirus disease 2019 vaccine. J Dermatol. 2022:1-2 Previously administered products included for Adverse event: Prednisolone (Patient was previously treated with prednisolone for fever, rash, Raynaud's phenomenon, arthritis and and leukopenia). Past adverse reactions to the above products included No adverse event with Prednisolone. Concurrent medical conditions included SLE (12-year history of systemic lupus erythematosus (SLE)) since 2009 and Erythema facial (Patient experienced slight facial erythema symptom which persisted) since February 2021. Concomitant products included HYDROXYCHLOROQUINE SULFATE (HYDROXYCHLOROQUINE ACTAVIS) for an unknown indication. On 16-Apr-2021, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna Intramuscular Injection) (unknown route) 1 dosage form.	level 5	possible	information is based on the original literature. A 41-year-old woman with a 12-year history of systemic lupus erythematosus (SLE) was previously treated with prednisolone for fever, rash, Raynaud's phenomenon, arthritis, and leukopenia. Since 2017, she had maintained a stable condition, including blood tests. She experienced a slight facial erythema symptom in February 2021, which persisted. On 16 April 2021, she received her first dose of the mRNA-1273 and developed fever and worsening erythema 2 weeks later. A butterfly rash was observed on 7 May 2021, and the anti-dsDNA titer was normal. Anti-RNP and anti- Sm were positive, but anti-Ro/ SSA and antiphospholipid antibodies were negative. The complement levels of CH50, C3 and C4, 10 were low. Following her second vaccine dose on 28 May 2021, she developed high fever, muscle pain, epistaxis, stomatitis, and facial and arm skin rash exacerbation. At 6 days after the second vaccination, she developed widespread facial erythema with digital ulcers and gangrene, and additional chest pain, hair loss and pleurisy. Laboratory tests showed white blood cell and platelet counts were low respectively. Serum levels of creatine kinase, AST, AST, LCD, and ferritin were normal. Triglycerides and fibrinogen were normal. dsDNA titer, CH50 and C3 were low, and C4 borderline. She was diagnosed with severe SLE exacerbation and was suspected of having hemophagocytic syndrome (HLH). However, no bone marrow examination was performed. Her condition improved, and she was discharged after 2 weeks following steroid treatment. The author considered injected type I interferon (IFN) production and SLE exacerbation being induced by the mRNA-1273. The case did not report MIS-A. it was more likely an	[redacted]

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	On 28-May-2021, received second dose of mRNA-1273 (COVID-19 Vaccine Moderna Intramuscular Injection) (unknown route) dosage was changed to 1 dosage form. On 28-May-2021, the patient experienced INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (Inappropriate schedule of vaccine administered). On an unknown date, the patient experienced SYSTEMIC LUPUS ERYTHEMATOSUS (severe SLE exacerbation) (seriousness criteria hospitalization and medically significant). The patient was hospitalized from 04-Jun-2021 to 17-Jun-2021 due to HAEMOPHAGOCYTIC LYMPHOHISTIOCYTOSIS, and then from sometime in 2021 to sometime in 2021 due to SYSTEMIC LUPUS ERYTHEMATOSUS. The patient was treated with PREDNISONE from May 2021 to 2021 at a dose of .3 milligram/kilogram once a day; PREDNISONE from 2021 to 2021 at a dose of 1 milligram/kilogram once a day; PREDNISONE ongoing from 2021 at a dose of 10 milligram once a day and METHYLPREDNISOLONE from 2021 to 2021 for Systemic lupus erythematosus syndrome aggravated, at a dose of 1000 milligram. On 28-May-2021, INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (Inappropriate schedule of vaccine administered) had resolved. At the time of the report, SYSTEMIC LUPUS ERYTHEMATOSUS (severe SLE exacerbation) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 07-May-2021, Physical examination: butterfly rash A butterfly rash was observed upon physical examination. In 2021, Alanine aminotransferase: 282 iu/l 282 IU/L. In 2021, Antinuclear antibody: positive (Positive) Positive, negative (Negative) Negative and positive (Positive) Positive. In 2021, Antiphospholipid antibodies: negative (Negative) Negative. In 2021, Aspartate aminotransferase: 708 iu/l 708 IU/L. In 2021, Blood creatine phosphokinase: 1072 iu/l 1072 IU/L. In 2021, Blood fibrinogen (200-400): 282 mg/dl (normal) 282 mg/dl. In 2021, Blood lactate dehydrogenase: 1724 iu/l 1724 IU/L.			exacerbation of underlying SLE. HLH was also suspected but no evidence to confirm. The case is considered level 5 due to an alternative etiology. The causal relation of vaccine and SLE exacerbation may be possible because of no other concurrent risks and a TTO of 6 days.	

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	In 2021, Blood triglycerides: 109 mg/dl 109 mg/dl. In 2021, Chest X-ray: pleural effusion Pleural effusion was observed on chest X-ray, indicating pleurisy.. In 2021, Complement factor C3 (73-138): 39 mg/dl (Low) 39 mg/dl and 46 mg/dl (Low) 46 mg/dl. In 2021, Complement factor C4 (11-31): 10 mg/dl (Low) 10 mg/dl and 11 mg/dl (normal) 11 mg/dl. In 2021, Double stranded DNA antibody (Unknown-12): 4.1 iu/ml (normal) 4.1 IU/ml and 5.2 iu/ml (normal) 5.2 IU/ml. In 2021, Platelet count: 82000/µl 82000/µl. In 2021, Serum ferritin: 9609 ng/ml 9609 ng/ml. In 2021, Total complement activity test (30-46): 18.5 u/ml (Low) 18.5 U/ml and 23.2 u/ml (Low) 23.2 U/ml. In 2021, White blood cell count: 1880/µl 1880/µl. For mRNA-1273 (COVID-19 Vaccine Moderna Intramuscular Injection) (Unknown), the reporter considered SYSTEMIC LUPUS ERYTHEMATOSUS (severe SLE exacerbation) to be related. No further causality assessment was provided for INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (Inappropriate schedule of vaccine administered). Patient's race was reported as East/Southeast Asian. No allergies were reported to medications, food, and other products. Patient has never been diagnosed with/tested positive for COVID-19 Since 2017, patient had maintained a stable condition, including blood tests. Patient received her first dose of the mRNA-1273 coronavirus disease 2019 (COVID-19) vaccine (Moderna) and developed fever and worsening erythema 2 weeks later. Following her second vaccine dose, patient developed high fever, muscle pain, epistaxis, stomatitis, and facial and arm skin rash exacerbation. Start date of exacerbation of rash was 28-May-2021 and recovery date was 25-Jun-2021, with hospitalization from 04-Jun-2021 to 17-Jun-2021. At 6 days				

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	after the second vaccination, she developed widespread facial erythema with digital ulcers and gangrene. Start date of digital ulcer and gangrene was 29-May-2021 and recovery date was 25-Jun-2021, with hospitalization from 04-Jun-2021 to 17-Jun-2021. Additionally, she experienced chest pain and hair loss. No bone marrow examination was performed. Subsequently after treatment, patient's condition improved, and she was discharged after 2 weeks. At 1 week after discharge, her fingers were healed. Prednisolone was gradually reduced to 10 mg at 3 months after discharge, at which point no disease activity was observed, including hypocomplementemia. Hydroxychloroquine was the only concomitant drug used for SLE during this period. Company Comment: This is a literature non-study case concerning a 41-year-old female patient with medical history of Systemic Lupus Erythematosus, who experienced the unexpected serious events of worsening of Systemic Lupus Erythematosus (SLE), additionally Hemophagocytic Lymphohistiocytosis was suspected. On 16 April, patient received the first dose of the mRNA-1273 vaccine and developed fever and worsening erythema 2 weeks later, both symptoms were assessed as part of SLE aggravation and treatment with prednisone was initiated. Following second vaccine dose of mRNA-1273 on 28 May 2021 (inappropriate schedule of dose administration), patient developed high fever, muscle pain, epistaxis, stomatitis, and facial and arm skin rash exacerbation. At 6 days after the second vaccination, patient developed widespread facial erythema with digital ulcers and gangrene. Additionally, she experienced chest pain and hair loss. Pleural effusion was observed on chest X-ray, indicating pleurisy. Diagnostic tests results were consistent with diagnosis of worsening of SLE and additionally Hemophagocytic syndrome was suspected. All symptoms improved after high dose of prednisolone was initiated. Patient was hospitalized for 2 weeks and was discharge with improvement. The medical history of Systemic Lupus Erythematosus remains a confounder as the patient is prone to exacerbations due the natural history of the disease. The				

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 02-Mar-2022: Follow up received by safety on 02-MAR-2022 has Email with FTA received from SARA team and contains significant information: citation details (page number), Medical History, medication history, laboratory details, treatment medication, concomitant medication, intensity and outcome of the event updated. On 16-Mar-2022: Follow up received by safety on 17-MAR-2022 has Email with FTA received from SARA team and contains significant information: Reporter information, Patient details, Medical History, Product and event details updated.				
[redacted]	This case was initially received via Takeda Pharmaceuticals (Reference number: [redacted] on 26-Feb-2022. The most recent information was received on 06-Jun-2022 and was forwarded to Moderna on an unknown date. This literature-non-study case was reported in a literature article and describes the occurrence of CARDIOGENIC SHOCK (Cardiogenic shock), MYOCARDITIS (Fulminant Myocarditis) and MULTIPLE ORGAN DYSFUNCTION SYNDROME (Multiple organ damage) in a 47-year-old female patient who received mRNA-1273 (COVID-19 Vaccine Moderna Intramuscular Injection) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. LITERATURE REFERENCE: Kazama S, Okumura T, Kimura Y, Ito R, Araki T, Mizutani T et al. Biopsy-proven fulminant myocarditis requiring mechanical circulatory support following COVID-19 mRNA vaccination. CJC Open. 2022 Kazama S, Okumura T, Ito R, Kimura H, Oishi H, Araki T, Mizutani T. A case of fulminant myocarditis diagonosed with myocardial biopsy after COVID-19 mRNA vaccination. CJC Open. 2021:103 The patient's past medical history included Veno-arterial extracorporeal membrane oxygenation (Venoarterial	level 5	possible	The information is based on the original article. A 48-year-old woman experienced persistent malaise for 1 week after receiving the second dose of mRNA-1273; dyspnea appeared on the 7th day following vaccination. The second dose was administered 28 days after the first, and she had also experienced malaise after the first dose, which had resolved spontaneously. She had no significant past medical history and was postmenopausal. She had never experienced any previous side effects to the vaccine, and there was no history of autoimmune disorders in the patient or her family. She had been taking acetaminophen since vaccination but had not used any other drug. At presentation, temperature was 36.1℃; blood pressure, 83/60 mmHg; pulse rate, 113 beats/min; respiratory rate, 24 breaths/min; and saturation, 88% on 6L of oxygen. She was pale, with cold clammy extremities. Laboratory tests showed multiple organ damage and the following; lactate, 10.8 mmol/L (normal 0.4-0.8 mmol/L); AST, 5,358 U/L (normal 13-30 U/L); ALT, 3079 U/L (normal 7-23 U/L); LDH, 4,453 U/L (normal 124-222 U/L); CK, 15,962 U/L (normal 41-153 U/L); CK-MB, 349 ng/mL (normal <5 ng/mL); and creatinine, 1.64 mg/dL (normal 0.46-0.79 mg/dL). Troponin I and brain natriuretic peptide increased to 25.2 ng/mL (normal <0.026 ng/mL) and 1,160 pg/mL (normal <18.4 pg/mL), respectively. Electrocardiogram showed ST-segment elevation in the V1–V4 inductions (Figure 1A). Echocardiography showed a diffusely decreased left	[redacted]

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	extracorporeal membrane oxygenation and Impella R support were essential in achieving hemodynamic stability. On day 4, VA-ECMO was removed), Intra-aortic balloon placement (VA-ECMO and IABP were immediately introduced with ventilatory support owing to cardiogenic shock.), Rehabilitation therapy (The patient underwent rehabilitation and was discharged on day 23 with no residual symptoms) and Temporary mechanical circulatory support (To unload the left ventricle and relieve pulmonary congestion, IABP was changed to Impella CP). Concurrent medical conditions included Postmenopause. On an unknown date, the patient received second dose of mRNA-1273 (COVID-19 Vaccine Moderna Intramuscular Injection) (unknown route) 1 dosage form. On an unknown date, received first dose of mRNA-1273 (COVID-19 Vaccine Moderna Intramuscular Injection) (unknown route) dosage was changed to 1 dosage form. On an unknown date, the patient experienced CARDIOGENIC SHOCK (Cardiogenic shock) (seriousness criteria hospitalization, medically significant and life threatening), MYOCARDITIS (Fulminant Myocarditis) (seriousness criteria hospitalization, medically significant and life threatening), MULTIPLE ORGAN DYSFUNCTION SYNDROME (Multiple organ damage) (seriousness criteria hospitalization, medically significant and life threatening) and MALAISE (Malaise after the first dose). The patient was hospitalized for 23 days due to CARDIOGENIC SHOCK and MYOCARDITIS. The patient was treated with ACETAMINOPHEN for Adverse event, at a dose of 1 dosage form; DOBUTAMINE for Pulmonary congestion, at a dose of 5 microgram/kilogram/min. and DOBUTAMINE for Pulmonary congestion, at a dose of 2 microgram/kilogram/min.. At the time of the report, CARDIOGENIC SHOCK (Cardiogenic shock), MYOCARDITIS (Fulminant Myocarditis), MULTIPLE ORGAN DYSFUNCTION SYNDROME (Multiple organ damage) and MALAISE (Malaise after the first dose) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Alanine aminotransferase: 3079 u/l 3079 U/L (enzyme unit per litre).			ventricular ejection fraction (LVEF) of 11%, and right ventricular contraction was also markedly decreased. After establishing mechanical circulatory support (MCS), coronary angiography demonstrated no significant stenosis; PCR test for SARS-CoV-2 was negative. An endomyocardial biopsy (EMB) of the right ventricular septum showed marked infiltration by inflammatory cells, mainly lymphocytes, and immunostaining showed significant differentiation cluster staining (i.e., [CD] 3, CD 4, CD 8 [CD4 <CD8], and CD 68). A PCR test of EMB specimens did not detect any viral genomes, such as adenoviruses, enteroviruses (including coxsackievirus and parvovirus), and human herpes virus. Paired serology also showed no significant increase in the levels of the antibodies of the abovementioned viruses. The patient underwent rehabilitation and was discharged on day 23 with no residual symptoms. The case did not report MIS-A. it presented a fulminant myocarditis which led cardiac failure, shock and multi organ injury. No fever was reported, and additional clinical features for MIS were unavailable. Of note, myocarditis is one of the known adverse reactions for mRNA-1273. Therefore, it is considered level 5 for MIS-A due to an alternative etiology. The causal relation is possible for WHO based on a TTO with no other concurrent risks.	

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	On an unknown date, Angiocardiogram: demonstrated no significant stenosis demonstrated no significant stenosis. On an unknown date, Aspartate aminotransferase: 5358 u/l 5358 U/L (enzyme unit per litre). On an unknown date, Biopsy heart: abnormal Endomyocardial biopsy revealed lymphocytic infiltration with predominant immunostaining for CD8 and CD68 positive cells. Histopathological results of EMB showed significant differentiation cluster staining i.e., CD 3, CD 4, CD 8 (CD4 <CD8), and CD 68 and significant differentiation cluster staining Histopathological results of EMB showed significant differentiation cluster staining i.e., CD 3, CD 4, CD 8 (CD4 <CD8), and CD 68. On an unknown date, Blood creatine phosphokinase: 15962 u/l (High) 15962 U/L (enzyme unit per litre). On an unknown date, Blood creatine phosphokinase MB: 349 ng/ml 349 ng/mL. On an unknown date, Blood creatinine: 1.64 mg/dl 1.64 mg/dL. On an unknown date, Blood lactate dehydrogenase: 4453 u/l 4453 U/L (enzyme unit per litre). On an unknown date, Blood lactic acid: 10.8 mmol/l 10.8 mmol/L. On an unknown date, Blood pressure measurement: 83/60 mmhg Test Result:83/60 mm[Hg]. On an unknown date, Body temperature: 36.1°C 36.1°C. On an unknown date, Brain natriuretic peptide: 1,160 pg/ml (High) Test Result:1,160 pg/mL. On an unknown date, Chest X-ray: enhanced pulmonary congestion (abnormal) enhanced pulmonary congestion. On an unknown date, Echocardiogram: abnormal (abnormal) diffusely decreased left ventricular ejection fraction (LVEF) of 11%, and right ventricular contraction was also markedly decreased. severe left ventricular systolic dysfunction with an LVEF of <5.0% and persistent aortic valve closure. on day 17 showed that LVEF had improved to 59.8%,with no significant valvular disease, abnormal (abnormal) severe left ventricular systolic dysfunction with an LVEF of <5.0% and persistent aortic valve closure. and lvef had improved to 59.8% on day 17 showed that LVEF had improved to 59.8%,with no significant valvular disease. On an unknown date, Ejection fraction: improved Left				

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	ventricular ejection fraction improved significantly after treatment with mechanical circulatory support On day 4, LVEF improved to 32.6 % and 32.6 % On day 4, LVEF improved to 32.6 %. On an unknown date, Electrocardiogram: st-segment elevation (abnormal) ST-segment elevation in the V1–V4 inductions. On an unknown date, Heart rate: 113 beats/min 113 beats/min. On an unknown date, Histology: no giant cells or frequent eosinophil no giant cells or frequent eosinophil. On an unknown date, Magnetic resonance imaging heart: normal (normal) performed on day 21 showed no abnormalities. On an unknown date, Oxygen saturation: 88% on 6l of oxygen 88% on 6L of oxygen. On an unknown date, Polymerase chain reaction: negative (Negative) Negative and normal (normal) A PCR test of EMB specimens did not detect any viral genomes, such as adenoviruses, enteroviruses (including coxsackievirus and parvovirus), and human herpes virus.. On an unknown date, Respiratory rate: 24 breaths/min 24 breaths/min. On an unknown date, Serology test: normal (normal) no significant increase in the levels of the antibodies of the abovementioned viruses. On an unknown date, Troponin I: 25.2 ng/ml (High) 25.2 ng/mL. For mRNA-1273 (COVID-19 Vaccine Moderna Intramuscular Injection) (Unknown), the reporter considered CARDIOGENIC SHOCK (Cardiogenic shock), MYOCARDITIS (Fulminant Myocarditis), MULTIPLE ORGAN DYSFUNCTION SYNDROME (Multiple organ damage) and MALAISE (Malaise after the first dose) to be possibly related. No concomitant medication was reported. Patient experienced persistent malaise for 1 week after receiving the second dose of the Moderna COVID-19 (mRNA-1273) vaccine, dyspnea appeared on the 7th day following vaccination. Her symptoms did not improve, and				

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	she was taken to the emergency department of her local hospital on the 9th day It was reported, the second dose was administered 28 days after the first dose. Patient had no significant past medical history and was postmenopausal. There was no history of autoimmune disorders to patient or her family. Patient was pale, with cold clammy extremities and laboratory tests showed multiple organ damage at presentation. VA-ECMO was inserted through the right femoral artery and vein, and IABP was inserted through the left femoral artery. After establishing mechanical circulatory support (MCS), coronary angiography was performed, which demonstrated no significant stenosis. The patient was transferred to hospital for intensive care. Her chest radiography showed enhanced pulmonary congestion despite the use of Dobutamine (5μg/kg/min). Therefore, to unload the left ventricle and relieve pulmonary congestion, IABP was changed to Impella CP® (Abiomed, Danvers, MA) and after the introduction of Impella CP, the dose of dobutamine was reduced to 2μg/kg/min. On day 2 of hospitaliza				
[redacted]	This case was received via European Medicines Agency (Reference number: [redacted] on 15-Mar-2022 and was forwarded to Moderna on 15-Mar-2022. This regulatory authority case was reported by a physician and describes the occurrence of VACCINE ASSOCIATED ENHANCED RESPIRATORY DISEASE (Vaccine associated enhanced respiratory disease) in a 68-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 018G21A) for COVID-19 vaccination. Concurrent medical conditions included Chronic respiratory failure, Asthma and Allergy NOS. On 15-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 16-Dec-2021, the patient experienced VACCINE ASSOCIATED ENHANCED RESPIRATORY DISEASE (Vaccine associated enhanced respiratory disease). At the time of the report, VACCINE ASSOCIATED ENHANCED	level 5	unassessable	This regulatory authority case concerned a 68-year-old female patient who experienced vaccine associated enhanced respiratory disease in received mRNA-1273. Concurrent medical conditions included Chronic respiratory failure, Asthma and Allergy NOS. On 15-Dec-2021, the patient received a dose of mRNA-1273. One day later on 16-Dec-2021, the patient experienced the above-mentioned event. At the time of the report, the event was resolving. No concomitant medication was reported. The case did not mention MIS and provided insufficient information for MIS case level evaluation. It reported an alternative enhanced respiratory disease in a patient with underlying chronic respiratory failure and asthma. It also lacks information for the WHO categories assessment including the nature and progress of the event, and other potential confounding factors around the event development, despite a TTO of 1 day.	[redacted]

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	RESPIRATORY DISEASE (Vaccine associated enhanced respiratory disease) was resolving. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medication was reported. No treatment information was reported. Company Comment: The event is non-serious, non AESI, non-pregnancy and not lack of efficacy, hence no CC is provided				
[redacted]	This case was received via European Medicines Agency (Reference number: [redacted]) on 21-Mar-2022 and was forwarded to Moderna on 21-Mar-2022. This regulatory authority case was reported by a consumer and describes the occurrence of INJECTION SITE ERYTHEMA (Erythema in the injection area), SYSTEMIC INFLAMMATORY RESPONSE SYNDROME (Systemic inflammatory response syndrome), LYMPHADENOPATHY (Clavicular lymphadenopathy) and CHEST PAIN (Substernal chest pain) in a 29-year-old female patient who received mRNA-1273 (Spikevax) (batch nos. 3005244 and 214020) for COVID-19 vaccination. The patient's past medical history included COVID-19 (COVID-19 has passed). Concomitant products included DEXKETOPROFEN TROMETAMOL (ENANTYUM) for Pain menstrual. On 17-Aug-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 17-Sep-2021, received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. On 01-Sep-2021, the patient experienced SYSTEMIC INFLAMMATORY RESPONSE SYNDROME (Systemic inflammatory response syndrome) (seriousness criteria disability and congenital anomaly), LYMPHADENOPATHY (Clavicular lymphadenopathy) (seriousness criteria disability and congenital anomaly) and CHEST PAIN (Substernal chest pain) (seriousness criteria	level 4	unassessable	This regulatory authority case concerned a 29-year-old female patient who experienced injection site erythema, systemic inflammatory response syndrome, lymphadenopathy and chest pain after received mRNA-1273. Medical history included COVID-19. Concomitant products included enantyum for pain menstrual. On 17-Aug-2021, she received first dose of mRNA-1273 and second dose on 17-Sep-2021. It was reported in between the two doses, on 01-Sep-2021, she experienced the above-mentioned events. At the time of the report, the events had resolved with sequelae except chest pain which was resolving. No treatment information was provided. Although systemic inflammatory response syndrome was reported after about two weeks following the first vaccination, no details on fever, clinical features, lab evidence of inflammation, measures of disease activity and other differential information were provided. Therefore, the case is considered level 4 for MIS-A. Due to the lack of information, a causality relation is also unassessable for the WHO categories.	[redacted]

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	disability and congenital anomaly). On an unknown date, after starting mRNA-1273 (Spikevax), the patient experienced INJECTION SITE ERYTHEMA (Erythema in the injection area) (seriousness criteria disability and congenital anomaly). At the time of the report, INJECTION SITE ERYTHEMA (Erythema in the injection area) had resolved, SYSTEMIC INFLAMMATORY RESPONSE SYNDROME (Systemic inflammatory response syndrome) and LYMPHADENOPATHY (Clavicular lymphadenopathy) had resolved with sequelae and CHEST PAIN (Substernal chest pain) was resolving. No treatment information was provided. Company Comment: This regulatory case concerns a 29-year-old, female patient with no reported relevant medical history, who experienced the unexpected, serious (disability, congenital anomaly per RA document) AESI of Systemic inflammatory response syndrome, along with events of Chest pain, Lymphadenopathy and Injection site erythema. The event of Injection site erythema occurred 12 days after receiving the second dose of mRNA-1273 while rest of events occurred 16 days post-vaccination. Clinical course and treatment details were not provided in the case. The benefit-risk relationship of mRNA-1273 is not affected by this report. Events' seriousness was assessed as per Regulatory Authority's report, however there was no information in the source document supporting that the events resulted in a persistent/permanent incapacity. Additionally, congenital anomaly was provided as a seriousness criterion of the events in an adult case.				
[redacted]	This literature-non-study case was reported in a literature article and describes the occurrence of CAPILLARY LEAK SYNDROME (typical flare of Clarkson's disease with severe hypovolemic shock and refractory multiple organ failure), CONDITION AGGRAVATED (typical flare of Clarkson's disease with severe hypovolemic shock and refractory multiple organ failure), HYPOVOLAEMIC SHOCK (typical flare of Clarkson's disease with severe hypovolemic shock and refractory multiple organ failure) and MULTIPLE ORGAN DYSFUNCTION SYNDROME	level 5	possible	Based on the original literature, this clinical communications report discussed systemic capillary leak syndrome (SCLS), also known as Clarkson's disease, and COVID-19 and its preventive vaccines, which may trigger presence and relapse of Clarkson disease. The authors aimed to describe the outcome of European patients with Clarkson disease from the EurêClark registry during the COVID-19 pandemic. Thirty patients were included. It was mentioned that all experienced typical flare of Clarkson's disease with severe hypovolemic shock and	[redacted]

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	(typical flare of Clarkson's disease with severe hypovolemic shock and refractory multiple organ failure) in a [redacted]-year-old [redacted] patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. LITERATURE REFERENCE: Pineton de Chambrun M, Moyon Q, Faguer S, Urbanski G, Mathian A, Zucman N et. al.. The consequences of COVID-19 pandemic on patients with monoclonal gammopathy-associated systemic capillary leak syndrome (Clarkson disease). J Allergy Clin Immunol Pract. 2021;10(2):626-9 Concurrent medical conditions included IgG gammopathy (Immunoglobulin G kappa light chain gammopathy) since 2016 and Capillary leak syndrome since 2016. Concomitant products included IMMUNOGLOBULINS NOS (IMMUNOGLOBULIN I.V) from 2016 to an unknown date for IgG gammopathy. On an unknown date, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On an unknown date, the patient experienced CAPILLARY LEAK SYNDROME (typical flare of Clarkson's disease with severe hypovolemic shock and refractory multiple organ failure) (seriousness criteria hospitalization and medically significant), CONDITION AGGRAVATED (typical flare of Clarkson's disease with severe hypovolemic shock and refractory multiple organ failure) (seriousness criteria hospitalization and medically significant), HYPOVOLAEMIC SHOCK (typical flare of Clarkson's disease with severe hypovolemic shock and refractory multiple organ failure) (seriousness criteria hospitalization and medically significant) and MULTIPLE ORGAN DYSFUNCTION SYNDROME (typical flare of Clarkson's disease with severe hypovolemic shock and refractory multiple organ failure) (seriousness criteria hospitalization and medically significant). At the time of the report, CAPILLARY LEAK SYNDROME (typical flare of Clarkson's disease with severe hypovolemic shock and refractory multiple organ failure), CONDITION AGGRAVATED (typical flare of Clarkson's disease with severe hypovolemic shock and refractory multiple organ			refractory multiple-organ failure. Twenty patients underwent COVID-19 vaccination, including a [redacted]-year-old [redacted] patient who was mentioned to receive mRNA-1273 vaccine. However, the report did not discuss any case in detail at case level. it focused on aggregate analysis of Clarkson and virus/vaccine. The article also did not report MIS-A. No information is provided for assessment of MIS for the Clarkson's disease patient receiving mRNA-1273 vaccine. It is considered level 5 for MIS-A. Of note, the article indicated an underlying Clarkson's disease flare 3 days after the patient received her second dose of mRNA-1273 vaccine. Therefore, a causal relation is possible for WHO categories based on a TTO.	

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	failure), HYPOVOLAEMIC SHOCK (typical flare of Clarkson's disease with severe hypovolemic shock and refractory multiple organ failure) and MULTIPLE ORGAN DYSFUNCTION SYNDROME (typical flare of Clarkson's disease with severe hypovolemic shock and refractory multiple organ failure) outcome was unknown. For mRNA-1273 (Spikevax) (Unknown), the reporter considered CAPILLARY LEAK SYNDROME (typical flare of Clarkson's disease with severe hypovolemic shock and refractory multiple organ failure), CONDITION AGGRAVATED (typical flare of Clarkson's disease with severe hypovolemic shock and refractory multiple organ failure), HYPOVOLAEMIC SHOCK (typical flare of Clarkson's disease with severe hypovolemic shock and refractory multiple organ failure) and MULTIPLE ORGAN DYSFUNCTION SYNDROME (typical flare of Clarkson's disease with severe hypovolemic shock and refractory multiple organ failure) to be related. No concomitant and treatment medications were reported. The patient experienced flare of Clarkson's disease and was admitted to the intensive care unit The patient was alive. The Authors reported that the COVID-19 vaccination can trigger severe relapse of systemic capillary leak syndrome (Clarkson disease). Company Comment: This is a literature non-study case concerning a [redacted]-year-old [redacted] patient with reported medical history of IgG gammopathy and Capillary leak syndrome, who experienced the unexpected serious events of Capillary Leak Syndrome, Hypovolemic Shock, Multi Organ Dysfunction Syndrome, and Condition Aggravated. The events were medically significant and led to the hospitalization of the patient and occurred on an unknown date after receiving the second dose of mRNA-1273 Vaccine. As reported, the patient experienced a flare of Clarkson's disease 3 days after receiving the second dose of				

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	mRNA-1273 vaccine and was admitted at the Intensive care unit. The patient received treatment with IVIG and was reported alive, however the outcome of the events was not stated is currently unknown. The medical history of IgG gammopathy and Capillary leak syndrome remains a confounder. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report. The events were considered related to the product per the reporter's assessment. Most recent FOLLOW-UP information incorporated above includes: On 31-Mar-2022: Follow up received by safety on 31-Mar-2022 included an Email with FTA received from SARA team and contains significant information (Reporter details, Medical History, Product details, Event details). On 31-Mar-2022: Follow up received on 06-Apr-2022 included translated FTA received from translation team which contained no new information.				
[redacted]	This case was received via Takeda Pharmaceuticals (Reference number: [redacted] on 28-Mar-2022 and was forwarded to Moderna on 31-Mar-2022. This case was reported from a physician via the Drug Information Center. Multisystem inflammatory syndrome was assessed as serious by the MAH. On an unknown date, the patient received this vaccine (unknown number of doses). After the vaccination, multisystem inflammatory syndrome developed. The outcome of multisystem inflammatory syndrome was unknown. Follow-up investigation will be made. Company Comment: The event developed after the administration of ELASOMERAN and there is temporal relationship.	level 4	unassessable	A physician reported case concerned a 30-year-old adult of unknown gender who experienced multisystem inflammatory syndrome after receiving ELASOMERAN. Medical history, co-meds, # of dose, date of administration, TTO, treatment and the event outcome were unavailable. No fever, clinical features, lab evidence of inflammation, and measures of disease activities were provided. The case is considered level 4 for MIS-A, and unassessable for WHO causality categories due to insufficient information.	[redacted]
[redacted]	This literature-non-study case was reported in a literature article and describes the occurrence of MULTISYSTEM INFLAMMATORY SYNDROME IN ADULTS (hyperinflammatory syndrome), COVID-19 (breakthrough COVID-19 infection) and ATRIAL FIBRILLATION (atrial fibrillation) in a 63-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. LITERATURE REFERENCE:	level 1	unlikely	Based on information from the origianl article, a 63-year-old female presented in August 2021 with a two-day history of bilateral leg weakness and left facial droop. She also reported feeling fatigued with subjective fevers, dry cough, diarrhea, and shortness of breath for a week. Her past medical history was significant for hypertension, type 2 diabetes, end-stage renal disease on dialysis, heart failure, and stroke. Past surgical history was notable for coronary artery bypass graft and percutaneous coronary intervention. She got the SARS-CoV-2 infection from	[redacted]

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	Narvel H, Kaur A, Seo J, Kumar A. Multisystem inflammatory syndrome in adults or hemophagocytic lymphohistiocytosis: A clinical conundrum in fully vaccinated adults with breakthrough COVID-19 infections. Cureus. 2022;14(2):e22123 The patient's past medical history included Dialysis, Coronary artery bypass graft and Percutaneous coronary intervention. Concurrent medical conditions included Hypertension, Type 2 diabetes mellitus, End stage renal disease (end-stage renal disease on dialysis), Heart failure and Stroke. In 2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. In 2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. In 2021, the patient experienced MULTISYSTEM INFLAMMATORY SYNDROME IN ADULTS (hyperinflammatory syndrome) (seriousness criteria hospitalization and medically significant), COVID-19 (breakthrough COVID-19 infection) (seriousness criteria hospitalization and medically significant) and ATRIAL FIBRILLATION (atrial fibrillation) (seriousness criteria hospitalization and medically significant). The patient was hospitalized from sometime in 2021 to sometime in 2021 due to ATRIAL FIBRILLATION, COVID-19 and MULTISYSTEM INFLAMMATORY SYNDROME IN ADULTS. The patient was treated with CEFTRIAXONE in 2021 for Pneumonia, at an unspecified dose and frequency; AZITHROMYCIN in 2021 for Pneumonia, at an unspecified dose and frequency; DEXAMETHASONE on 25-Aug-2021 for Adverse event, at a dose of 20 milligram; DEXAMETHASONE on 07-Sep-2021 for Adverse event, at a dose of 10 milligram and APIXABAN in 2021 at an unspecified dose and frequency. At the time of the report, MULTISYSTEM INFLAMMATORY SYNDROME IN ADULTS (hyperinflammatory syndrome) was resolving and COVID-19 (breakthrough COVID-19 infection) and ATRIAL FIBRILLATION (atrial fibrillation) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in			her daughter although she was fully vaccinated with two doses of mRNA-1273 four months ago. She was positive SARS-CoV-2 by PCR at the time. Her right-sided lung infiltrate was seen on chest Xray. A new-onset atrial fibrillation on ECG and echo showed decreased ejection fraction and left ventricular hypokinesis. Lab showed remarkably elevated troponin and pro-B-type natriuretic peptide, microcytic anemia and leucocytosis with lymphocytes, splenomegaly, and suspicion for lymphoproliferative disorder. Chronic Lymphocytic Leukemia was also suspected by lab testing. The authors discussed possible differential diagnosis for hyperinflammatory presentation included MIS-A, Hemophagocytic Lymphohistiocytosis (HLH), or macrophage activation syndrome (MAS). The case focused on discussion of differentiation of two inflammatory events following a breakthrough Covid 19 infection. The author considered that the patient met the level 1 case definition for MIS-A. However, it is unlikely related to mRNA-1273 vaccination due to a TTO of 4 months, and an alternative recent Covid-19 infection.	

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	parenthesis if available): On an unknown date, Alanine aminotransferase: >700 u/l (High) >700 U/L. On an unknown date, Aspartate aminotransferase: 681 u/l (High) 681 U/L. On an unknown date, Blood culture: negative negative. On an unknown date, Blood fibrinogen: 446 mg/dl (normal) 446 mg/dL. On an unknown date, Blood pressure measurement: 118/67 mmhg 118/67 mmHg. On an unknown date, Blood smear test: abundant mature-appearing small lymphocytes A peripheral blood smear was reviewed, which showed abundant mature-appearing small lymphocytes and smudge cells raising concern for CLL. Several left-shifted polymorphonuclear leukocytes with toxic granules were noted, which would be consistent with acute infectious processes.. On an unknown date, Blood triglycerides: 166 mg/dl (normal) 166 mg/dL. On an unknown date, Body temperature: afebrile afebrile. On an unknown date, C-reactive protein: 183.5 mg/dl (High) 183.5 mg/dL (elevated). On an unknown date, Chemokine test: elevated elevated chemokine (C-X-C motif) ligand 9 (CXCL9) level at 6,000 pg/ml. On an unknown date, Chest X-ray: the right-sided infiltrate seen on the chest x-ray The right-sided infiltrate seen on the chest X-ray was not seen on the CT chest.. On an unknown date, Computerised tomogram: unremarkable Computed tomography (CT) scan of the head without contrast was done due to concern for neurologic deficits, which was unremarkable.. On an unknown date, Computerised tomogram thorax: revealed multiple bulky bilateral axillary, hilar CT pulmonary angiography with contrast showed no pulmonary embolism or focal consolidation but revealed multiple bulky bilateral axillary, hilar, and mediastinal lymph nodes raising suspicion for underlying hitherto undiagnosed lymphoproliferative disorder. On an unknown date, Echocardiogram: did not show any valvular vegetations did not show any valvular vegetations or cardiac thrombi but did note decreased ejection fraction of 40% and left ventricular hypokinesis..				

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	On an unknown date, Electrocardiogram: abnormal patient was found to be in new-onset atrial fibrillation on ECG (sinus rhythm present on ECG done on day one), raising suspicion for a cardio-embolic event as a cause for TIA.. On an unknown date, Fibrin D dimer: 2,573 ng/ml 2,573 ng/mL. On an unknown date, Flow cytometry: suggestive of cd5+ lymphoproliferative disorder Flow cytometry showed aberrant B cells (79%), indeterminate for kappa and lambda, positive for CD19, CD23, CD5, and dim CD20, and negative for CD10, CD38, and FMC-7, which was suggestive of CD5+ lymphoproliferative disorder, likely CLL.. On an unknown date, HIV test: negative negative. On an unknown date, Haemoglobin: 9.6 g/dl Initial complete blood count showed hypochromic, microcytic anemia (hemoglobin: 9.6 g/dL). On an unknown date, Heart rate: 73 beats/min 73 beats/min. On an unknown date, Hepatitis viral test: negative negative. On an unknown date, Interleukin-2 receptor assay (175 pg/ml-858 pg/ml): 3,527 pg/ml elevated soluble interleukin-2 receptor level at 3,527 pg/ml. On an unknown date, Lymphocyte count: 86.8% lymphocytes 86.8% lymphocytes (36.15 lymphocytes/nL). On an unknown date, Neurological examination: abnormal remarkable for mild flattening of the nasolabial fold on the left side, intact sensory examination in all four extremities, and mild bilateral leg weakness on motor examination (strength 4/5).. On an unknown date, Oxygen saturation: normal maintaining normal oxygen saturation on room air. On an unknown date, Physical examination: decreased breath sounds Decreased breath sounds over the right lung field. On an unknown date, Procalcitonin: 5.32 ng/ml 5.32 ng/mL on day one. On an unknown date, Prohormone brain natriuretic peptide: elevated (High) Elevated. On an unknown date, Respiratory rate: 21 breaths/min 21 breaths/min. On an unknown date, SARS-CoV-2 antibody test: elevated (High) Patient also had significantly elevated titers of COVID-19 spike antibody (>2,500 U/ml) showing an				

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	appropriate response to vaccination. On an unknown date, SARS-CoV-2 test: positive (Positive) The patient completed eight weeks of steroid taper, however, did continue to have prolonged viral shedding with positive COVID-19 PCR test and positive found to have positive SARS-CoV-2 polymerase chain reaction (PCR) from nasopharyngeal swab and reactive total SARS-CoV-2 antibody. On an unknown date, Serum ferritin: 17,899 µg/l (High) 17,899 µg/L. On an unknown date, Troponin: 2.270 µg/l (High) 2.270 µg/L (elevated troponin). On an unknown date, Ultrasound abdomen: splenomegaly depicted splenomegaly with spleen size 14.1 cm. On an unknown date, White blood cell count: 41.66 white blood cells/nl 41.66 white blood cells/nL (leucocytosis). For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter considered MULTISYSTEM INFLAMMATORY SYNDROME IN ADULTS (hyperinflammatory syndrome), COVID-19 (breakthrough COVID-19 infection) and ATRIAL FIBRILLATION (atrial fibrillation) to be related. CC:This is a Literature-Non-Study case concerning a 63-year-old female patient, with medical history of Percutaneous coronary intervention, Coronary artery bypass graft and Stroke and concurrent condition of Hypertension, Type 2 diabetes mellitus, End stage renal disease, Dialysis and Heart failure and had no known diagnosis of an underlying rheumatologic condition; who experienced the serious unexpected AESIs of Multisystem inflammatory syndrome in adults, COVID-19 and Atrial fibrillation (serious criteria Medically Significant and Hospitalized); that occurred in an unknown date, approximately 4 months after the administration of the second dose of the mRNA-1273 vaccine. Relevant tests were performed that showed: Vital signs: normal range; normal oxygen saturat, decreased breath sounds over the right lung field; Xray: right-s				
[redacted]	This regulatory authority case was reported by an other health care professional and describes the occurrence of SEPSIS (Sepsis), LIVER ABSCESS (Liver abscess,	level 5	unassessable	A health care professional reported case concerned a 65-year-old male patient who experienced sepsis, Liver abscess, bacteremia, and septic shock on the same day	[redacted]

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	bacteremia, septic shock), BACTERAEMIA (Liver abscess, bacteremia, septic shock) and SEPTIC SHOCK (Liver abscess, bacteremia, septic shock) in a 65-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 2100685) for COVID-19 vaccination. No Medical History information was reported. On 16-Feb-2022, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) .5 milliliter. On 26-Feb-2022, the patient experienced SEPSIS (Sepsis) (seriousness criterion hospitalization), LIVER ABSCESS (Liver abscess, bacteremia, septic shock) (seriousness criterion hospitalization), BACTERAEMIA (Liver abscess, bacteremia, septic shock) (seriousness criterion hospitalization) and SEPTIC SHOCK (Liver abscess, bacteremia, septic shock) (seriousness criterion hospitalization). The patient was hospitalized until 15-Mar-2022 due to BACTERAEMIA, LIVER ABSCESS, SEPSIS and SEPTIC SHOCK. At the time of the report, SEPSIS (Sepsis), LIVER ABSCESS (Liver abscess, bacteremia, septic shock), BACTERAEMIA (Liver abscess, bacteremia, septic shock) and SEPTIC SHOCK (Liver abscess, bacteremia, septic shock) was resolving. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. The WWID number for the case was reported as [redacted] Concomitant product use was not provided by the reporter. On 16-Feb-2022, the patient received Moderna vaccine and experienced dizziness, weakness of limbs, chillness, somnolence, and unsteady gait after returning home. On 22-Feb-2022 he went to clinic for medical advice and			after he received first dose of mRNA-1273 on 16-Feb-2022. No Medical History and concomitant product use information were reported. He developed dizziness, weakness, chills, lethargy, and unsteady walking on the same day of vaccination. About 10 days later, he suffered fever and fecal incontinence, and was diagnosed with sepsis and hepatic abscess and hospitalized for treatment on 26-Feb-2022. The case did not report MIS-A. The clinical presentation was more likely a bacterial infection nature which induced septic shock. It is considered level 5 for MIS-A based on reported liver abscess, bacteremia, sepsis, and septic shock. Due to limited information including underlying conditions and other concurrent confounding risks around the event development, a causal relation of vaccine and events is considered unassessable for WHO categories.	

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	diagnosed as common code. He was advised to go to a larger hospital if symptoms not improved. On 26-Feb-2022 patient had fever and gatism and was sent to other hospital. Sepsis and liver abscess were found, and the patient was hospitalized for treatment. He was discharged on 15-Mar-2022 for rest. As per recent report his consciousness was not very clear and his daughter-in-law will assist in submitting documents for VICP application. Treatment information was not provided. Company Comment: This regulatory case concerns a 65-year-old male patient, with no reported medical history, who experienced the unexpected serious (hospitalization) events of Sepsis, Liver abscess, Bacteraemia and Septic shock that occurred 10 days after receiving the 1st dose of mRNA-1273 vaccine. Patient developed dizziness, weakness, chills, somnolence, and unsteady walking in the afternoon after receiving the mRNA-1273 vaccine. Six days post vaccination, patient sought consult for treatment and was diagnosed with common colds. Patient diagnosed with sepsis and hepatic abscess. Treatment details were not reported. Patient was discharged after 17 days of hospitalization and remained with mild loss of consciousness. At the time of reporting, the outcome of event was resolving. The benefit-risk relationship of mRNA-1273 is not affected by this report. Events' seriousness was assessed as per Regulatory Authority's report. Most recent FOLLOW-UP information incorporated above includes: On 25-Apr-2022: Follow up document received wherein inarrative was updated				
[redacted]	This literature-non-study case was reported in a literature article and describes the occurrence of CARDIAC ARREST (Cardiac arrest), SEPTIC SHOCK (Septic shock), ENTEROCOCCAL INFECTION (high-grade vancomycin-resistant enterococcal infection), CLOSTRIDIUM DIFFICILE INFECTION (Clostridium difficile infection), APLASTIC ANAEMIA (Severe aplastic anemia), PNEUMONIA (Pneumonia) and FEBRILE NEUTROPENIA (Recurrent neutropenic fever) in a 60-year-old male patient who received mRNA-1273 (Moderna	level 5	possible	Based on information from the original article, a 60-year-old male patient received the second dose of Moderna mRNA vaccination and experienced easy bruising on his arms and legs the following day after vaccination. After 2 weeks, he presented to the emergency department with worsening epistaxis but did not have a fever, chest pain, cough, shortness of breath or abdominal pain. He had no personal or family history of hematological conditions. He had bruises in various stages involving the upper and lower extremities. Laboratory data revealed white blood	[redacted]

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	COVID-19 Vaccine) for COVID-19 vaccination. LITERATURE REFERENCE: Sridhara S, Nair R, Stanek M. Severe aplastic anemia after receiving SARS-CoV-2 Moderna mRNA vaccination. J Hematol. 2022;11(1):34-9 The patient's past medical history included Alcohol use (rarely consumed alcohol.) and Nasal cavity packing (He had a nasal packing with no active bleeding and oral mucosa showed no petechiae). Concurrent medical conditions included Clostridial infection. On an unknown date, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On an unknown date, the patient experienced CARDIAC ARREST (Cardiac arrest) (seriousness criteria death, hospitalization prolonged and medically significant), SEPTIC SHOCK (Septic shock) (seriousness criteria death, hospitalization prolonged and medically significant), ENTEROCOCCAL INFECTION (high-grade vancomycin-resistant enterococcal infection) (seriousness criteria death, hospitalization prolonged and medically significant), CLOSTRIDIUM DIFFICILE INFECTION (Clostridium difficile infection) (seriousness criteria death, hospitalization prolonged and medically significant), APLASTIC ANAEMIA (Severe aplastic anemia) (seriousness criteria hospitalization prolonged and medically significant), PNEUMONIA (Pneumonia) (seriousness criteria hospitalization prolonged and medically significant) and FEBRILE NEUTROPENIA (Recurrent neutropenic fever) (seriousness criteria hospitalization and medically significant). The patient was treated with CYCLOSPORINE (oral) for Immunosuppression, at a dose of 250 milligram twice a day; ANTITHYMOCYTE IMMUNOGLOBULIN (intravenous) for Immunosuppression, at a dose of 3200 milligram once a day; ELTROMBOPAG (oral) ongoing since an unknown date for Immunosuppression, at a dose of 150 milligram once a day; PREDNISONE for Immunosuppression, at an unspecified dose and frequency; CEFEPIME ongoing since an unknown date for			cell count of 1.2 ×103/mm3, hemoglobin of 8.0 g/dL, platelet count of 1 ×103/mm3, immature platelet fraction of 0.7%, absolute neutrophil count of 0 ×103/µL, lymphocytes of 1.1 ×103/µL, neutrophils of 3% and lymphocytes of 93%. He had normal liver and renal function tests. Bone marrow biopsy confirmed very severe aplastic anemia with severely hypocellular bone marrow. His platelets continued to downtrend despite platelet transfusions and steroids. He was treated with immunosuppressive therapy with cyclosporine, antithymocyte globulin, eltrombopag and prednisone. The patient was discharged but was readmitted to the hospital secondary to recurrent neutropenic fever and pneumonia. He had high-grade vancomycin resistant enterococcal infection and Clostridium difficile infection leading to septic shock and succumbing to cardiac arrest. The case did not report MIS-A. It presented a confirmed severe aplastic anemia, which may cause the recurrent neutropenic fever, pneumonia, enterococcal and clostridium infection leading to shock and cardiac arrest with a fatal outcome. The case is considered level 5 for MIS-A due to an alternative etiology. A causal relation for vaccine and event may be possible based on a TTO of 1 day.	

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	Neutropenic fever, at an unspecified dose and frequency; FLUCONAZOLE ongoing since an unknown date for Neutropenic fever, at an unspecified dose and frequency; VALACYCLOVIR [VALACICLOVIR] ongoing since an unknown date for Neutropenic fever, at an unspecified dose and frequency; METHYLPREDNISOLONE ongoing since an unknown date for Adverse event, at an unspecified dose and frequency; LEVOFLOXACIN ongoing since an unknown date for Antibiotic prophylaxis, at an unspecified dose and frequency; VANCOMYCIN ongoing since an unknown date for Clostridial infection, at an unspecified dose and frequency; AZITHROMYCIN ongoing since an unknown date for Adverse event, at an unspecified dose and frequency; DAPTOMYCIN ongoing since an unknown date for Adverse event, at an unspecified dose and frequency; MICAFUNGIN ongoing since an unknown date for Adverse event, at an unspecified dose and frequency; CEFTAROLINE ongoing since an unknown date for Adverse event, at an unspecified dose and frequency and TIGECYCLINE ongoing since an unknown date for Adverse event, at an unspecified dose and frequency. The patient died on an unknown date. The reported cause of death was Cardiac arrest and Septic shock. It is unknown if an autopsy was performed. At the time of death, APLASTIC ANAEMIA (Severe aplastic anemia), PNEUMONIA (Pneumonia) and FEBRILE NEUTROPENIA (Recurrent neutropenic fever) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 04-May-2021, Abdomen scan: exam did not reveal any hepatosplenomegaly exam did not reveal any hepatosplenomegaly. On 04-May-2021, Adenovirus test: negative (Negative) Negative. On 04-May-2021, Antineutrophil cytoplasmic antibody: negative (Negative) Negative. On 04-May-2021, Antinuclear antibody: 42 iu/ml 42 IU/mL were detected with normal complements (dsDNA antibody reference index < 4 IU/mL). On 04-May-2021, Auscultation: the chest was clear the chest was clear. On 04-May-2021, Biopsy bone marrow: very severe				

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	aplastic anaemia very severe aplastic anemia with severely hypocellular bone marrow. On 04-May-2021, Blood culture: did not reveal any bacterial growth (Negative) did not reveal any bacterial growth.. On 04-May-2021, Blood electrolytes: normal (normal) Normal. On 04-May-2021, Blood fibrinogen (200 mg/dl-465 mg/dl): 478 mg/dl (High) 478 mg/dL. On 04-May-2021, Blood lactate dehydrogenase (135 u/l-225 u/l): 203 u/l (normal) 203 U/L. On 04-May-2021, Blood pressure measurement: 125/71 mm hg 125/71 mm Hg. On 04-May-2021, Body temperature: 37.3 degree c 37.3 degree C. On 04-May-2021, Culture urine: did not reveal any bacterial growth. (Negative) did not reveal any bacterial growth.. On 04-May-2021, Cytomegalovirus test: negative (Negative) Negative and igg positive (Positive) IgG positive. On 04-May-2021, Electrophoresis protein: hypoalbuminemia (Low) hypoalbuminemia. On 04-May-2021, Epstein-Barr virus test: negative (Negative) Negative, viral capsid antigen (vca) igg index at 7.5 (Positive) viral capsid antigen (VCA) IgG index at 7.5 and nuclear antigen index 7.6 (Positive) nuclear antigen index 7.6. On 04-May-2021, Flow cytometry: no immunophenotypic evidence of lymphoproliferativ no immunophenotypic evidence of lymphoproliferative disorder, acute leukemia, or plasma cell neoplasm. On 04-May-2021, HIV test: negative (Negative) Negative. On 04-May-2021, Haemoglobin (13.5 g/dl-17g/dl): 8.0 g/dl (Low) 8.0 g/dL. On 04-May-2021, Haptoglobin (43 mg/dl-212 mg/dl): 242 mg/dl (High) 242 mg/dL. On 04-May-2021, Heart rate: 80/min 80/min. On 04-May-2021, Hepatitis B core antibody: negative (Negative) Negative. On 04-May-2021, Hepatitis B surface antigen: negative (Negative) Negative. On 04-May-2021, Hepatitis C antibody: negative				

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	(Negative) Negative. On 04-May-2021, Herpes simplex test: negative (Negative) Negative. On 04-May-2021, Human metapneumovirus test: negative (Negative) Negative. On 04-May-2021, Human rhinovirus test: negative (Negative) Negative. On 04-May-2021, Influenza A virus test: negative (Negative) Negative. On 04-May-2021, Influenza B virus test: negative (Negative) Negative. On 04-May-2021, Legionella test: negative (Negative) Negative. On 04-May-2021, Liver function test: normal (normal) Normal. On 04-May-2021, Lymphocyte count: 1.1x10^3/microl 1.1x10^3/microL. On 04-May-2021, Monocyte count (0.2 × 103/µl-1.0 × 103/µl): 0.0 × 103/µl (Low) 0.0 × 103/µL. On 04-May-2021, Neutrophil count (1.5x10^3/microl-7.8x10^3/microl): 0x10^3/microl (Low) 0x10^3/microL and 3% 3%. On 04-May-2021, Parvovirus B19 test: negative (Negative) Negative. On 04-May-2021, Platelet count (130 x10^3/mm^3-450 x10^3/mm^3): 1 x10^3/mm^3 (Low) 1 x10^3/mm^3. On 04-May-2021, Prothrombin time (9.4 s-12.5 s): 12.7 s (High) 12.7 s. On 04-May-2021, Renal function test: normal (normal) Normal. On 04-May-2021, Respiratory syncytial virus test: negative (Negative) Negative. On 04-May-2021, Reticulocyte count (26 × 103/µl-168 × 103/µl): 4 × 103/µl (Low) 4 × 103/µL. On 04-May-2021, SARS-CoV-2 RNA: negative (Negative) Negative. On 04-May-2021, SARS-CoV-2 antibody test (Unknown-0.99): positive igg index at greater than 20 (Positive) positive IgG index at greater than 20 suggestive of recent vaccination. On 04-May-2021, Serum ferritin (20 ng/ml-250 ng/ml): 534 ng/ml (High) 534 ng/mL. On 04-May-2021, Smear test: pancytopenia with a marked				

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	decrease in granulocyte pancytopenia with a marked decrease in granulocytes, normocytic anemia with non-specific anisocytosis, thrombocytopenia with unremarkable platelets and there were no schistocytes. Lymphocytes with mature chromatin, abundant cytoplasm and occasional forms with concentric irregular cytoplasmic projections concerning an atypical population were present.. On 04-May-202				
[redacted]	This case was received via European Medicines Agency (Reference number: [redacted] on 19-Apr-2022 and was forwarded to Moderna on 19-Apr-2022. This regulatory authority case was reported by a physician and describes the occurrence of ATRIAL FIBRILLATION (Atrial fibrillation), TYPE 1 DIABETES MELLITUS (IDDM) and MULTISYSTEM INFLAMMATORY SYNDROME (Multisystem inflammatory syndrome) in a 77-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 3002184) for COVID-19 vaccination. No Medical History information was reported. On 11-May-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 15-May-2021, the patient experienced ATRIAL FIBRILLATION (Atrial fibrillation) (seriousness criterion hospitalization), TYPE 1 DIABETES MELLITUS (IDDM) (seriousness criterion hospitalization) and MULTISYSTEM INFLAMMATORY SYNDROME (Multisystem inflammatory syndrome) (seriousness criterion hospitalization). At the time of the report, ATRIAL FIBRILLATION (Atrial fibrillation), TYPE 1 DIABETES MELLITUS (IDDM) and MULTISYSTEM INFLAMMATORY SYNDROME (Multisystem inflammatory syndrome) outcome was unknown. mRNA-1273 (Spikevax) (Intramuscular) was withdrawn on an unknown date. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.	level 4	unassessable	This regulatory authority case reported by a physician concerned a 77-year-old female patient who experienced atrial fibrillation, type 1 diabetes mellitus and multisystem inflammatory syndrome about 4 days after she received her first dose of mRNA-1273 vaccination. No Medical History information and no concomitant medication were reported. Although the MIS-A was one of the reported events, no information was provided for assessment of disease definition and potential causality evaluation. The case is considered level 4 for MIS-A, and unassessable for WHO categories.	[redacted]

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	No concomitant medication were reported. No treatment information was provided by the reporter. Company Comment: This regulatory authority case concerns a 77-year-old female patient with no medical history reported who experienced the unexpected serious (hospitalization) adverse event of special interest of Atrial fibrillation and unexpected serious(hospitalization) events of Type 1 diabetes mellitus and Multisystem inflammatory syndrome. The events occurred four days after receiving the first dose of mRNA-1273 vaccine. Patient was hospitalized but Information about the clinical course, diagnostic evaluation, and treatment details were not provided. Patient's advanced age is a risk factor for the event atrial fibrillation. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Events' seriousness was assessed as per regulatory authority's report.				
[redacted]	This regulatory authority case was reported by an other health care professional and describes the occurrence of PYREXIA (Fever) and CYTOKINE STORM (Suspect the cytokine storm or severe immune reaction after the Moderna vaccination.) in a 74-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. Concurrent medical conditions included Lung cancer (The 74 y/o man was a case of lung cancer adenocarcinoma, LLL with bilateral lung-lung, cervical, brain and bone mets.) and Hypertension. On 10-Mar-2022, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 28-Mar-2022, the patient experienced PYREXIA (Fever) (seriousness criterion medically significant) and CYTOKINE STORM (Suspect the cytokine storm or severe immune reaction after the Moderna vaccination.) (seriousness criterion medically significant). At the time of the report, PYREXIA (Fever) and CYTOKINE STORM (Suspect the cytokine storm or severe immune reaction after the Moderna vaccination.) was resolving. Not Provided	level 5	n/a	This regulatory authority case reported by an HCP concerned a 74-year-old male patient who experienced dry cough, low grade fever and suspected cytokine storm about 18 days after he received his first dose of mRNA-1273 vaccination. Concurrent medical conditions included a stage 4 lung cancer and hypertension. Concomitant medications were not provided. About 13 days after vaccination, Interleukin-6 (IL-6) was reported as 45.9. About 16 days after vaccination, he was intubated and received mechanical ventilator. No additional information is available. The case did not report a MIS-A, rather report a suspected cytokine storm for an elderly male with a stage 4 lung cancer. However, the case provided limited information for assessment of MIS-A. Additionally, IL6 is thought to be increased generally in cancer patients, and it was mildly increased in the case. Cough and low-grade fever could also be associated with underlying metastatic lung cancer. The case is considered level 5 for MIS-A, because MIS was not a reported event, no information was provided to support it and an alternative event of IL6 increased alone was reported. The WHO causality is not applicable.	[redacted]

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No history of drug allergy. Concomitant medications were not provided. Patient experienced dry cough, low grade fever and cough after first dose of Moderna. On 23 Mar 2022 Interleukin-6 (IL-6) was reported as 45.9 On 25 Mar 2022, the patient began desaturation and needed high flow. On 29 Mar 2022, Follow-up care was carried out but the patient was not reachable. On 26 Mar 2022 The patient was transferred to ICU, was intubated and received mechanical ventilator. The Worldwide UID was reported as [redacted] Company comment-This regulatory case concerns a 74-year-old male patient with relevant medical history of lung cancer adenocarcinoma reported, who experienced the unexpected serious (medically significant) events of Cytokine storm (AESI)(reported as Suspect the cytokine storm or severe immune reaction after the Moderna vaccination) and Pyrexia 18 days after first dose of mRNA-1273 Vaccine administration. Patient experienced dry cough and low grade fever after vaccination. On 23rd March 2022, Interleukin-6 (IL-6) report was 45.9. Two days later patient desaturated and needed high flow oxygen, shifted to ICU, intubated and put on mechanical ventilation. No further details on clinical course, other lab test results and treatment received were reported. Outcome of the events was resolving at the time of report. Relevant medical history of lung cancer adenocarcinoma could be a possible confounder to the event Cytokine storm. Benefit risk relationship of mRNA-1273 Vaccine is not affected by this				

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	report. The case seriousness was assessed as per Regulatory Authority report. Most recent FOLLOW-UP information incorporated above includes: On 25-Apr-2022: Follow up included no new information.				
[redacted]	This case was received via European Medicines Agency (Reference number: [redacted] on 20-Apr-2022 and was forwarded to Moderna on 20-Apr-2022. This regulatory authority case was reported by a consumer and describes the occurrence of MULTISYSTEM INFLAMMATORY SYNDROME (Multisystem inflammatory syndrome), MUSCLE CONTRACTIONS INVOLUNTARY (in the extremities.) and INSOMNIA (Sleeplessness) in a 62-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3004500) for COVID-19 vaccination. No Medical History information was reported. On 30-Nov-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On an unknown date, the patient experienced MULTISYSTEM INFLAMMATORY SYNDROME (Multisystem inflammatory syndrome), MUSCLE CONTRACTIONS INVOLUNTARY (in the extremities.) and INSOMNIA (Sleeplessness). At the time of the report, MULTISYSTEM INFLAMMATORY SYNDROME (Multisystem inflammatory syndrome), MUSCLE CONTRACTIONS INVOLUNTARY (in the extremities.) and INSOMNIA (Sleeplessness) had not resolved. The action taken with mRNA-1273 (Spikevax) (Intramuscular) was unknown. No relevant concomitant medications were reported. Treatment medication was not provided by the reporter. Company Comment: This is a regulatory case concerning a	level 4	unassessable	This regulatory authority case reported by a consumer concerned a 62-year-old male patient who experienced multisystem inflammatory syndrome, muscle contractions involuntary in the extremities and insomnia after he received a dose of mRNA-1273 vaccination. No Medical History information and no relevant concomitant medications were reported. This consumer case reported an event of MIS. However, no information was provided for assessment of MIS-A as well as the WHO causality due to an unknown TTO. It is considered level 4 for MIS-A, and unassessable for WHO categories.	[redacted]

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	62-year-old male patient with a medical history of kidney disease, who experienced the unexpected non-serious events of Multisystem inflammatory syndrome (AESI), Muscle contractions involuntary (in the extremities), and Insomnia which occurred unknown number of days after receiving a dose of mRNA-1273 Vaccine, dose number not provided. There was no available information regarding clinical course and treatment medication. The patient's medical history of kidney disease remains a confounder for event Muscle contractions involuntary while patient's age remains a confounder for Insomnia. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report.				
[redacted]	This case was initially received via Takeda Pharmaceuticals (Reference number: [redacted] on 25-Apr-2022. The most recent information was received on 07-Jun-2022 and was forwarded to Moderna on 15-Jun-2022. This case, initially reported to the [redacted] by a physician, was received via the [redacted] (Ref, [redacted]). On 07-Jun-2022, follow-up information was received from a physician. The vaccine recipient had suffered coxalgia for two years and used a cane when walking. On 10-Aug-2021, the patient received the 1st dose of non-company coronavirus modified uridine RNA vaccine (SARS-CoV-2). On 31-Aug-2021, the patient received the 2nd dose of non-company coronavirus modified uridine RNA vaccine (SARS-CoV-2). On 16-Mar-2022, the patient received the 3rd vaccination with this vaccine. The pre-existing hip pain worsened. On an unspecified date in Mar-2022, the patient visited a dentist because of a toothache due to dental caries. There were no findings that positively suggested dental infection. On 28-Mar-2022, after the rehabilitation, the patient felt ill and was unable to walk. On 30-Mar-2022, meal intake decreased. On 31-Mar-2022, around 12:00, a family member noticed dyslalia, but the patient was not aware of it. Around 18:00, the patient was aware of having slurred speech. On 01-Apr-2022, staphylococcus sepsis developed. Around 15:30, the family member found the patient having been unable to move for about an hour due to coxalgia. The patient had difficulty moving the body, and an emergency call was made. When the ambulance team arrived, the patient was found to have slurred speech.	level 5	n/a	The case reported by a physician concerned a 57-years-old female patient, who suffered staphylococcal infection, abscess in joint and psoas, disseminated intravascular coagulation, septic shock and arthralgia about 15 days after she received third dose of "a non-company RNA vaccine". Her medical history included coxalgia. She started worsening of pre-existing pain first, then felt ill, unable to walk, decreased intake, dyslalia and slurred speech. She was hospitalized and staphylococcus sepsis, joint abscess in the right shoulder, joint abscess in the right and left hip, abscess in the right and left retroperitoneum (iliacus muscle and psoas major) were found. Antibiotics were started and emergency surgery was performed for debridement and drainage in the right shoulder joint, right retroperitoneum, and left hip joint. She then developed disseminated intravascular coagulation. The events were ongoing at the time of report. The case did not report MIS, though sepsis was captured, which was mostly like due to multiple staphylococcus infections. The case is considered level 5 for MIS due to an alternative etiology. WHO causality assessment is not applicable for the case.	[redacted]

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	Staphylococcus sepsis, joint abscess in the right shoulder, joint abscess in the right and left hip, abscess in the right and left retroperitoneum (iliacus muscle and psoas major) were observed, and the patient was hospitalized. Drainage of the right retroperitoneum and left hip joint was performed. Gas-producing streptococcus was suspected, and treatment with TAZ/PIPC was performed at a dose of 2.25 g, 4 times/day. Platelets were 28,000/mcL. Thereafter, transfusions of RBCs, platelets, and FFP were performed as an emergency procedure. On 02-Apr-2022, staphylococcus was suspected in the blood culture. The antimicrobial agent was changed, and DAPT plus MEPM (covering combined infection of MRSA plus gas-producing bacteria) was started. Administration of DAPT 350 mg every 48 hours plus MEPM 1 g every 12 hours was performed. Emergency surgery was performed. Debridement and drainage were performed in the right shoulder joint, right retroperitoneum, and left hip joint. The patient was entered into the ICU. Disseminated intravascular coagulation was observed. On 04-Apr-2022, since the result was MSSA, medication was changed to TAZ/PIPC to cover anaerobes, with a dose of 2.25 g, 4 times/day. Administration of human anti-thrombin 3/freeze-dried concentrated was started. CHDF was started. On 05-Apr-2022, right shoulder drain (drainage kit for wound) was reinserted. On 07-Apr-2022, contrast-enhanced CT showed enlargement of abscess. The hematoma in the right shoulder was removed. On 08-Apr-2022, reoperation was performed. Debridement, removal of bilateral bone head parts, and a cement spacer were performed. On 11-Apr-2022, the patient was referred to a dermatologist because of a skin rash. Suspecting drug eruption due to TAZ/PIPC, the drug administration was discontinued. Only MSSA was shown by culture, and thus medication was changed to CEZ 1 g, 3 times/day. On 14-Apr-2022, the bed rest level was changed. The patient was able to be placed in a lateral decubitus position or sitting square, with non-weight bearing of both lower extremities. On 20-Apr-2022, CT-guided drainage of the right iliopsoas muscle was performed. Thereafter, because fluid was accumulated in the right hip joint, the cleaning line was inserted into the right hip joint and the drain was replaced. On 24-Apr-2022, since there was fluid accumulation under the skin of the left hip joint and the left hip joint drain was almost clogged, the drain was inserted under the skin of the left hip joint. A				

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	trocar with hip irrigation was inserted and continuous washing was initiated. On 25-Apr-2022, the dose of CEZ was increased to 2 g, 3 times/day, because renal function improved. On 26-Apr-2022, a consultation was made with an otolaryngologist. An evaluation for swallowing was made. Echocardiography was recommended. On 27-Apr-2022, the patient started oral intake with the soft vegetarian diet. Neck pain had been noted since admission, so a neck MRI was performed. Signal changes were observed in C 6.7 Th1 vertebral body and C 6/7 intervertebral disk, suggesting an infection. Echocardiography showed no findings suggestive of infectious endocarditis. On 30-Apr-2022, the drain above the left hip joint was removed, and the trocar on the right hip was cut to be connected to a drainage bag. The blockage was able to be unclogged. On 31-Apr-2022, disseminated intravascular coagulation was resolving. On 02-May-2022, since there was almost no discharge from the drain of the left hip joint and rectus femoris muscle, it was removed. One drainage kit for wound was removed from the right hip joint. APTT was about 60 and PT was normal. Coagulation disorder was observed. On 05-May-2022, CV was removed due to pyrexia and increased inflammatory reaction. Submission for culture was made. Since the position of indwelling drain of the left hip joint became shallow, the drain was removed. On 08-May-2022, the left hip wound was partially dehisced, and the hip joint was opened. Discharge of pus was noted. A 22 Fr double lumen and the drainage kit for wound were inserted into the same site. Washing with saline was resumed. On 09-May-2022, the left subcutaneous drain was removed because air entered the wound after the treatment on 08-May-2022. On 12-May-2022, CT guided drainage was performed. Drainage of the left psoas major muscle was performed, and left iliac muscle was treated with a drain. When the urinary catheter was inserted, cloudy pyuria was observed. Submission for culture was made. On 16-May-2022, tugging with steel wire on both sides was started at 5 kg each. It was suspected that the skin rash had worsened. On 17-May-2022, CV was inserted into the right internal cervix. On 19-May-2022, the drain of the left iliac muscle was removed because it was hard and unable to be reached when the saline solution was given. On 20-May-2022, due to worsening of drug eruption, CEZ was discontinued.				

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	Administration of minocycline 200 mg and levofloxacin 500 mg was started. The patient was admitted to the ICU. The patient was diagnosed with toxic epidermal necrolysis. Steroid pulse therapy was started. On 26-May-2022, as there was some discharge, the left drainage kit for wound was removed. On 29-May-2022, dosing of minocycline was changed to oral administration. On 03-Jun-2022, the hip joint was washed, and cement was placed. As sequelae, the patient was left with contractures of the shoulder, hand, fingers, and joints of hip and knee, and was unable to walk because bilateral femoral heads were resected. Once the infection improved, there is a possibility that the patient could walk by insertion of artificial joints. On 04-Jun-2022, the staphylococcus sepsis was ongoing and unchanged. The outcome of worsening of coxalgia and septic shock was unknown. The outcome of staphylococcal (MSSA) sepsis and right shoulder, bilateral hip, and right iliac abscess was reported as ongoing and unchanged. The outcome of disseminated intravascular coagulation syndrome was reported as resolving. No follow-up investigation will be made. Follow-up received on 07-JUN-2022 Updated: Patient Information, Other Relevant History, Lab Data, Product Information, Event Information, Narrative, Reporter Comments Company Comment: The events developed after the administration of ELASOMERAN and there is temporal relationship.				
[redacted]	This case was received via European Medicines Agency (Reference number: [redacted] on 06-May-2022 and was forwarded to Moderna on 06-May-2022. This regulatory authority case was reported by a consumer and describes the occurrence of SYSTEMIC INFLAMMATORY RESPONSE SYNDROME (systemic inflammatory response), HYPERTENSION (Hypertensive Episode), FATIGUE (Fatigue) and ARRHYTHMIA (Arrhythmie) in a 61-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 000109A) for COVID-19 vaccination. Previously administered products included for Prophylactic vaccination: COVID-19 Vaccine Janssen [redacted] COVID-19 Vaccine JanssenCOVID-19 [redacted] Ad26.COV2-S on 23-Nov-2021. Past adverse reactions to the above products included No	level 4	unassessable	This regulatory authority case reported by a consumer concerned a 61-year-old male patient who experienced systemic inflammatory response syndrome, hypertension, fatigue, and arrhythmia on 20-Jan-2022, next day after he received a dose of mRNA-1273 vaccination. The patient previously received Janssen COVID-19 vaccine on 23-Nov-2021, with no adverse event reported. No medical history, no concomitant medication information and no treatment information were provided. No lab and echo results were available. The case reported a SIRS, and not MIS-A. However, no information was provided for assessment of MIS disease definition, including fever and duration, clinical features, labs for inflammation and disease activity. It is also considered unassessable for WHO categories due to lack of information on medical history, co-meds and treatment.	[redacted]

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	adverse event with COVID-19 Vaccine Janssen [redacted] COVID-19 Vaccine JanssenCOVID-19-[redacted]Ad26.COV2-S. On 19-Jan-2022, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 2 dosage form. On 20-Jan-2022, the patient experienced SYSTEMIC INFLAMMATORY RESPONSE SYNDROME (systemic inflammatory response) (seriousness criteria hospitalization and life threatening), HYPERTENSION (Hypertensive Episode) (seriousness criteria hospitalization and life threatening), FATIGUE (Fatigue) (seriousness criteria hospitalization and life threatening) and ARRHYTHMIA (Arrhythmie) (seriousness criteria hospitalization and life threatening). At the time of the report, SYSTEMIC INFLAMMATORY RESPONSE SYNDROME (systemic inflammatory response), HYPERTENSION (Hypertensive Episode), FATIGUE (Fatigue) and ARRHYTHMIA (Arrhythmie) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Blood test: results not reported results not reported. On an unknown date, Echocardiogram: results not reported results not reported. The action taken with mRNA-1273 (Spikevax) (Intramuscular) was unknown. No concomitant medication information was provided. No treatment medication information was reported. Company comment: This regulatory authority case concerns a 61 year old male patient with no reported medical history, who experienced the unexpected serious (life threatening, hospitalization) events of Systemic inflammatory response syndrome (AESI), Hypertension , Fatigue and Arrhythmia(AESI) , 1 day after receiving a				

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	dose of COVID -19 vaccination with mRNA-1273 vaccine. No further information on clinical course and management of the events was available in the report. The lab reports of echocardiography and blood test were not disclosed. The events were 'not resolved'. The patient had earlier received a dose of COVID-19 Vaccine Janssen which could be confounding for the events. Interchange of vaccine products was noted. The benefit-risk relationship of mRNA-1273 is not affected by this report. Events' seriousness retained as per Regulatory Authority reporting.				
[redacted]	This case was received via European Medicines Agency (Reference number: [redacted] on 06-May-2022 and was forwarded to Moderna on 06-May-2022. This regulatory authority case was reported by a consumer and describes the occurrence of MALNUTRITION (Prolonged nutrient deficiency), CARDIAC ARREST (Advanced age with concomitant cardiac arrest), MOBILITY DECREASED (Inferior mobility), DECREASED APPETITE (Do not want to eat, do not drink), PERSONALITY CHANGE (Personality-changed (dropped a little of his good temper and mischievousness)), COVID-19 IMMUNISATION (Revaccination with different covid-19 vaccine), FATIGUE (Wearers and need to bed earlier, just want to sleep), GENERAL PHYSICAL HEALTH DETERIORATION (Tackled by) and MULTIPLE ORGAN DYSFUNCTION SYNDROME (Multiorgan failure) in a 94-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 016G21A) for COVID-19 vaccination. Co-suspect products included non-company products INFLUENZA VACCINE INACT SPLIT 4V (EFLUELDA) for an unknown indication, TOZINAMERAN (COMIRNATY) for an unknown indication and TOZINAMERAN (COMIRNATY) for an unknown indication. The patient's past medical history included Arm fracture, Colon cancer and Diarrhoea (as an allergic reaction after a penicillin cure after urinary tract infections.). Concurrent medical conditions included Penicillin allergy and Angina pectoris. On 04-Jun-2021, the patient received first dose of	level 5	n/a	This regulatory authority case reported by a consumer concerned a 94-year-old female patient who experienced malnutrition, cardiac arrest, mobility decreased, decreased appetite, personality change, covid-19 immunization (revaccination with different covid-19 vaccine), fatigue, general physical health deterioration and multiple organ dysfunction syndrome with a fatal outcome within an unspecified day after she received the mRNA-1273 vaccination. The medical history included colon cancer and allergic diarrhea, penicillin allergy and angina pectoris. Information on concomitant medications and treatment was unavailable. Co-suspect products included non-Moderna influenza vaccine (Efluelda) and Covid 19 vaccine Tozinameran (Comirnaty). The patient received first and second dose of vaccine on 04-Jun and 21-Jul-2021, respectively. On 04-Nov-2021, the patient received a dose of influenza vaccine (Efluelda). Information regarding the adverse reactions was unavailable for the two doses of Tozinameran and the one dose of Efluelda vaccination. On 28-Dec-2021, the patient received third dose of Covid 19 vaccine with mRNA-1273. In an unspecified day in 2021, the patient experienced the above events and died on 15-Jan-2022. The cause of death was reported as unspecified nutritional deficiency, cardiac arrest and multi organ failure. The case did not report a MIS-A. No detailed information was provided for assessment of MIS. Of note, the patient had medical history of colon cancer and angina pectoris and underlying nutritional deficiency, which may confound the clinical presentations, including cardiac arrest and multi organ failure. The case is considered level 5 for MIS-A, based on the confounding risks and alternative etiologies.	[redacted]

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	TOZINAMERAN (COMIRNATY) (unknown route) 1 dosage form. On 21-Jul-2021, the patient received second dose of TOZINAMERAN (COMIRNATY) (unknown route) 1 dosage form. On 04-Nov-2021, the patient received dose of INFLUENZA VACCINE INACT SPLIT 4V (EFLUELDA) (unknown route) .7 milliliter. On 28-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. In 2021, the patient experienced FATIGUE (Wearers and need to bed earlier, just want to sleep) (seriousness criteria death and medically significant). In December 2021, the patient experienced MOBILITY DECREASED (Inferior mobility) (seriousness criteria death and medically significant), DECREASED APPETITE (Do not want to eat, do not drink) (seriousness criteria death and medically significant), PERSONALITY CHANGE (Personality-changed (dropped a little of his good temper and mischievousness)) (seriousness criteria death and medically significant) and GENERAL PHYSICAL HEALTH DETERIORATION (Tackled by) (seriousness criteria death and medically significant). On 28-Dec-2021, the patient experienced COVID-19 IMMUNISATION (Revaccination with different covid-19 vaccine) (seriousness criteria death and medically significant). On an unknown date, the patient experienced MALNUTRITION (Prolonged nutrient deficiency) (seriousness criteria death and medically significant), CARDIAC ARREST (Advanced age with concomitant cardiac arrest) (seriousness criteria death and medically significant) and MULTIPLE ORGAN DYSFUNCTION SYNDROME (Multiorgan failure) (seriousness criteria death and medically significant). The patient died on 15-Jan-2022. The reported cause of death was Unspecified nutritional deficiency, Cardiac arrest and Multi organ failure. It is unknown if an autopsy was performed. The action taken with mRNA-1273 (Spikevax) (Unknown) was unknown.				

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	No concomitant medications were provided. No treatment information was provided. COMPANY COMMNET: This regulatory authority case concerns a 94 years old female patient with relevant past medical history of colon cancer, who experienced unexpected fatal serious events of malnutrition, cardiac arrest, mobility decreased, decreased appetite, personality change, fatigue, general physical health deterioration, multiple organ dysfunction, which occurred unspecified days after third dose of mRNA-1273 vaccine. Additionally Covid-19 immunization is also reported. The patient was noted to have received two doses with COMINARTY 5 months 7 days prior to mRNA-1273 (Interchange of vaccine products). Patient died on 15-Jan-2022. Reported cause of death was Unspecified nutritional deficiency, Cardiac arrest and Multi organ failure. It is unknown if an autopsy was performed. past medical history of colon cancer remains as confounding for the events malnutrition, decreased appetite, fatigue. The benefit-risk relationship of mRNA-1273 is not affected by this report. The event was assessed as serious as per Regulatory Authority's report.				
[redacted]	This case was received via European Medicines Agency (Reference number: [redacted] on 09-May-2022 and was forwarded to Moderna on 09-May-2022. This regulatory authority case was reported by a physician and describes the occurrence of DYSPNOEA (Dyspnea), PLEURAL EFFUSION (Effusion pleural), PERICARDITIS (Pericarditis) and SYSTEMIC INFLAMMATORY RESPONSE SYNDROME (Systemic inflammatory response syndrome) in a 57-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3005888) for COVID-19 vaccination. No medical history was provided by reporter. Concomitant products included COVID-19 VACCINE NRVV AD26 (JNJ 78436735) (COVID-19 VACCINE JANSSEN) from 23-May-2021 to 23-May-2021 for COVID-19 vaccination. On 27-Nov-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. In	level 4	unassessable	This regulatory authority case reported by a physician concerned a 57-year-old male patient who experienced dyspnea, pleural effusion, pericarditis, and systemic inflammatory response syndrome after he received mRNA-1273 vaccination. Information on medical history, co-meds and treatment for the events was unavailable. The patient previously received JANSSEN COVID-19 vaccine on 23-May-2021. On 27-Nov-2021, he received second dose of vaccination with mRNA-1273. Based on the information captured in the database, he experienced the above events as follow: dyspnea in an unspecified day in January 2022, pleural effusion about 2 months and 21 days after the second dose, pericarditis, and systemic inflammatory response approximately 3 months after the second dose of mRNA-1273 vaccine. The case did not report an MIS-A but reported a SIRS. It provided no information for assessment of MIS disease definition, including fever and duration, clinical features and labs for inflammation and disease activity. Additionally, no information was available for medical history, co-meds and treatment. It is considered level 4 for MIS, and unassessable for WHO categories.	[redacted]

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	January 2022, the patient experienced DYSPNOEA (Dyspnea) (seriousness criterion hospitalization). On 16-Feb-2022, the patient experienced PLEURAL EFFUSION (Effusion pleural) (seriousness criterion hospitalization). On 03-Mar-2022, the patient experienced PERICARDITIS (Pericarditis) (seriousness criterion hospitalization) and SYSTEMIC INFLAMMATORY RESPONSE SYNDROME (Systemic inflammatory response syndrome) (seriousness criterion hospitalization). At the time of the report, DYSPNOEA (Dyspnea), PLEURAL EFFUSION (Effusion pleural), PERICARDITIS (Pericarditis) and SYSTEMIC INFLAMMATORY RESPONSE SYNDROME (Systemic inflammatory response syndrome) was resolving. mRNA-1273 (Spikevax) (Intramuscular) was withdrawn on 27-Nov-2021. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No treatment medications were provided. Company Comment: This is a Regulatory Authority case concerning a 57-year-old male patient, with no medical history reported, who experienced the expected, serious (due to hospitalization) and AESI of Pericarditis, and the unexpected and serious (due to hospitalization) events of Systemic inflammatory response syndrome (AESI), Dyspnoea and Pleural effusion. Patient started with Dyspnoea approximately 1 month and a half after the second dose of mRNA-1273 vaccine. Pleural effusion was experienced 2 months and 21 days after the second dose, and Pericarditis and Systemic inflammatory response occurred approximately 3 months after the second dose of mRNA-1273 vaccine. Previous dose received Janssen vaccine (Interchange of vaccine products). At the time of the report, the events were resolving. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.				
[redacted]	This case was initially received via Takeda Pharmaceuticals (Reference number: [redacted] on 06-	level 3a	conditional	This regulatory case reported by a physician was concerned a 63 years-old male patient who experienced	[redacted]

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[redacted]	May-2022. The most recent information was received on 02-Jun-2022 and was forwarded to Moderna on 10-Jun-2022. This case, initially reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by a physician, was received via the PMDA (Ref, [redacted]). On 02-Jun-2022, follow-up information was received from a physician. On an unknown date, the patient received the 1st dose of a novel coronavirus vaccine (product name unknown). On an unknown date, the patient received the 2nd dose of a novel coronavirus vaccine (product name unknown). On 11-Apr-2022, the patient received the 3rd vaccination with this vaccine. On 12-Apr-2022, the patient experienced a pyrexia in the 38 degrees Celsius range. Around 13:00, due to the sudden onset of convulsions, the patient visited the emergency room of the reporting hospital by ambulance. The patient was status epilepticus at the time of the visit, and anticonvulsants were administered, which stopped the convulsions. Hypotension was observed, and vasoconstrictor was administered, and the patient was weaned from circulatory disorder. Due to persisting consciousness disturbed, endotracheal intubation was performed, and the patient was admitted to the intensive care unit for ventilatory management. The patient was hospitalized. On 13-Apr-2022, the patient developed acute liver disorder, acute kidney injury, and rhabdomyolysis, and was observed to have multi-organ failure. On 17-Apr-2022, hemodialysis was started. On 20-Apr-2022, a tracheostomy was performed. On 21-Apr-2022, the patient was in a state of multi-organ failure with disturbed consciousness with semi-comatose, acute kidney injury requiring dialysis, and persistent liver disorder when leaving the intensive care unit. On 06-May-2022, the patient experienced sepsis and entered the intensive care unit. On 13-May-2022, the patient left the intensive care unit. On 21-May-2022, the patient died. The cause of death was multi-organ failure. No autopsy was performed. The outcome of pyrexia was reported as ongoing and unchanged. The outcome of hypotension, consciousness disturbed, rhabdomyolysis, and semi-coma was unknown. The outcome of convulsion, status epilepticus, multi-organ failure, and sepsis was reported as fatal. No follow-up investigation will be made. Reporter comments continuation: The relationship between the occurrence of adverse events and concomitant drugs is			altered state of consciousness, depressed level of consciousness, hypotension, multiple organ dysfunction syndrome, Pyrexia, Rhabdomyolysis, Seizure, Sepsis and Status epilepticus about 1 day after he received third dose of mRNA-1273. No information on medical history and co meds was available. He started to experience a pyrexia in the 38 degrees Celsius range first (ongoing during the disease process), status epilepticus and hypotension. He then developed acute liver disorder, acute kidney injury, and rhabdomyolysis, and multi-organ failure. He further experienced sepsis and died despite intensive medical attentions about 40 days after the vaccination. The cause of death was multi-organ failure. No autopsy was performed. The case did not report MIS-A. However, the patient had a fever > 3 consecutive days. His clinical features included hypotension and neurologic sign convulsion. The case lacked lab evidence of inflammation and measures of disease activity , such as elevated BNP or NT-proBNP or troponin, cardiac involvement by echocardiography or physical stigmata of heart failure, or EKG changes consistent with myocarditis or myo-pericarditis. in addition, it was heavily confounded by the diagnosis of sepsis, acute liver disorder, lack of information on medical history. It is considered conditional for MIS-A. . WHO causality is considered possible based on the time to onset for the events. Of note, no prior and concurrent medical conditions and co meds were provided for the case, confounding risks may not be fully assessed.	[redacted]

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	unknown. The relationship between the occurrence of adverse events and pathological factors of underlying diseases and complications is unknown. The relationship between the cause of death and adverse events is unknown because the patient died of multi-organ failure after convulsion. The patient with symptomatic epilepsy experienced pyrexia and convulsion and died of multi-organ failure probably due to status epilepticus after receiving this vaccine, although the relationship is unclear. Follow-up received on 02-JUN-2022 Updated: Patient Information, Other Relevant History, Lab Data, Product Information, Event Information, Narrative, Reporter Comments Company Comment: Status epilepticus developed after the administration of ELASOMERAN, factors such as concurrent conditions may have also had an influence. Pyrexia, seizure, hypotension, altered state of consciousness, rhabdomyolysis, multiple organ dysfunction syndrome, depressed level of consciousness, and sepsis developed after the administration of ELASOMERAN and there is temporal relationship.				
[redacted]	This case was received via Takeda Pharmaceuticals (Reference number: [redacted] on 09-May-2022 and was forwarded to Moderna on 13-May-2022. CLARIFICATION REQUIRED: The product was autocoded as Spikevax with WORLD licence and did not stop for adjudication. This case was presented at "The 49th Annual Meeting of the [redacted]. Multisystem inflammatory syndrome was assessed as serious by the MAH. A 52-year-old woman presented to our hospital with fever, transient loss of consciousness and hypotension. Four days ago, she received second COVID-19 Moderna vaccination. At presentation to the hospital, troponin I, C-reactive protein, Neutrophil and NT-pro BNP were elevated, but electrocardiogram didnt show ST-segment change. Transthoracic echocardiography showed depression of cardiac function and cardiac magnetic resonance imaging demonstrated edema and inflammation of both ventricles. After administrating of antibiotics, cardiovascular agents and hydrocortisone intravenously, hemodynamic status and inflammation markers became improved. As diarrhea rash were presented during the clinical course, we diagnosed as MIS according to the case definition. Follow-up	level 1	possible	No original article is available for the case. This meeting presentation case concerned a 52-year-old woman who experienced multisystem inflammatory syndrome four days after she received second COVID-19 Moderna vaccination. She presented fever (unspecified duration), transient loss of consciousness and hypotension. Troponin I, C-reactive protein, Neutrophil and NT-pro BNP were elevated. However, electrocardiogram did not show ST-segment change. Transthoracic echocardiography showed depression of cardiac function and cardiac magnetic resonance imaging demonstrated edema and inflammation of both ventricles. After administrating of antibiotics, cardiovascular agents and hydrocortisone intravenously, hemodynamic status and inflammation markers became improved. Diarrhea and rash were also presented during the clinical course. The case met MIS-A based on the clinical features of multiple organ involvement, lab evidence of inflammation with increased CRP, measures of disease activity of increased Troponin and NT-pro BNP, and evidence of heart function depression and myocarditis. Because the fever duration was unavailable, it may be considered either level 1 or 2 for MIS-A. It is conservatively classified as level 1. WHO causality is considered possible based on the temporal relation of 4	[redacted]

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	investigation will be made. Company Comment: The event developed after the administration of elasomeran and there is temporal relationship.			days.	
[redacted]	This case was received via European Medicines Agency (Reference number [redacted]) on 13-May-2022 and was forwarded to Moderna on 13-May-2022. This regulatory authority case was reported by a consumer and describes the occurrence of HYPOTENSION (Hypotensive derailment tachycardia cardiac arrhythmia), the first episode of PALPITATIONS (Hypotensive derailment tachycardia cardiac arrhythmia), TACHYCARDIA (Hypotensive derailment tachycardia cardiac arrhythmia), HYPOTENSIVE CRISIS (Hypotensive derailment tachycardia cardiac arrhythmia) and the second episode of PALPITATIONS (Hypotensive derailment tachycardia cardiac arrhythmia) in a 64-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 214012) for COVID-19 vaccination. Concurrent medical conditions included Blood pressure high (blood pressure patient with very good attitudes) and Cardiac arrhythmia. On 15-Nov-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 05-Dec-2021, the patient experienced HYPOTENSION (Hypotensive derailment tachycardia cardiac arrhythmia) (seriousness criterion hospitalization), the first episode of PALPITATIONS (Hypotensive derailment tachycardia cardiac arrhythmia) (seriousness criterion hospitalization), TACHYCARDIA (Hypotensive derailment tachycardia cardiac arrhythmia) (seriousness criterion hospitalization), HYPOTENSIVE CRISIS (Hypotensive derailment tachycardia cardiac arrhythmia) (seriousness criterion hospitalization) and the second episode of PALPITATIONS (Hypotensive derailment tachycardia cardiac arrhythmia) (seriousness criterion hospitalization). At the time of the report, HYPOTENSION (Hypotensive derailment tachycardia cardiac arrhythmia), TACHYCARDIA (Hypotensive derailment tachycardia cardiac arrhythmia), HYPOTENSIVE CRISIS (Hypotensive derailment tachycardia cardiac arrhythmia) and the last episode of PALPITATIONS (Hypotensive derailment tachycardia	level 5	n/a	This regulatory authority case reported by a consumer concerned a 64-year-old male patient who experienced and describes the occurrence of hypotension, palpitations, tachycardia, hypotensive crisis about 20 days after he received second dose of mRNA-1273 vaccination. Concurrent medical conditions included blood pressure high and cardiac arrhythmia. No co meds were reported. On an unknown date, Blood pressure measurement was 200/125 (High). The case did not report MIS. Based on the limited information, the case was not MIS-A assessment. The events may be more likely associated with the underlying cardiovascular conditions. It is considered level 5 for MIS. The WHO causality is not applicable for the case.	[redacted]

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	cardiac arrhythmia) had resolved with sequelae. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Blood pressure measurement: 200/125 (High) hypertensive derailment with blood pressure values above 200/125. No concomitant medication were reported. Patient had blood pressure with very good attitudes suddenly occurring up until this time. After emergency measures, continued higher values with two additional drugs necessary for good attitude. Heart arrhythmia disorders decayed but were present. Company comment: This regulatory case concerns a 64-year-old male patient with concurrent cardiac arrhythmia, who experienced the unexpected serious events of Hypotension, Palpitations (reported twice), Tachycardia, and Hypotensive crisis, 20 days after receiving second dose of mRNA-1273 vaccine in the COVID-19 vaccination series that led to hospitalization. Outcome of the events was reported as resolved with sequela. No information was provided on the first dose of COVID-19 vaccine previously received by the patient prior to current mRNA-1273 vaccine. The concurrent cardiac arrhythmia remains a confounder for all events. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report. The case seriousness was assessed as per Regulatory Authority report.				
[redacted]	This literature-non-study case was reported in a literature article and describes the occurrence of MULTISYSTEM INFLAMMATORY SYNDROME IN CHILDREN (Multisystem inflammatory syndrome in children) in a 12-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. LITERATURE REFERENCE: Ouldali N, Bagheri H, Salvo F, Antona D, Pariente A,	level 1	possible	This literature non-study case concerns a 12-year-old female patient, who experienced Multisystem inflammatory syndrome in children (MIS-C) 24 days after receiving the 2nd dose of mRNA-1273 vaccine. Her medical history included transit thyroiditis. According to the authors, she had fever > 3 days, mucocutaneous involvement, shock, cardiac involvement, coagulopathy, acute gastrointestinal symptoms, elevated markers of inflammation after vaccination with no other obvious	[redacted]

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	Leblanc C, et al. Hyper inflammatory syndrome following COVID-19 mRNA vaccine in children: A national post-authorization pharmacovigilance study. Lancet Reg Health Eur. 2022;00:100393 Concurrent medical conditions included Thyroiditis. On an unknown date, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On an unknown date, received first dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. In October 2021, after starting mRNA-1273 (Spikevax), the patient experienced MULTISYSTEM INFLAMMATORY SYNDROME IN CHILDREN (Multisystem inflammatory syndrome in children) (seriousness criteria hospitalization and medically significant). The patient was hospitalized for 5 days due to MULTISYSTEM INFLAMMATORY SYNDROME IN CHILDREN. The patient was treated with IMMUNOGLOBULINS NOS (IMMUNOGLOBULIN I.V) ongoing since an unknown date for MIS-C, at an unspecified dose and frequency. At the time of the report, MULTISYSTEM INFLAMMATORY SYNDROME IN CHILDREN (Multisystem inflammatory syndrome in children) had resolved. Related DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, C-reactive protein: 150 mg/l 150 mg/L. On an unknown date, Ejection fraction: yes (50%) Yes (50%). On an unknown date, Haemoglobin: 11.8 g/dl 11.8 g/dL. On an unknown date, Lymphocyte count: 580/mm3 580/mm3. On an unknown date, Neutrophil count: 9,560 /mm3 9,560 /mm3. On an unknown date, Platelet count: 2,20,000/mm3 2,20,000/mm3. On an unknown date, SARS-CoV-2 antibody test: negative (Negative) Anti-N: negative. On an unknown date, SARS-CoV-2 test: negative (Negative) Negative.			microbial cause. Other manifestations were cytolytic hepatitis, hepato-splenomegaly and lymphopenia. The abnormal lab tests included CRP 150 mg/L. No history of SARS-CoV-2 infection was reported. SARS-CoV-2 test was negative. Considering > 3 days fever, additional clinical features, lab evidence of inflammation and measures of disease activity, the case is considered level 1 for MIS-C. based on the TTO of 24 days in the absence of covid 19 infection, it is considered possible for WHO causality. As the authors stated: "A causal association between COVID-19 mRNA vaccines and hyper-inflammatory syndrome could not be asserted. Indeed, despite extensive investigation for previous SARS-CoV-2 infection in all cases, pauci or asymptomatic SARS-CoV-2 infections are frequent in children, and may not have been documented. Furthermore, false negatives can be observed for anti-Nucleocapsid serology. Thus, we cannot exclude that some of the cases reported here could be related to undiagnosed SARS-CoV-2 infections."	

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	On an unknown date, White blood cell count: 10,400 /mm3 10,400 /mm3. For mRNA-1273 (Spikevax) (Unknown), the reporter considered MULTISYSTEM INFLAMMATORY SYNDROME IN CHILDREN (Multisystem inflammatory syndrome in children) to be related. Concomitant medication was not reported. PICU transfer was reported as no. Delay from first vaccine injection to SARS-CoV-2 antibody testing was 50 days. The impressive number of suspected adverse drug reaction reports (>80,000 between January 2021 and January 2022 in [redacted]) suggest that underreporting may have been very rare, especially for serious adverse drug reactions. Company Comment: This literature non-study case concerns a 12-year-old female patient, with medical history of thyroiditis, overweight, who experienced the unexpected serious medically significant AESI Multisystem inflammatory syndrome in children that occurred 24 days (48 days from first injection) after receiving the 2nd dose of mRNA-1273 vaccine. Patient had fever > 3 days, mucocutaneous involvement, shock, cardiac involvement, coagulopathy, acute gastrointestinal symptoms, elevated markers of inflammation, and no other obvious microbial cause. Other manifestations reported were cytolytic hepatitis, hepato-splenomegaly and lymphopenia. The following lab tests were performed: CRP 150 mg/L, hemoglobin 11.8 g/dl, leucocytes 10400 / mm3, neutrophils 9560 / mm3, lymphocytes 580 / mm3, platelets 220000 / mm3, and LVEF 50%. Patient has no past history of SARS-CoV-2 infection. SARS-CoV-2 test was negative. SARS-CoV-2 antibody Anti-Spike reported positive and Anti-N negative. Patient did not require intensive care nor hemodynamic support. Patient was started on intravenous immunoglobulins plus steroids therapy with favorable outcome and was discharged fully recovered after 5 days of hospitalization. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Event's seriousness assessed based on medical judgement.				

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	This case was linked to [redacted] (E2B Linked Report).				
[redacted]	This literature-non-study case was reported in a literature article and describes the occurrence of MULTISYSTEM INFLAMMATORY SYNDROME IN CHILDREN (Multisystem inflammatory syndrome in children) in a 13-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. LITERATURE REFERENCE: Ouldali N, Bagheri H, Salvo F, Antona D, Pariente A, Belot A, et al. Hyper inflammatory syndrome following COVID-19 mRNA vaccine in children: A national post-authorization pharmacovigilance study. Lancet Public Health. 2022;00 No Medical History information was reported. On an unknown date, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On an unknown date, received first dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. On an unknown date, the patient experienced MULTISYSTEM INFLAMMATORY SYNDROME IN CHILDREN (Multisystem inflammatory syndrome in children) (seriousness criteria hospitalization and medically significant). The patient was hospitalized for 5 days due to MULTISYSTEM INFLAMMATORY SYNDROME IN CHILDREN. At the time of the report, MULTISYSTEM INFLAMMATORY SYNDROME IN CHILDREN (Multisystem inflammatory syndrome in children) had resolved. Related DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, C-reactive protein: 109 mg/l CRP was 109 mg/L. On an unknown date, Eosinophil count: 320 mm3 Eosinophils was 320 mm3. On an unknown date, Haemoglobin: 13.4 g/dl Hemoglobin was 13.4 g/dL. On an unknown date, Lymphocyte count: 510 mm3	level 3a	possible	This literature non-study case concerns a 13-year-old male patient who experienced Multisystem inflammatory syndrome in children (MIS-C) 1 day after receiving the 2nd dose of mRNA-1273 vaccine. No medical history was reported. The patient presented with fever > 3 days, mucocutaneous involvement, coagulopathy, acute gastrointestinal symptoms, neurological involvement and elevated markers of inflammation following vaccination with no other obvious microbial cause. Other manifestations were cytolytic hepatitis, lymphopenia, poly-arthralgia, and myalgia. The abnormal lab tests included CRP 109 mg/L. SARS-CoV-2 test was negative. In consideration of > 3 days fever, additional clinical features, lab evidence of inflammation but with no information on measures of disease activity, the case is considered level 3a for MIS-C. based on the TTO of 1 day in the absence of covid 19 infection, it is considered possible for WHO causality. As the authors stated: "A causal association between COVID-19 mRNA vaccines and hyper-inflammatory syndrome could not be asserted. Indeed, despite extensive investigation for previous SARS-CoV-2 infection in all cases, pauci or asymptomatic SARS-CoV-2 infections are frequent in children, and may not have been documented. Furthermore, false negatives can be observed for anti-Nucleocapsid serology. Thus, we cannot exclude that some of the cases reported here could be related to undiagnosed SARS-CoV-2 infections."	[redacted]

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	Lymphocytes was 510 mm3. On an unknown date, Neutrophil count: 6730 mm3 Neutrophils was 6730 mm3. On an unknown date, Platelet count: 192000 mm3 Platelets was 192000 mm3. On an unknown date, SARS-CoV-2 antibody test: negative (Negative) Negative. On an unknown date, SARS-CoV-2 test: negative (Negative) Nasopharyngeal SARS-CoV-2 PCR was negative. On an unknown date, White blood cell count: 8000 mm3 Leucocytes was 8 000 mm3. For mRNA-1273 (Spikevax) (Unknown), the reporter considered MULTISYSTEM INFLAMMATORY SYNDROME IN CHILDREN (Multisystem inflammatory syndrome in children) to be related. No concomitant product reported. Patient reported specific therapy as steroids. Patient had no past history of SARS-CoV-2 infection. It was reported that patient did not required PICU transfer Hemodynamic support.Patient was not overweight and also did not have any comorbidity condition. Cytolytic hepatitis, lymphopenia, myalgia and arthralgia all were manifestation reported. Symptoms onset date was reported as Oct-2021. Delay from COVID-19 mRNA last injection to symptoms onset was 1 days from first injection. Details of MIS-C WHO criteria were Fever > 3 days, Mucocutaneous involvement, Coagulopathy, Acute gastrointestinal symptoms, Elevated markers of inflammation, No other obvious microbial cause. Delay from first vaccine injection to SARS-CoV-2 antibody testing was of 24 days. Company Comment: This literature non-study case concerns a 13-year-old male patient, with no reported medical history, who experienced				

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	the unexpected serious medically significant AESI Multisystem inflammatory syndrome in children that occurred 1 day (21 days from first injection) after receiving the 2nd dose of mRNA-1273 vaccine. Patient presented with fever > 3 days, mucocutaneous involvement, coagulopathy, acute gastrointestinal symptoms, elevated markers of inflammation. No other obvious microbial cause. Other manifestations were cytolytic hepatitis, lymphopenia, poly-arthralgia neurological involvement, and myalgia. The following lab tests were performed: CRP 109mg/L, hemoglobin 13.4g/dl, leucocytes 8000/ mm3, neutrophils 6730/ mm3, lymphocytes 510 mm3, eosinophils 320/ mm3, and platelets 192000/ mm3. SARS-CoV-2 test was negative. SARS-CoV-2 antibody (Anti-N) negative. Patient did not require intensive care nor hemodynamic support. Patient was started on steroids therapy with favorable outcome and was discharged fully recovered after 5 days of hospitalization. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. This case was linked to [redacted] (E2B Linked Report).				
[redacted]	This case was initially received via European Medicines Agency (Reference number: [redacted] on 18-May-2022. The most recent information was received on 27-Jun-2022 and was forwarded to Moderna on 27-Jun-2022. This regulatory authority case was reported by a consumer and describes the occurrence of DIZZINESS (Dizziness), PARAESTHESIA (Paresthesia), AUTOANTIBODY POSITIVE (Postural tachycardia syndrome (diagnosis confirmed, on likely through vaccination), autoantibodies to GPCR, ACE2 and FGFR3, Wed 2 beta, gliadin, SCL-70, PCNA. IL 8 increased 10x. ME/CFS?), INFLUENZA (Flu symptoms), FATIGUE (Fatigue), MYALGIA (Myalgia), AUTOINFLAMMATORY DISEASE (Hyperinflammation), the first episode of POSTURAL ORTHOSTATIC TACHYCARDIA SYNDROME (Postural tachycardia syndrome (diagnosis confirmed, on likely through vaccination), autoantibodies to GPCR, ACE2 and FGFR3, Wed 2 beta, gliadin, SCL-70, PCNA. IL 8 increased 10x. ME/CFS?), the second episode of POSTURAL ORTHOSTATIC TACHYCARDIA SYNDROME (Postural tachycardia syndrome (diagnosis	level 5	n/a	This physician reported concerned an 84-year-old female patient who experienced Bacterial infection, Multiple organ dysfunction syndrome, Pneumonia, Pulmonary alveolar haemorrhage, Respiratory failure, Vasculitis with a fatal outcome after receiving her third dose of RNA vaccine. On unknown dates, the patient received the 1st dose and the 2nd dose of non-company coronavirus modified uridine RNA vaccine. On 27-Feb-2022, she received the 3rd vaccination. On an unknown date, she experienced severe vasculitis. On 01-Mar-2022, diffuse alveolar haemorrhage and respiratory failure developed. Pyrexia of 38.3 C was noted. On 02-Mar-2022, she was diagnosed with severe pneumonia, with CT evidence of diffuse infiltrative shadows mainly in both upper lung fields. On 03-Mar-2022, the respiratory status was rapidly deteriorated. Intubation and artificial respiration were started. A large amount of foamy bloody sputum was aspirated via the intubation tube. The patient was diagnosed with diffuse alveolar hemorrhage. Pneumonia in both lower lobes was shown on the image. MRSA was detected by culture. Bacterial infection was observed. Antibiotic treatment was performed. On an unknown date,	[redacted]

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	confirmed, on likely through vaccination), autoantibodies to GPCR, ACE2 and FGFR3, Wed 2 beta, gliadin, SCL-70, PCNA. IL 8 increased 10x. ME/CFS?), CHRONIC FATIGUE SYNDROME (Postural tachycardia syndrome (diagnosis confirmed, most likely through vaccination), autoantibodies to GPCR, ACE2 and FGFR3, Wed 2 beta, gliadin, SCL-70, PCNA. IL 8 increased 10x. ME/CFS?), AUTOIMMUNE DISORDER (autoimmunopathy suspected, vaccine-induced inflammation reaction suspected, various autoantibodies!!), POST VACCINATION SYNDROME (Postural tachycardia syndrome (diagnosis confirmed, on/the likely through vaccination), autoantibodies to GPCR, ACE2 and FGFR3, Mi 2 Beta, gliadin, SCL-70, PCNA. IL 8 increased 10x. ME/CFS?), HEADACHE (Headache), FEELING HOT (Feeling hot) and CHILLS (Chills) in a 30-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 214008) for Prophylactic vaccination. Concurrent medical conditions included Migraine. On 21-Jul-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 21-Jul-2021, the patient experienced INFLUENZA (Flu symptoms) (seriousness criterion hospitalization), FATIGUE (Fatigue) (seriousness criterion hospitalization) and HEADACHE (Headache) (seriousness criterion hospitalization). On 22-Jul-2021, the patient experienced CHILLS (Chills) (seriousness criterion hospitalization). On 31-Jul-2021, the patient experienced DIZZINESS (Dizziness) (seriousness criterion hospitalization), PARAESTHESIA (Paresthesia) (seriousness criterion hospitalization) and FEELING HOT (Feeling hot) (seriousness criterion hospitalization). On 04-Aug-2021, the patient experienced AUTOANTIBODY POSITIVE (Postural tachycardia syndrome (diagnosis confirmed, on likely through vaccination), autoantibodies to GPCR, ACE2 and FGFR3, Wed 2 beta, gliadin, SCL-70, PCNA. IL 8 increased 10x. ME/CFS?) (seriousness criterion hospitalization), the first episode of POSTURAL ORTHOSTATIC TACHYCARDIA SYNDROME (Postural tachycardia syndrome (diagnosis confirmed, on likely through vaccination), autoantibodies to GPCR, ACE2			the patient suffered multiple organ failure, and died on 11-Apr-2022. The case did not report MIS-A. No evidence was provided to support a diagnosis of MIS-A. The clinical presentation was likely a pneumonia and alveolar hemorrahge led to respiratory failure and led to multiple organ dysfunction in this elderly female patient. it is considered level 5 for MIS-A, due to an alternative etiology of pneumonia.	

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	and FGFR3, Wed 2 beta, gliadin, SCL-70, PCNA. IL 8 increased 10x. ME/CFS?) (seriousness criterion hospitalization), the second episode of POSTURAL ORTHOSTATIC TACHYCARDIA SYNDROME (Postural tachycardia syndrome (diagnosis confirmed, on likely through vaccination), autoantibodies to GPCR, ACE2 and FGFR3, Wed 2 beta, gliadin, SCL-70, PCNA. IL 8 increased 10x. ME/CFS?) (seriousness criterion hospitalization), CHRONIC FATIGUE SYNDROME (Postural tachycardia syndrome (diagnosis confirmed, most likely through vaccination), autoantibodies to GPCR, ACE2 and FGFR3, Wed 2 beta, gliadin, SCL-70, PCNA. IL 8 increased 10x. ME/CFS?) (seriousness criteria hospitalization and disability) and POST VACCINATION SYNDROME (Postural tachycardia syndrome (diagnosis confirmed, on/the likely through vaccination), autoantibodies to GPCR, ACE2 and FGFR3, Mi 2 Beta, gliadin, SCL-70, PCNA. IL 8 increased 10x. ME/CFS?) (seriousness criterion hospitalization). On 05-Aug-2021, the patient experienced MYALGIA (Myalgia) (seriousness criterion hospitalization), AUTOINFLAMMATORY DISEASE (Hyperinflammation) (seriousness criterion hospitalization) and AUTOIMMUNE DISORDER (autoimmunopathy suspected, vaccine-induced inflammation reaction suspected, various autoantibodies!!) (seriousness criterion hospitalization). At the time of the report, DIZZINESS (Dizziness), AUTOANTIBODY POSITIVE (Postural tachycardia syndrome (diagnosis confirmed, on likely through vaccination), autoantibodies to GPCR, ACE2 and FGFR3, Wed 2 beta, gliadin, SCL-70, PCNA. IL 8 increased 10x. ME/CFS?), INFLUENZA (Flu symptoms), FATIGUE (Fatigue), MYALGIA (Myalgia), AUTOINFLAMMATORY DISEASE (Hyperinflammation), the last episode of POSTURAL ORTHOSTATIC TACHYCARDIA SYNDROME (Postural tachycardia syndrome (diagnosis confirmed, on likely through vaccination), autoantibodies to GPCR, ACE2 and FGFR3, Wed 2 beta, gliadin, SCL-70, PCNA. IL 8 increased 10x. ME/CFS?), CHRONIC FATIGUE SYNDROME (Postural tachycardia syndrome (diagnosis confirmed, most likely through vaccination), autoantibodies to GPCR, ACE2 and FGFR3, Wed 2 beta, gliadin, SCL-70, PCNA. IL 8 increased 10x. ME/CFS?), AUTOIMMUNE DISORDER (autoimmunopathy suspected, vaccine-induced				

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	inflammation reaction suspected, various autoantibodies!!), POST VACCINATION SYNDROME (Postural tachycardia syndrome (diagnosis confirmed, on/the likely through vaccination), autoantibodies to GPCR, ACE2 and FGFR3, Mi 2 Beta, gliadin, SCL-70, PCNA. IL 8 increased 10x. ME/CFS?), HEADACHE (Headache), FEELING HOT (Feeling hot) and CHILLS (Chills) had not resolved and PARAESTHESIA (Paresthesia) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Antibody test: negative (Negative) Negative before vaccination. The action taken with mRNA-1273 (Spikevax) (Unknown) was unknown. The concomitant medication was not reported by reporter. It was reported that the patient was experiencing the symptoms like burning headache, dizziness, nausea, tingling, blurred vision, odoriness, metallic taste, electric feeling, restless/confusion, diarrhea, paralysis, sleep paralysis, 3 stroke-like seizures, swallowing disorders, swollen eyelids, suffocation attacks during sleep, sleep disturbance, nerve vibrating,10kilos weight loss, loss of appetite,brain fog, derealization, blood pressure crises, postural tachycardia syndrome, cardiac arrhythmia, tingling in the heart, itching, new allergies, mast cell activation syndrome, muscle twitching, Petechiae, bruising, earache, pressure on the ears, tinnitus, feeling not being able to breathe deeply, not being able to properly end yawning, skin changes, terror, arbitrary/groundless adrenaline surges, stress intolerance, temperature perception and balance disturbed, increased cell count in nerve water, nerve conduction velocity in one leg worsens for a short time, small fiber neuropathy,skin detaches(face, hands, feet), eye pains and pressure, none more tear fluid, polyuria, polydypsia, pain such as needle pricks everywhere,whole body numb and falls asleep, goosebumps.Her freeze autoantibodies were ACE2, beta 2 adrenergic receptor,FGF				

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	receptor3, beta1 adrenoceptor,alpha1 adrenoceptor,endotheline receptor at risk,muscarinergic receptor 2. It was stated that her migraine now still gliadin, sCL-70, PCNA and myositis Mi2 beta AAK.Postural tachycardia syndrome confirmed by university hospital, most likely by vaccination. It was reported that the autoimmunopathy was suspected, Borellia and toxoplasmosis reactivated, suspected vaccine-induced inflammation reaction, dermatomyositis and Sjogren suspected, but could not be confirmed. suspicion of expired myocarditis. ME/CFS similar symptomatology, long covid-like symptomatology, blood pressure crises, regulation disorder of the skin vessels. Sicca syndrome,Raynaud confirmed. Company Comment : This is a regulatory case concerning a 30-year-old female patient with medical history of migraine, who experienced the unexpected serious (hospitalization) events of Dizziness, Paraesthesia,				
[redacted]	This case was received via Takeda Pharmaceuticals (Reference number: [redacted] on 23-May-2022 and was forwarded to Moderna on 24-May-2022. This case, initially reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by a physician, was received via the PMDA (Ref, [redacted]. On an unknown date, the patient received the 1st dose of non-company coronavirus modified uridine RNA vaccine (SARS-CoV-2). On an unknown date, the patient received the 2nd dose of non-company coronavirus modified uridine RNA vaccine (SARS-CoV-2). On 27-Feb-2022, the patient received the 3rd vaccination with this vaccine. On an unknown date, the patient experienced severe vasculitis. On 01-Mar-2022, diffuse alveolar haemorrhage and respiratory failure developed. Pyrexia of 38.3 degrees Celsius was noted. On 02-Mar-2022, the patient was referred to a nearby physician with a diagnosis of severe pneumonia. Computed tomography (CT) on admission showed diffuse infiltrative shadows mainly in the upper lung fields of both lungs. On 03-Mar-2022, the respiratory status was rapidly deteriorated. Since SpO2 became 70% to 80% even with oxygen of 15 L/min, intubation was performed, and artificial respiration was started. A large amount of foamy bloody sputum was aspirated via the intubation tube. The	level 5	n/a	This pharmacist reported case concerned a 64-year-old male patient who experienced vaccination failure, COVID-19 pneumonia, atrial fibrillation, pneumothorax and vaccine associated enhanced respiratory disease with a fatal outcome about 7.5 months after he received his second dose of mRNA-1273. Past medical history included Chronic venous insufficiency and Anxio-depressive syndrome. On 13-May-2021, he received second dose of mRNA-1273. On 26-Dec-2021, the patient experienced above events, and died on 20-Jan-2022. The reported cause of death was covid-19 pneumonia. SARS-CoV-2 test was positive. The case did not report MIS-A. No information was provided for assessment of MIS-A. The events occurred over 7 months after last vaccination. Furthermore, there was concurrent Covid 19 infection. The case is considered level 5 for MIS-A.	[redacted]

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	patient was diagnosed with diffuse alveolar hemorrhage. Steroid pulse therapy was started. On 15-Mar-2022, the mechanical ventilation was removed. On 22-Mar-2022, respiratory status worsened again, and the patient was intubated again. Pneumonia in both lower lobes was shown on the image. MRSA was detected by culture. Bacterial infection was observed. Antibiotic treatment was performed. On an unknown date, the patient suffered multiple organ failure. On 11-Apr-2022, the patient died. The outcome of severe pneumonia, and vasculitis was unknown. The outcome of diffuse alveolar hemorrhage, respiratory failure, multi-organ failure, and bacterial infection was reported as fatal. Follow-up investigation will be made. Company Comment: The events developed after the administration of ELASOMERAN and there is temporal relationship.				
[redacted]	This case was received via European Medicines Agency (Reference number: [redacted] on 24-May-2022 and was forwarded to Moderna on 24-May-2022. This regulatory authority case was reported by a pharmacist and describes the occurrence of VACCINATION FAILURE (Vaccination failure), COVID-19 PNEUMONIA (Bilateral pneumonia), ATRIAL FIBRILLATION (Fibrillation), PNEUMOTHORAX (Pneumothorax) and VACCINE ASSOCIATED ENHANCED RESPIRATORY DISEASE (Vaccine associated enhanced respiratory disease) in a 64-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 3001532 and 3001177) for COVID-19 vaccination. The patient's past medical history included Chronic venous insufficiency and Anxiodepressive syndrome. On 14-Apr-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 13-May-2021, received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. On 26-Dec-2021, the patient experienced VACCINATION FAILURE (Vaccination failure) (seriousness criterion death), COVID-19 PNEUMONIA (Bilateral pneumonia) (seriousness criterion death), ATRIAL FIBRILLATION (Fibrillation) (seriousness criterion death) and VACCINE ASSOCIATED ENHANCED RESPIRATORY DISEASE (Vaccine	level 5	n/a	This consumer reported case concerned a 47-year-old female patient who experienced cerebral venous sinus thrombosis, vaccination failure and vaccine associated enhanced respiratory disease more than 7 months after she received her second dose of mRNA-1273. Her past medical history included COVID-19 infection in January 2022, Microalbuminuria, Brucellosis, Sacroiliitis and Hypothyroidism. Previously administered products included Enalapril. No concomitant medication and treatment medications were reported. On 07-Jul-2021, the patient received second dose of mRNA-1273. On 14-Feb-2022, she experienced the above events. The case did not report MIS-A. No information relevant for assessment of MIS-A was available. Rather alternative etiologies and events were provided. The events occurred over 7 months after her last vaccination. The case is considered level 5 for MIS-A.	[redacted]

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	associated enhanced respiratory disease) (seriousness criterion death). On 01-Jan-2022, the patient experienced PNEUMOTHORAX (Pneumothorax) (seriousness criterion death). The patient died on 20-Jan-2022. The reported cause of death was covid-19 pneumonia (10084380). It is unknown if an autopsy was performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 25-Dec-2021, SARS-CoV-2 test positive: positive (Positive) Positive. On 26-Dec-2021, Blood test: abnormal Blood count at admission: Hb 14.2, hto 41. Leukocytes 6830.83% Gr. Lymphocytes 440 Platelets 171000. - Coagulation at admission: INR 1.19 - D-dimer: 962 - Biochemistry: Glu 127, urea 38, Cr 0.94, FG 85, albumin 4, LDH 276, GOT 24, GPT 17 - PCT at admission: 0.17 - PCR at admission 195 - Tp I 15.85 - ProBNP: 1900 - GAB: ph 7.48, pCO2 33, Po2 51, Sat 89%. On 26-Dec-2021, Chest X-ray: bilateral infiltrates patched in tarnished glass bilateral infiltrates patched in tarnished glass. On 26-Dec-2021, Electrocardiogram: fa at 120 bpm (after taking bisoprolol 2.5 and afe FA at 120 bpm (after taking bisoprolol 2.5 and afebryl, FA at 100 bpm). On 28-Dec-2021, Chest X-ray: worsening worsening with respect to previous RX with progression of alveolo-interstitial infiltrates in both HT.. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. No concomitant medications were reported. No treatment medications were reported. Company comment: This fatal regulatory authority case concerns 64-year-old male patient, with no relevant medical history, who experienced the unexpected, serious (due to death) events of VACCINATION FAILURE, PNEUMOTHORAX and VACCINE ASSOCIATED ENHANCED RESPIRATORY DISEASE; and the unexpected, serious (due to death) AESIs of COVID-19 PNEUMONIA and ATRIAL FIBRILLATION. The events				

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	VACCINATION FAILURE, VACCINE ASSOCIATED ENHANCED RESPIRATORY DISEASE, COVID-19 PNEUMONIA and ATRIAL FIBRILLATION occurred 7 months after the second dose of mRNA-1273 vaccine; a week later PNEUMOTHORAX developed. He died twenty days later. The cause of death was covid-19 pneumonia. A positive SARS-CoV-2 test was performed and the chest X-ray showed initially bilateral infiltrates patched in tarnished glass, and two days later showed worsening with progression of alveolo-interstitial infiltrates. It is unknown if an autopsy was performed. The benefit-risk relationship of mRNA-1273 is not affected by this report. Event´s seriousness assessed as per Regulatory Authority's report.				
[redacted]	This case was received via European Medicines Agency (Reference number: [redacted]) on 27-May-2022 and was forwarded to Moderna on 27-May-2022. This regulatory authority case was reported by a consumer and describes the occurrence of CEREBRAL VENOUS SINUS THROMBOSIS (Thrombosis of venous sinuses), VACCINATION FAILURE (Vaccine failure) and VACCINE ASSOCIATED ENHANCED RESPIRATORY DISEASE (Intensification associated with respiratory disease vaccine) in a 47-year-old female patient who received mRNA-1273 (Spikevax) (batch nos. 214002 and 3002623) for COVID-19 vaccination. The patient's past medical history included COVID-19 (COVID19 infection IN JANUARY 2022 with mild symptoms (malaise)) in January 2022, Microalbuminuria (Microalbuminuria in treatment with low dose ACEI.), Brucellosis (with HLA B27 (+) and Brucella Serology +.), Sacroiliitis and Hypothyroidism (due to thyroiditis, currently untreated because thyroid function was normalized). Previously administered products included for Product used for unknown indication: Enalapril (Enalapril 5 mg comprimido). Past adverse reactions to the above products included No adverse event with Enalapril. On 09-Jun-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 07-Jul-2021, received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1	level 4	unassessable	The original article is unavailable from source document. This case presented at a [redacted] scientific meeting concerned a male patient of unknown age, who experienced hyper-inflammatory syndrome after receiving a dose of Moderna COVID-19 mRNA vaccine. The case provided no information on fever, clinical features and lab tests for assessment of MIS. In addition, patient's age, medical history including covid 19 infection, co-meds, vaccine and event TTO were unavailable. The case is considered level 4 for MIS, and unassessable for WHO causality due to insufficient information provided.	[redacted]

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	dosage form. On 14-Feb-2022, the patient experienced CEREBRAL VENOUS SINUS THROMBOSIS (Thrombosis of venous sinuses) (seriousness criteria hospitalization, medically significant and life threatening), VACCINATION FAILURE (Vaccine failure) (seriousness criteria hospitalization, medically significant and life threatening) and VACCINE ASSOCIATED ENHANCED RESPIRATORY DISEASE (Intensification associated with respiratory disease vaccine) (seriousness criteria hospitalization, medically significant and life threatening). At the time of the report, CEREBRAL VENOUS SINUS THROMBOSIS (Thrombosis of venous sinuses), VACCINATION FAILURE (Vaccine failure) and VACCINE ASSOCIATED ENHANCED RESPIRATORY DISEASE (Intensification associated with respiratory disease vaccine) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 14-Feb-2022, Blood test: abnormal Blood count: Hb 12.6, Hto 38.3, Leukocytes 9.1 (N6.62-L1.57), platelets 249. - Coagulation: prothrombin 96 act, TP 12, aptT 27.6, Fibrinogen 5. DD 3690. - Biochemistry: glucose 89, urea 25, creatinine 0.79, sodium 142, potassium 4.5.. On 14-Feb-2022, Scan brain: abnormal No signs of acute bleeding or other intracranial expansive effects are observed. Low-attenuation focal lesion in the left lenticular nucleus, in probable relation to dilated perivascular space/lacunar infarction. Ventricular system of morphology and normal size, without signs of hydrocephalus. Centered midline. After administration of intravenous iodized contrast, repletion defects are observed in the left sigmoid sinus, gulf of the left jugular and doubtful focal repletion defect in the transverse sinus, associated with dilation of occipital cortical veins and left cerebellar, findings compatible with venous sinus thrombosis. No relevant bone lesions are observed. Diagnosis: Findings compatible with venous sinus thrombosis. JC: - Cerebral vein thrombosis.. On 16-Feb-2022, Magnetic resonance imaging head: abnormal In line with CT prior to 14/02/2022, the occupation of the left transverse sinus and the left sigmoid sinus was observed, with artifact in sequences of ferromagnetic susceptibility, in relation to already known venosa thrombosis. There are no signs of intra or extraxial				

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	bleeding, areas of diffusion restriction suggesting infarction as a complication or other notable supra or infratentorial alterations, with the exception of two oval and hyperintense images in long TR sequences located posterior left periventricular and capsulo-nodal area left unspecific but suggestive of large spaces of Virchow-Robin. Rest of the study without other hallazgos. venosa thrombosis in the transverse sinus and left sigmoid without visible secondary complications. On 21-Feb-2022, Blood test: abnormal VSG: normal. - Biochemistry: Glucose 74 mg/dL. Glycosylated hemoglobin (Hb A1c) 5.6%. Glycosylated hemoglobin (Hb A1c) 38 mmol/mol. Urea 18 mg/dL. Creatinine 0.78 mg/dL. ESTIMATED FG (CKD-EPI) 90. Total proteins 6.6 g/dL. Albumin 3.8 g/dL. Urate 5.9 mg/dL. Total bilirubin 0.34 mg/dL. Sodium 37 mmol/L. Potassium 4.50 mmol/L. Chlorine 105 mmol/L. Calcium 8.9 mg/dL. Iron 101 µg/dL. Phosphate 2.5 * mg/dL. Magnesium 1.84 mg/dL. Calculated osmolality 270.9 * mOsm/kg. Triglycerides 117 mg/dL. Cholesterol 173 mg/dL. HDL cholesterol 49 mg/dL. Total Cholesterol/HDL Cholesterol Index 4. LDL cholesterol 101 mg/dL. LDH 139 IU/L. Creatinkinase (CK) 95 IU/L. GOT 11 IU/L. GPT 11 IU/L .GGT 18 IU/L Amylase 52 IU/L. Alkaline phosphatase (ALP) 87 IU/L. T4 free 1.20 ng/dL. TSH 2.44 UUI/ml. Folic Acid 6.6 ng/mL. Vitamin B12 368 pg/mL. Protein C reactive 11.5 * mg/L. Ferritin 172.4 * ng/mL. Transferrin 175 mg/dL. Transferrin saturation index 45% - Homocysteine 13.3 µmol/L - Tumor markers: CA 19-9 Ag 40.6 * U/mL, normal rest. - Proteinogram: normal. - Anticardiolipin antibodies: negative. - Serologies: brucela, borrelia, syphilis, HIV, hepatitis, HSV, CMV, negative.. No concomitant medication was reported. No treatment medications was reported. Company comment: This regulatory authority case concerns a 47-year-old, female patient with no relevant medical history reported, who experienced the unexpected serious events of Cerebral venous sinus thrombosis and Vaccine associated enhanced				

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	respiratory disease (seriousness criterion life threatening, hospitalization and medically significant) which occurred on 223 days after the second dose of mRNA-1273 vaccine. Vaccination failure was reported as additional event. The investigation performed between 14-feb-2022 to 16-feb-2022 showed the Brain Scan with abnormal findings with no signs of acute bleeding or other intracranial expansive effects are observed. Low-attenuation focal lesion in the left lenticular nucleus, in probable relation to dilated perivascular space/lacunar infarction. Magnetic resonance imaging head showed abnormal left transverse sinus and the left sigmoid sinus, with artifact in sequences of ferromagnetic susceptibility, in relation to already known venous thrombosis. The benefit-risk relationship of mRNA-1273 is not affected by this report. The events were assessed as serious as per Regulatory Authority´s report.				
[redacted]	This case was received via Takeda Pharmaceuticals (Reference number: [redacted] on 30-May-2022 and was forwarded to Moderna on 06-Jun-2022. This case was presented at "The 66th Annual General [redacted]. Since the proprietary name of the suspect drug was not specified, the drug is handled as a Takeda product in this case report. A male patient developed hyper-inflammatory syndrome after the vaccination of COVID-19 mRNA vaccine (proprietary name was unknown). Event outcome was recovery. Details such as clinical courses were unknown. Information on the patient's age, complications, and concomitant agents was unknown. Follow-up investigation will be made. Companion cases: [redacted] Company Comment: The event developed after the administration of elasomeran and there is temporal relationship.	level 4	unassessable	The original article is unavailable from source document. This case presented at a [redacted] scientific meeting concerned a male patient of unknown age, who experienced hyper-inflammatory syndrome after receiving a dose of Moderna COVID-19 mRNA vaccine. The case provided no information on fever, clinical features and lab tests for assessment of MIS. In addition, patient's age, medical history including covid 19 infection, co-meds, vaccine and event TTO were unavailable. The case is considered level 4 for MIS, and unassessable for WHO causality due to insufficient information provided.	[redacted]
[redacted]	This case was received via Takeda Pharmaceuticals (Reference number: [redacted]) on 30-May-2022 and was forwarded to Moderna on 06-Jun-2022. This case was received via Takeda Pharmaceuticals (Reference number: [redacted]) on 30-May-2022 and was forwarded to Moderna on 06-Jun-2022. This case was presented at "The 66th Annual General [redacted]	level 4	unassessable	The original article is unavailable from source document. This case presented at a [redacted] scientific meeting concerned a female patient of unknown age, who experienced hyper-inflammatory syndrome after receiving a dose of Moderna COVID-19 mRNA vaccine. Despite of elevated CRP and serum ferritin, the case provided no information on fever, clinical features, and measures of disease activity for assessment of MIS. In addition,	[redacted]

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	[redacted]. Since the proprietary name of the suspect drug was not specified, the drug is handled as a Takeda product in this case report. A male patient developed hyper-inflammatory syndrome after the vaccination of COVID-19 mRNA vaccine (proprietary name was unknown). Event outcome was recovery. Details such as clinical courses were unknown. Information on the patient's age, complications, and concomitant agents was unknown. Follow-up investigation will be made. Companion cases: [redacted] Company Comment: The event developed after the administration of elasomeran and there is temporal relationship.			patient's age, medical history including covid 19 infection, co-meds, vaccine and event TTO were unavailable. The case is considered level 4 for MIS, and unassessable for WHO causality due to insufficient information provided.	
[redacted]	This literature-non-study case was reported in a literature article and describes the occurrence of MULTISYSTEM INFLAMMATORY SYNDROME (Hyper-inflammatory syndrome) in a female patient of an unknown age who received mRNA-1273 (Spikevax) for COVID-19 vaccination. LITERATURE REFERENCE: Senzaki K, Ito H, Hanaoka H, Yoshida M, Yamada H.. Hyper-inflammatory syndrome developed after vaccination of COVID-19 vaccine.. The 66th Annual General Assembly and Scientific Meeting of the Japan College of.. 2022:727 No Medical History information was reported. On an unknown date, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On an unknown date, the patient experienced MULTISYSTEM INFLAMMATORY SYNDROME (Hyper-inflammatory syndrome) (seriousness criteria hospitalization and medically significant). At the time of the report, MULTISYSTEM INFLAMMATORY SYNDROME (Hyper-inflammatory syndrome) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, C-reactive protein: elevated Test Result:Elevated. On an unknown date, Fibrin D dimer: elevated Test	level 4	unassessable	The original article is unavailable from source document. This case presented at a [redacted] scientific meeting concerned a female patient of unknown age, who experienced hyper-inflammatory syndrome after receiving a dose of Moderna COVID-19 mRNA vaccine. The case provided no information on fever, clinical features and lab tests for assessment of MIS. In addition, patient's age, medical history including covid 19 infection, co-meds, vaccine and event TTO were unavailable. The case is considered level 4 for MIS, and unassessable for WHO causality due to insufficient information provided.	[redacted]

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	Result:Elevated. On an unknown date, Serum ferritin: elevated Test Result:Elevated. The action taken with mRNA-1273 (Spikevax) (Unknown) was unknown. For mRNA-1273 (Spikevax) (Unknown), the reporter considered MULTISYSTEM INFLAMMATORY SYNDROME (Hyper-inflammatory syndrome) to be possibly related. BP Comment: The event developed after the administration of elasomeran and there is temporal relationship. This case was linked to [redacted] (E2B Linked Report).				
[redacted]	This case was received via Takeda Pharmaceuticals (Reference number: [redacted] on 30-May-2022 and was forwarded to Moderna on 06-Jun-2022. This case was presented at 'The 66th Annual General Assembly and Scientific Meeting of the Japan College of Rheumatology'. Since the proprietary name of the suspect drug was not specified, the drug is handled as a Takeda product in this case report. A female patient developed hyper-inflammatory syndrome after the vaccination of COVID-19 mRNA vaccine (proprietary name was unknown). Event outcome was recovery. Details such as clinical courses were unknown. Information on the patient's age, complications, and concomitant agents was unknown. Follow-up investigation will be made. Companion cases: [redacted] Company Comment: The event developed after the administration of elasomeran and there is temporal relationship	level 5	n/a	This case reported by a pharmacist and a physician concerned a 40-year-old male patient, who experienced pyrexia, respiratory discomfort, and diarrhea on same day after receiving his second dose of Moderna mRNA vaccine. Two days later, he developed pneumonia confirmed by CT examination, dyspnea, lung abscess and multi-organ failure with a fatal outcome. The case did not report MIS-A. The clinical course may be more likely a concurrent respiratory bacterial infection origin, led to lung abscess, presenting fever, dyspnea, and diarrhea, and further led to multi organ failure and a fatal outcome. The case is considered level 5 for MIS-A due to an alternative etiology presence.	[redacted]
[redacted]	This case was initially received via Takeda Pharmaceuticals (Reference number: [redacted] on 03-Jun-2022. The most recent information was received on 09-Jun-2022 and was forwarded to Moderna on 15-Jun-2022. This case was reported by a pharmacist via a medical representative. On 06-Jun-2022, additional information, reported to the Pharmaceuticals and Medical Devices	level 5	n/a	This case reported by a pharmacist and a physician concerned a 40-year-old male patient, who experienced pyrexia, respiratory discomfort, and diarrhea on same day after receiving his second dose of Moderna mRNA vaccine. Two days later, he developed pneumonia confirmed by CT examination, dyspnea, lung abscess and multi-organ failure with a fatal outcome. The case did not	[redacted]

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	Agency (PMDA) by a physician, was received via the PMDA (Ref, [redacted]. On 09-Jun-2022, additional information, reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by a physician, was received via the PMDA (Ref, [redacted]. On an unknown date, the patient received the 1st dose of this vaccine. On 01-Nov-2021, the patient received the 2nd dose of this vaccine. Around 14:00, the patient experienced pyrexia, respiratory discomfort, and diarrhea. On 03-Nov-2021, pneumonia, dyspnea, and multi-organ failure developed. The house-visiting physician examined the patient and made an emergency call. Hyperthermia, tachypnea, and cyanosis were noted, and the patient was transported to the medical emergency center of the reporting hospital. An image of pneumonia was shown on the result of CT examination, and the patient was diagnosed with pneumonia. The patient was intubated and put on mechanical ventilator. Steroid pulse therapy was performed, but multi-organ failure including lung progressed. On 07-Nov-2021, the patient was transferred to another hospital as ECMO was indicated. Lung abscess also developed. On 26-Nov-2021, the patient was readmitted to the reporting hospital because the patient was able to be weaned from ECMO. The patient's general condition did not improve thereafter. On 27-Dec-2021, the patient died. On an unknown date, the results of the pathological autopsy revealed that respiratory failure due to lung abscess was the main cause of death and that there were multiple small cerebral infarctions and herpes simplex infection due to decreased immunocompetence associated with infection. The outcome of pyrexia, respiratory failure, diarrhea, pneumonia, multi-organ failure, and lung abscess was reported as fatal. The outcome of multiple small cerebral infarction and herpes simplex infection was unknown. Follow-up investigation will be made. Follow-up received on 09-JUN-2022 Updated: Event Information, Narrative, Reporter Comments Company Comment: The events developed after the administration of ELASOMERAN and there is temporal relationship.			report MIS-A. The clinical course may be more likely a concurrent respiratory bacterial infection origin, led to lung abscess, presenting fever, dyspnea, and diarrhea, and further led to multi organ failure and a fatal outcome. The case is considered level 5 for MIS-A due to an alternative etiology presence.	
[redacted]	This regulatory authority case was reported by a physician and describes the occurrence of SEPTIC SHOCK (Septic shock//Fever//Nausea//Vomiting//Cough//Respiratory insufficiency), PYREXIA (Septic shock//Fever//Nausea//Vomiting//Cough//Respiratory insufficiency), NAUSEA (Septic	level 3b	possible	This regulatory authority case reported by a physician concerned an 18-year-old male who experienced septic shock, pyrexia, nausea, vomiting, cough, and respiratory failure on an unknown date after he received mRNA-1273 vaccine on an unknown date. No medical history was provided. Co meds included acetaminophen,	[redacted]

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	shock//Fever//Nausea//Vomiting//Cough//Respiratory insufficiency), VOMITING (Septic shock//Fever//Nausea//Vomiting//Cough//Respiratory insufficiency), COUGH (Septic shock//Fever//Nausea//Vomiting//Cough//Respiratory insufficiency) and RESPIRATORY FAILURE (Septic shock//Fever//Nausea//Vomiting//Cough//Respiratory insufficiency) in an 18-year-old male patient who received mRNA-1273 (COVID 19 Vaccine Moderna) for COVID-19 prophylaxis. Concomitant products included ACETAMINOPHEN, ACETYLSALICYLIC ACID, OLANZAPINE and RISPERIDONE for an unknown indication. On an unknown date, the patient received dose of mRNA-1273 (COVID 19 Vaccine Moderna) (unknown route) 1 dosage form. On an unknown date, the patient experienced SEPTIC SHOCK (Septic shock//Fever//Nausea//Vomiting//Cough//Respiratory insufficiency) (seriousness criterion medically significant), PYREXIA (Septic shock//Fever//Nausea//Vomiting//Cough//Respiratory insufficiency) (seriousness criterion medically significant), NAUSEA (Septic shock//Fever//Nausea//Vomiting//Cough//Respiratory insufficiency) (seriousness criterion medically significant), VOMITING (Septic shock//Fever//Nausea//Vomiting//Cough//Respiratory insufficiency) (seriousness criterion medically significant), COUGH (Septic shock//Fever//Nausea//Vomiting//Cough//Respiratory insufficiency) (seriousness criterion medically significant) and RESPIRATORY FAILURE (Septic shock//Fever//Nausea//Vomiting//Cough//Respiratory insufficiency) (seriousness criterion medically significant). At the time of the report, SEPTIC SHOCK (Septic shock//Fever//Nausea//Vomiting//Cough//Respiratory insufficiency), PYREXIA (Septic shock//Fever//Nausea//Vomiting//Cough//Respiratory insufficiency), NAUSEA (Septic shock//Fever//Nausea//Vomiting//Cough//Respiratory insufficiency), VOMITING (Septic			acetylsalicylic acid, olanzapine, and risperidone. No treatment medications were reported. The case is considered level 3b for MIS-C, as the case is medically confirmed, the patient had fever of unknown period, and clinical presentations showed GI and circulation involvement, but no Laboratory evidence of inflammation and measures of disease activity are available. The respiratory failure could be the outcome of shock. However, the WHO is considered unassessable due to lack of sufficient information, including TTO for events.	

Case ID	Narrative (Complete)	Brighton	WHO	MAH comment	WW Identifier
	shock//Fever//Nausea//Vomiting//Cough//Respiratory insufficiency), COUGH (Septic shock//Fever//Nausea//Vomiting//Cough//Respiratory insufficiency) and RESPIRATORY FAILURE (Septic shock//Fever//Nausea//Vomiting//Cough//Respiratory insufficiency) had not resolved. 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. No treatment medications were reported. Company comment: This regulatory authority case concerns an 18-year-old male patient with no reported medical history, who experienced the unexpected serious (medically significant) events of Septic shock, Pyrexia, Nausea, Vomiting, Cough, and Respiratory failure which occurred unknown days after administration of an unspecified dose of mRNA-1273 vaccine. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Events' seriousness assessed as per Regulatory Authority's report.				

Appendix 11.19i Multisystem Inflammatory Syndrome (MIS): Various synonymous terms of SPIKEVAX

Elasomeran/ or 2019-nCoV Vaccine mRNA-1273/ or (mRNA-1273 or "mRNA 1273" or mRNA1273 or "modernatx 1273" or "modernatx- 1273" or "moderntx 1273" or "moderntx-1273" or m-1273 or "m 1273" or "Moderna Covid19 Vaccine" or "Moderna Covid-19 Vaccine" or "Moderna-Covid-19-Vaccine" or "Moderna Covid 19 Vaccine" or SPIKEVAX or Spike-vax or Elasomeran or "CX-024414" or "TAK-919" or "TAK 919" or TAK919

Appendix 11.20a Chronic Urticaria: Cases classified by the MAH as Chronic Urticaria Flare/Worsening (n=9)

Cases classified by the MAH as Chronic Urticaria Flare / Worsening (n=9)

Case ID	ALL PTs	Age	Sex	Medical History	Concomitant Medications	Diagnostic certainty	WHO-UMC Causality	Causality Justification	TTO per Medical Review	Dose per Medical Review	WW Identifier
[redacted]	Angioedema, Chronic spontaneous urticaria	74.00	Female	Rhinitis allergic(H); Chronic spontaneous urticaria(H); Angioedema(H)		Definite	Possible	The patient with a preceding history of CSU, which was controlled in past with first generation H1 antihistamine, developed a relapse of CSU following administration of 1st dose of mRNA vaccine (TTO unreported), which resolved (treatment data not provided). Given temporal association of administration of the mRNA vaccine and CSU aggravation, possible causal relationship cannot be excluded.	unreported	#1	[redacted]
	Angioedema, Condition aggravated, Injection site reaction, Pruritus, Urticaria, Urticaria chronic	36.00	Female	Urticaria chronic(C); Factor VIII deficiency(C)	BELLOZAL	Definite	Possible	The patient with a preceding history of CSU, developed a relapse of CSU 2 days later following administration of 1st dose of mRNA vaccine, which resolved in 20 days. Given temporal association of administration of the mRNA vaccine and CSU aggravation, possible causal relationship cannot be excluded.	2	#1	
	Angioedema, Chronic spontaneous urticaria, Urticaria	55.00	Male			Definite	Possible	The patient with a preceding nine-year long history of CSU, developed a relapse of CSU 24 days after administration of 1st dose of mRNA vaccine, associated with severe intermittent angioedema of the tongue, lips, and throat and noted reactions to previously unsuspected food (patient was on strict diet due to CSU). Change of diet and medical treatment eventually brought a relief, and the patient got 2nd dose of vaccine. A week later he developed another flair-up with worsening food sensitivity to "all cereal". Given temporal correlation between two separate vaccine administrations and ensuing aggravation of CSU, causal association considered possible.	24	#1	
	Disease recurrence, Urticaria chronic	46.00	Female	Urticaria chronic(H)		Definite	Possible	The patient with a preceding history of CSU developed a relapse of CSU 1 day after administration of 2nd dose of mRNA vaccine, which reported to be resolved. Given temporal correlation of administration of the mRNA vaccine and CSU aggravation, causal association deemed possible.	1	#2	
	Condition aggravated, Urticaria chronic	24.00	Female			Definite	Possible	The patient with a history of CSU developed worsening of symptoms 7 day after administration of 1st dose of mRNA vaccine, which was treated with increased doses of antihistamine and came to baseline in a few weeks. Given temporal association of administration of the mRNA vaccine and CSU aggravation, causal association considered possible.	7	#1	

Case ID	ALL PTs	Age	Sex	Medical History	Concomitant Medications	Diagnostic certainty	WHO-UMC Causality	Causality Justification	TTO per Medical Review	Dose per Medical Review	WW Identifier
[redacted]	Condition aggravated, Urticaria chronic	23.00	Female	COVID-19 VACCINE MODERNA(H)		Definite	Possible	The patient with a history of CSU experienced worsening of symptoms of existing chronic urticaria 7 days after administration of the 2nd dose of the mRNA-1273 vaccine which was treated with increased doses of antihistamine and came to her baseline and to the same dose of antihistamines in a few weeks. Given temporal correlation of administration of the mRNA vaccine and CSU aggravation, causal association deems possible.	7	#2	[redacted]
	Burning sensation, Chronic spontaneous urticaria, Erythema, Fatigue, Pruritus, Urticaria contact	61.00	Male	Chronic spontaneous urticaria(H); Immunodeficiency(C); Venomous sting(H)	INFLUENZA VIRUS	Definite	Possible	Causality of the event is considered possibly related due to temporal association with TTO 3 days after 3rd dose of mRNA-1273, and while the patient had a history of chronic idiopathic urticaria caused by jellyfish sting that resolved 5 years ago, new onset of chronic urticaria secondary to vaccination cannot be ruled out.	3	#3	
	Skin reaction, Urticaria, Urticaria chronic	37.00	Unknown		COVID-19 VACCINE MODERNA	Potential	Possible	Causality of the event assessed as possible due to temporal association with TTO of 7 days after 1st dose administration, no exacerbation after second dose (negative rechallenge) and exacerbation of symptoms following the 3rd dose (positive rechallenge) of vaccine; however, missing information of medical history,concomitant medications, and clinical course preclude robust case and causality assessment.	7	#1	
	Angioedema, Chronic spontaneous urticaria	37.00	Male	Chronic spontaneous urticaria(C); Angioedema(C); SPIKEVAX; SPIKEVAX	MONTELUKAST	Definite	Possible	The patient with a prolonged history of CSU associated with angioedema and treated with corticosteroid, was administered 1st and 2nd doses of mRNA 1273, which were well-tolerated, however, developed aggravation of CSU symptoms 5 days following administration of the 3rd dose. Given temporal correlation of administration of the mRNA vaccine and CSU aggravation, causal association considered possible, confounded by underlying history of >20 years of CSU.	5	#3	

Cases classified by the MAH as Chronic Urticaria New Onset (n=91)

Case ID	ALL PTs	Age	Sex	Medical History	Concomitant Medications	Diagnostic certainty	WHO-UMC Causality	Causality Justification	TTO per Med Review	Dose per Med Review	WW Identifier
[redacted]	Urticaria chronic	62.00	Male			Potential	Unlikely	Unlikely due to TTO 154 days after the 2nd dose: temporal relationship is unlikely/improbable.	154	#2	[redacted]
	Urticaria chronic	61.00	Female	Ear pruritus(C); Basedow's disease(H); Allergy to metals	LEVAXIN	Potential	Possible	Causality of the event assessed as possible due to temporal association with TTO of 6 days after vaccination, considering patient's allergy to nickel as attributable confounder.	6	#1	
	Angioedema, Oedema peripheral, Pyrexia, Urticaria chronic	59.00	Female	Drug hypersensitivity(C); Coeliac disease(C); Sjogren's syndrome(C); Urticaria(H)		Potential	Possible	Causality of the event assessed as possible due to temporal association with TTO of 7 days following 1st dose of vaccine; medical history of episodes of acute urticaria to drugs, celiac disease, and Sjogren's syndrome are also considered additional potential confounders to the event. (Front Immunol. 2019; 10: 627. Published online 2019 Mar 29. doi: 10.3389/fimmu.2019.00627 PMCID: PMC6450064 PMID: 30984191 Autoimmune Theories of Chronic Spontaneous Urticaria Sonali J. Bracken,1 Soman Abraham,2,3 and Amanda S. MacLeod3,4,)	7	#1	
	Pruritus, Urticaria chronic	50.00	Female	Autoimmune thyroiditis(C); Arthralgia(C); Drug hypersensitivity	DIBASE	Potential	Possible	Given temporal association of TTO of 0 days following 1st dose administration, event's causality assessed as possible; additional plausible attributing confounder could be known drug sensitivity and history of autoimmune thyroiditis. J Adv Pharm Technol Res. 2018 Oct-Dec; 9(4): 158–161. doi: 10.4103/japtr.JAPTR_342_18 PMCID: PMC6302681 PMID: 30637235 Relationship between Chronic urticaria and autoimmune thyroid disease Mostafa Najafipour,1,2 Masoumeh Zareizadeh,3 and Farzad Najafipour	0	#1	
	Drug hypersensitivity, Hypersensitivity, Urticaria, Urticaria chronic	48.00	Male	Hypersensitivity; Urticaria(H)		Potential	Possible	Causality of the event assessed as possible due to temporal association of administration of 1st dose of vaccine with TTO of 3 days, taking to consideration history of urticaria and drug sensitivity as attributable confounders to the event.	3	#1	

Case ID	ALL PTs	Age	Sex	Medical History	Concomitant Medications	Diagnostic certainty	WHO-UMC Causality	Causality Justification	TTO per Med Review	Dose per Med Review	WW Identifier
[redacted]	Chronic spontaneous urticaria, Contusion, Peripheral swelling, Urticaria	57.00	Male	Asthma(C); Benign prostatic hyperplasia(C); Anaemia(H); Allergy to chemicals; Food allergy	ZYRTEC [CETIRIZINE HYDROCHLORIDE]; BUDESONIDE;FORMOTEROL FUMARATE DIHYDRATE; MULTIVITAMIN IRON; FLONASE [FLUTICASONE PROPIONATE]; TADALAFIL	Potential	Possible	Given temporal association with onset of event in a few hours after administration of 2nd vaccine, causal attribution assessed as possible, while ongoing asthma, allergy to food and chemicals considered potential confounders.	0	#2	[redacted]
	Arthralgia, Chronic spontaneous urticaria, Impaired work ability, Pain	40.00	Female			Potential	Possible	Given temporal association with onset of event 12 days after administration of 2nd dose, causal attribution of the vaccination considered possible, taking to consideration missing information of medical history and concomitant medications as limitations in case assessment, and of note reporter also described ongoing arthralgia.	12	#2	
	Urticaria, Urticaria chronic	44.00	Female			Potential	Unlikely	In absence of additional data for this case, e.g., medical history, concomitant medications, results of tests, dermatology consultation, and given prolonged event latency, causality of the event assessed as unlikely. On and off urticaria started 21 days after first dose and resolved; after 2nd dose there was another incident of urticaria, which resolved. Event recurred in 2 months after 2nd dose and is ongoing despite treatment. Of note, according to the no the source docs note, patient had one remote episode of urticaria 10 years ago).	>150 days after Dose 1 (unknown date of Dose 2)	#2	
	Chronic spontaneous urticaria, Mechanical urticaria, Urticaria	30.00	Female	Disease risk factor(H); SPIKEVAX	ETHINYLESTRADIOL/LEVONORGESTREL	Potential	Possible	Given temporal association with event onset 13 days after 2nd dose with lmiited medical history (noted only as "disease risk factor"), causal attribution of vaccination to CSU assessed as possible.	13	#2	
	Urticaria chronic	29.00	Female		CANDESARTAN	Potential	Unassessable	1st dose of mRNA-1273 was given on 1st day of month, event occurred on unreported day of the same month. TTO is unknown, however, temporal relationship is deemed plausible. Urticaria did not resolve but was successfully managed with	unreported	#1	

Case ID	ALL PTs	Age	Sex	Medical History	Concomitant Medications	Diagnostic certainty	WHO-UMC Causality	Causality Justification	TTO per Med Review	Dose per Med Review	WW Identifier
								antihistamine. The second vaccination was a non-Moderna, mRNA vaccine. Unknown if the administration of a non-Moderna mRNA vaccine could have contributed be to the persistance of the chronic urticaria,thus causality related to the chronic urticaria unassessable.			
[redacted]	Urticaria chronic	54.00	Female			Potential	Possible	Temporal association of vaccination with Urticaria onset with TTO 2 days after 2nd dose in a patient with limited information reported, causal attribution of vaccination to CSU assessed as possible.	2	#2	[redacted]
	Chronic spontaneous urticaria	39.00	Female			Definite	Possible	Causality of the event assessed as possible due to temporal association of 2nd dose administration with TTO of 25 days, taking into consideration missing information of medical history and concomitant medications as potential attributable confounders.	25	#2	
	Anaphylactic reaction, Inappropriate schedule of product administration, Urticaria chronic	30.00	Female	Dermatitis(H); Food allergy; Diabetes mellitusFH; HypertensionFH; Ex-tobacco user(H); Alcohol use(C); FLU; OMEPRAZOLE(H); ZYRTEC [CETIRIZINE HYDROCHLORIDE](H); BENADRYL [DIPHENHYDRAMINE HYDROCHLORIDE](H); Contraception; Substance use(H)	SPIRONOLACTONE; SERTRALINE; TRI-SPRINTEC	Potential	Unlikely	Due to TTO 262 days after 1st and 241 days after the 2nd dose, temporal relationship deemed unlikely/improbable. Moreover, given personal and family history of hypersensitivity, that after discontinuation of concomitant medications (spironolactone, Trispentec (birth control pills) and Sertaline) her symptoms improved, and some or all of them could trigger and attribute to the event.	262	#2	
	Angioedema, Burning sensation, Chest discomfort, Chest pain, Dysphagia, Erythema, Fatigue, Impaired quality of life, Mechanical urticaria, Paraesthesia, Urticaria chronic	49.00	Female	Herpes zoster(C)		Definite	Possible	Temporal association of vaccination with Urticaria TTO 5 days after 3rd dose in a patient with no prior history of allergies or hypersensitivity and no apparent confounders, although limited clinical and diagnostic information (reported by patient, not HCP), causal attribution of vaccination to CSU is deemed possible.	5	#3	
	Chronic spontaneous urticaria, Eczema, Erythema, Insomnia, Mechanical urticaria, Pain, Rash, Sunburn, Urticaria	55.00	Female			Potential	Unlikely	Although atypical rash red little bumps started 2 days after dose 1 and another patch 2 days after Dose 2, hives and "chronic urticaria" occurred 84 days after the 2nd dose, given the long latency seems unlikely to be related to vaccination and atypical clinical presentation with limited information	84	#2	
	Loss of consciousness, Pain in extremity,	41.00	Female	In vitro fertilisation; Deafness(C)	MERIOFERT; SUPRECUR	Definite	Possible	Causality evaluated as possible due to a temporal association with TTO of 3 days following 3rd dose of vaccine in a	3	#3	

Case ID	ALL PTs	Age	Sex	Medical History	Concomitant Medications	Diagnostic certainty	WHO-UMC Causality	Causality Justification	TTO per Med Review	Dose per Med Review	WW Identifier
	Pyrexia, Rash pruritic, Urticaria chronic							patient with no history of allergies or hypersensitivity, possible confounding/attribution of the concomitant medications given for assisted fertilization (menotrophin and buserelin, progesterone-induced urticaria) cannot be ruled out.			
	Chronic spontaneous urticaria, Idiopathic urticaria, Mast cell activation syndrome, Rash pruritic	37.00	Female		COVID-19 VACCINE MODERNA; COVID-19 VACCINE MODERNA	Potential	Possible	Causality is evaluated as probable due to a temporal association of Urticaria with TTO of 8 days following 3rd dose of vaccine in a patient, noting that case has limited information (no reported medical or allergy history) to assess confounders.	8	#3	
	Erythema, Fatigue, Feeling abnormal, Hypoaesthesia, Musculoskeletal stiffness, Purpura, Rash pruritic, Skin burning sensation, Skin discolouration, Tremor, Urticaria chronic, Vaccination complication	73.00	Female			Potential	Possible	Causality of event assessed as possible due to temporal association with TTO of 7 days, however, considering lack of information, including patient's medical history, concomitant medications, clinical course, attribution of unreported potential confounders cannot be excluded; furthermoe patient reported symptoms of tremor, Raynaud's, musculoskeletal stiffness and fatigue.	7	#3	
	Insomnia, Urticaria chronic	28.00	Male			Potential	Possible	Causality of the event assessed as possible considering temporal association of 3rd dose of vaccine with TTO of 10 days, however, due to lack of information including missing medical history, list of concomitant medications, attribution of other potential confounders cannot be excluded.	10	#3	
	Urticaria chronic	37.00	Male			Definite	Possible	Temporal relationship of 30 days seems remote; however, possible causality of vaccine administration cannot be completely ruled out, therefore, causal link between event and vaccine is considered possible. Significant confounder of the event are patient's allergies, including hay fever, allergy to amoxicillin and asthma; history of urticaria; concomitant medications were unknown/not reported which limits assessment of other, possible confounders.	30	#1	
	Urticaria chronic	21.00	Female	Lactose intolerance; Inflammatory bowel disease(C); COVID-19(H)	LINZESS; IBGARD	Potential	Possible	Causality of the event assessed as possible related to the vaccination due to a temporal association with administration of 3rd dose of mRNA-1273 vaccine with TTO of 11 days; medical history of irritable bowel syndrome (which has been reported to	11	#3	

Case ID	ALL PTs	Age	Sex	Medical History	Concomitant Medications	Diagnostic certainty	WHO-UMC Causality	Causality Justification	TTO per Med Review	Dose per Med Review	WW Identifier
								be associated with urticaria in some studies) is a confounder.			
[redacted]	Urticaria, Urticaria chronic	26.00	Female			Definite	Possible	Causality of the event assessed as possibly related to the vaccination due to a temporal association with administration of 3rd dose of mRNA-1273 vaccine with TTO of 10 days; lack of information on past medical history, clinical course, concomitant medications limites a robust case and causality assessment.	10	#3	[redacted]
	Chronic spontaneous urticaria, Mast cell activation syndrome	30.00	Female			Definite	Possible	Given temporal association with event onset 10 days after 3rd dose causal attribution of vaccination to CSU considered possible, however there is limited information (medical history, concomitant medication, etc.) to do a robust case and causality assessment. .	10	#3	
	COVID-19, Urticaria chronic, Vaccination failure	40.00	Female			Potential	Possible	Causality of the event assessed as possible considering temporal association of vaccine administration with TTO of 13 days, however, no medical history or concomitant medications were unreported which limits assessment.	13	#3	
	Abnormal weight gain, Arthralgia, Chills, Chronic spontaneous urticaria, Fatigue, Mechanical urticaria, Myalgia, Pruritus, Pyrexia, Urticaria	35.00	Female		Moderna CoviD-19 Vaccine; Moderna CoviD-19 Vaccine	Definite	Possible	Causality of the event was assessed as possible considering temporal association of 3rd dose of vaccine with TTO of 9 days with no reported history of allergies or hives.	9	#3	
	Chronic spontaneous urticaria	39.00	Female			Potential	Possible	Causality of the event assessed as possible considering temporal association of with TTO of 7 days after administration of the 3rd vaccine in a patient with no reported medical history and concomitant medications, which potentially might be confounding attributing factors to the event.	7	#2	
	Urticaria chronic	62.00	Female	Osteoarthritis(C)		Potential	Possible	Causality of the event assessed as possible considering temporal association of with TTO of 2 days after administration of the 3rd vaccine; very limited information of medical hisotry, clinical course, treatment, and no concomitant medications reported; which precludes a robust case and causality assessment.	2	#3	
	Urticaria chronic	35.00	Female			Potential	Unlikely	The causality of the event to vaccination with mRNA-1273 was evaluated as unlikely due to remote temporal relationship with event onset	76	#1	

Case ID	ALL PTs	Age	Sex	Medical History	Concomitant Medications	Diagnostic certainty	WHO-UMC Causality	Causality Justification	TTO per Med Review	Dose per Med Review	WW Identifier
								occurring 76 days after the 1st dose administration; limited information precludes a robust case assessment.			
[redacted]	Mechanical urticaria, Urticaria chronic	35.00	Male			Potential	Possible	Causality of the event assessed as possible given temporal association of TTO of 11 days after the third dose; however, there is limited information including missing medical history and concomitant medications which precludes a robust case and causality assessment.	11	#3	[redacted]
	Angioedema, Chronic spontaneous urticaria, Idiopathic urticaria	35.00	Female			Potential	Possible	Causality of the event assessed as possible given temporal association of TTO of 7 days after the first dose; however, missing medical history and concomitant medications preclude robust case and causality assessment.	7	#1	
	Urticaria chronic	27.00	Female	Coeliac disease(C); Allergy to arthropod sting	COVID-19 VACCINE MODERNA	Potential	Possible	Causality of the event assessed as possible due to temporal association of TTO of 9 days after Dose 3; confounded by hisotry of allergies, and robust casea and causality assessed are precluded by limited information.	9	#3	
	Inappropriate schedule of product administration, Urticaria chronic	34.00	Female			Potential	Possible	Due to temporal association of vaccination TTO of 15 days after administration of 3rd dose in a patient with no history of allergies or hives, no concomitant medications and no apparent confounders,; however, there is limited information on clinical course treatemnt or HCP assessment/information, causal attribution of vaccination to CSU assessed as possible.	15	#3	
	Angioedema, Chronic spontaneous urticaria, Condition aggravated	34.00	Female			Potential	Possible	Patient with confirmed no history of allergies or hives, no concomitant medications and no apparent confounders had chronic urticaria after the second and third dose; due to temporal association of vaccination TTO of 11 days after 3rd dose administration in a patient with, given the possible positive rechallenge (chronic urticaria after Dose 2, but limited information and no TTO), and considering the absence of alternate etiologies, however the duration of the urticaria is not documented thus case diagnostic certainty is classified as possible and the causal attribution of vaccination to CSU assessed as possible.	11	#3, and unknown TTO after #2	
	Chronic spontaneous urticaria, Erythema, Heart rate increased,	62.00	Male		ROSUVASTATIN; METOPROL	Potential	Possible	Due to temporal association of vaccination TTO “within three weeks” after 3rd dose administration in a	"within 3 weeks"	#3	

Case ID	ALL PTs	Age	Sex	Medical History	Concomitant Medications	Diagnostic certainty	WHO-UMC Causality	Causality Justification	TTO per Med Review	Dose per Med Review	WW Identifier
	Paraesthesia, Pruritus, Rash, Urticaria				OL; CLOPIDOGREL			patient with no history of allergies or hives, no new concomitant medications, no change in diet and no apparent confounders, causal attribution of vaccination to CSU assessed as probable.			
	Urticaria chronic	35.00	Male			Potential	Possible	Causality of the event assessed as possible: while considering temporal association of 3rd dose of vaccine with TTO of 10 days, however lack of medical history, concomitant medication and clincal course/treatment precludes a robust case and causality assessment.	10	#3	
	Chills, Chronic spontaneous urticaria, Feeling hot, Inappropriate schedule of product administration, Palpitations	38.00	Male			Potential	Possible	Causality of the event assessed as possible: while considering temporal association of 3rd dose of vaccine with TTO of 12 days, due to missing medical history and concomitant medications, attribution of other potential confounders cannot be excluded.	12	#3	
	Urticaria chronic	39.00	Female			Potential	Possible	Given temporal association TTO on the day of vaccination with 3rd dose, the event's causality assessed as possible, taking to consideration missing medical history and concomitant medications as attribution of other potential confounders cannot be excluded.	0	#3	
	Chronic spontaneous urticaria, Pruritus	30.00	Female			Potential	Unlikely	The causality of the event to vaccination with mRNA-1273 was evaluated as unlikely due to remote temporal relationship with event onset occurring over two months days after administration of the 3rd dose.	Approx. 2 months	#3	
	Mechanical urticaria, Urticaria chronic	33.00	Male			Potential	Possible	Given temporal association TTO of 10 days after vaccination with 3rd dose, the event's causality assessed as possible; however, limited information precludes robust casea nd causality assessment.	0 (but 10 days, within same narrative)	#3	
	Angioedema, Asthma, Dyspepsia, Gastrooesophageal reflux disease, Urticaria, Urticaria chronic	52.00	Female			Definite	Possible	Causality of the event assessed as possible due to temporal association of 3rd dose of vaccine with TTO on the day of vaccination; however, limited infomraiton including medical history, concomitnat medications, and clinical course, precludes robust case and causality assessment.	0	#3	
	Urticaria chronic	31.00	Female		CONCERTA; BETMIGA; MICROGYN	Potential	Unassessable	Causality of the event assessed as unassessable given unknown TTO. In absence of medical history report and given multiple concomitant medications, including ethinyl	unreported date, reported month of vaccination,	unreported	

Case ID	ALL PTs	Age	Sex	Medical History	Concomitant Medications	Diagnostic certainty	WHO-UMC Causality	Causality Justification	TTO per Med Review	Dose per Med Review	WW Identifier
								estradiol and levonorgestrel for contraception and mirabegron methylphenidate hydrochloride for attention deficit/hyperactivity disorder, attribution of other potential confounders cannot be excluded.	event occurred in a middle of next month.		
[redacted]	Urticaria chronic	52.00	Female			Potential	Possible	Causality of the event assessed as possible due to temporal association of vaccine administration with TTO of 10 days; however, missing infomration such as medical history, concomitnat medication and clinical course precludes robust case and causality assessment.	10	unreported	[redacted]
	Urticaria chronic	51.00	Female			Potential	Possible	Due to temporal association of vaccination TTO of 5 days after 3rd dose administration in a patient with no history of urticaria, limited information (including lack of concomitant medications) precludes a robust case and causality assessment.	5	#3	
	Serum sickness-like reaction, Urticaria chronic	42.00	Male			Potential	Unlikely	Causality of the event assessed as unlikely given long latency >7 months after vaccination	>210 days	#3	
	Urticaria chronic	64.00	Female			Potential	Possible	Causality of the event assessed as possible given temporal association of 28 days; however, clincal course, medical history and concomitant medications are unreported which precludes a robust case and causality assessment.	28	unreported	
	Urticaria chronic	29.00	Female			Definite	Possible	Causality of the event assessed as possible due to temporal association of vaccine administration with TTO of 9 days, however, lack of infomratino on medical history and concomitant medicines, and details about the clinical course precludes robust case and causality assessment.	9	#3	
	Urticaria chronic	19.00	Male			Potential	Possible	Causality of the event assessed as possible due to temporal association of 3rd dose administration with TTO of 7 days, taking to consideration missing information of medical history and concomitant medications as potential attributable confounders.	7	#3	
	Urticaria chronic	34.00	Unknown			Potential	Possible	Causality of the event assessed as possible due to temporal association of 3rd dose administration with TTO of 9 days; however, missing information of medical history, concomitant medications, and clinical course precludes roduct case and causality assessment.	9	#3	

Case ID	ALL PTs	Age	Sex	Medical History	Concomitant Medications	Diagnostic certainty	WHO-UMC Causality	Causality Justification	TTO per Med Review	Dose per Med Review	WW Identifier
[redacted]	Mechanical urticaria, Urticaria chronic	29.00	Female		VAQTA	Potential	Possible	Due to temporal association of vaccination TTO of 12 days after 3rd dose administration in a patient with no history of health issues and no apparent confounders; however limited information precludes a robust case and causality assessment.	12	#3	[redacted]
	Urticaria chronic	24.00	Male			Potential	Possible	Causality of the event assessed as possible due to temporal association of 3rd dose administration with TTO of 9 days; however, missing information of medical history, concomitant medications and clinical course preclude a robust case and causality assessment.	9	#3	
	Mechanical urticaria, Urticaria chronic	31.00	Female	FLU VACCINE VII	MULTIVITAMINS [VITAMINS NOS]	Potential	Possible	Causality of the event assessed as possible due to temporal association of 3rd dose of vaccine with TTO on 19 days of vaccination, taking to consideration missing information of medical history as well as concommitant birth control medications and flu vaccine as potential attributable confounders.	19	#3	
	Urticaria, Urticaria chronic	41.00	Female	MODERNA COVID-19 VACCINE; MODERNA COVID-19 VACCINE		Potential	Possible	Causality of the event assessed as possible due to temporal association of 3rd dose administration with TTO on the day of vaccination;however, missing information of medical history, concomitant medications, and clinical course preclude robust case and causality assessment.	0	#3	
	Urticaria chronic	51.00	Female			Potential	Possible	Causality of the event assessed as possible due to temporal association with TTO 21 days of after 2nd dose of vaccination, not a typical clinical presentation, as this case describes papular urticar with vesicles; missing information of medical history, concomitant medications, and clinical course preclude robust case and causality assessment.	21	#2	
	Disturbance in attention, Emotional distress, Impaired quality of life, Restlessness, Urticaria chronic	43.00	Male			Potential	Possible	Causality of the event assessed as possible due to temporal association of 3rd dose of vaccine with TTO of 3 days of vaccination, taking to consideration missing information of medical history as well as concomitant medications as potential attributable confounders.	3	#3	
	Chronic spontaneous urticaria	41.00	Female	Autoimmune thyroiditis(H); MODERNA COVID-19 VACCINE; MODERNA COVID-19 VACCINE		Potential	Possible	Causality of the event assessed as possible due to temporal association owith TTO 13 days of 3rd dose of vaccination,medical history hypothyroidism is a risk factor for	13	#3	

Case ID	ALL PTs	Age	Sex	Medical History	Concomitant Medications	Diagnostic certainty	WHO-UMC Causality	Causality Justification	TTO per Med Review	Dose per Med Review	WW Identifier
								chronic urticaria; limited information on clinical course precludes robust case and causality assessment.			
[redacted]	Mechanical urticaria, Urticaria chronic	25.00	Female	Polycystic ovaries(C); Skin reaction(H)		Potential	Possible	Causality of the event assessed as possible in a view of temporal association of vaccine administration with TTO of 18 days of vaccination after unknown dose in a patient with current history of polycystic ovarian syndrome, and the medical history of skin sensitivity to creams and sweat for which she is taking inositol is a strong confounder.	18	unreported	[redacted]
	Headache, Urticaria chronic	19.00	Female	Autoimmune thyroiditis(H)	[redacted]	Potential	Possible	Causality of the event assessed as possible due to temporal association of mRNA vaccine administration with TTO 2 days after an unreported dose. Additional plausible attributable confounding factors include a current history of Hashimoto's thyroiditis, and administration of ethinyl estradiol and levonorgestrel for contraception. Limited infomration on clinical course precludes a robust case and causality assessment.	2	unreported	
	Urticaria chronic	47.00	Male			Potential	Possible	Causality of the event assessed as possible due to temporal association with TTO of 7 days of vaccination after an unknown dose; however, very limited information and missing information of medical history, concomitant medications, and clinical course preclude a robust case and causality assessment.	7	unreported	
	Urticaria chronic	35.00	Male			Potential	Possible	Causality of the event assessed as possible due to temporal association with TTO of 7 days of 3rd dose,however, very limited information and missing information of medical history, concomitant medications, and clinical course preclude a robust case and causality assessment.	7	#3	
	Urticaria chronic	32.00	Male			Potential	Possible	Causality of the event assessed as possible due to temporal association with TTO of 7 days of 3rd dose; however, very limited information and missing information of medical history, concomitant medications, and clinical course preclude a robust case and causality assessment.	7	#3	
	Skin reaction, Urticaria, Urticaria chronic	37.00	Unknown		COVID-19 VACCINE MODERNA	Potential	Possible	Causality of the event assessed as possible due to temporal association with TTO of 7 days after 1st dose administration, no exacerbation after	7	#1	

Case ID	ALL PTs	Age	Sex	Medical History	Concomitant Medications	Diagnostic certainty	WHO-UMC Causality	Causality Justification	TTO per Med Review	Dose per Med Review	WW Identifier
[redacted]								second dose (negative rechallenge) and exacerbation of symptoms following the 3rd dose (positive rechallenge) of vaccine; however, missing information of medical history,concomitant medications, and clinical course preclude robust case and causality assessment.			[redacted]
	Skin reaction, Urticaria cholinergic, Urticaria chronic	41.00	Female		COVID-19 Vaccine Moderna; COVID-19 Vaccine Moderna; CERAZETTE [CEFALORIDINE]	Definite	Possible	Causality of the event assessed as possible due to temporal association with TTO of 10 days after 3rd dose, concomitant administration of birth control pill cefaloridine is a potential confounders; limited informatino on medical history and clinical course, preclude a robust case and causality assessment.	10	#3	
	Mechanical urticaria, Skin reaction, Urticaria chronic	35.00	Male			Definite	Possible	Causality of the event assessed as possible due to temporal association with TTO of 14 days after 2nd dose, taking to consideration missing information of detailed medical history and concomitant medications as potential attributable confounders.	14	#2	
	Skin reaction, Urticaria chronic	48.00	Female	Primary biliary cholangitis(C)	COVID-19 Vaccine Moderna; COVID-19 Vaccine Moderna	Definite	Possible	Considering the temporal association of vaccination, TTO of 9 days after 3rd dose administration in a patient; Basophil degranulation test: positive (Positive) Positive for Moderna, Pfizer and Polysorbate 80; confounded by primary biliary cholangitis, and limited information of clinical course, or concomitant medications, causal attribution of vaccination to CSU assessed as possible.	9	#3	
	Skin reaction, Urticaria chronic	43.00	Male			Definite	Possible	Causality is considered possibe given temporal association of vaccination TTO of 11 days after 3rd dose administration; however limited medical history, concomitant medications, and clinical course preclude a robust case and causality assessment.	11	#3	
	Mechanical urticaria, Urticaria chronic	35.00	Male			Potential	Possible	Causality of the event assessed as possible due to temporal association with TTO of 9 days after administration of mRNA vaccine; however, missing information regarding medical history, concomitant medications and clinical course preclude robust case and causality assessment.	9	unreported	
	Urticaria chronic	52.00	Female	Non-tobacco user(H); SARS-CoV-2 test(H); Abstains from alcohol(H)	COVID-19 VACCINE MODERNA	Potential	Possible	Causality of the event assessed as possible due to temporal association with TTO of 10 days after 3rd	10	#3	

Case ID	ALL PTs	Age	Sex	Medical History	Concomitant Medications	Diagnostic certainty	WHO-UMC Causality	Causality Justification	TTO per Med Review	Dose per Med Review	WW Identifier
[redacted]								dose;however, missing information regarding medical history, concomitant medications and clinical course preclude robust case and causality assessment.			[redacted]
	Urticaria chronic	21.00	Female			Potential	Possible	Causality of the event assessed as possible due to temporal association with TTO of 10 days after 3rd dose; however, missing information regarding medical history, concomitant medications and clinical course preclude robust case and causality assessment.	10	#3	
	Mechanical urticaria, Skin reaction, Urticaria chronic	51.00	Female			Definite	Possible	Causality of the event assessed as possible due to temporal association with TTO of 13 days after 3rd dose; ; however, missing information regarding medical history, concomitant medications and clinical course preclude robust case and causality assessment.	13	#3	
	Skin reaction, Urticaria chronic	53.00	Female	SARS-CoV-2 test positive		Definite	Possible	Causality of the event assessed as possible due to temporal association with TTO of 10 days after 3rd dose, confounded by COVID-19 infection diagnosed on 1 day after 3rd dose administration (confirmed by positive PCR test).	10	#3	
	Mechanical urticaria, Skin reaction, Urticaria chronic	36.00	Female	COVID-19(H)	COVID-19 VACCINE MODERNA; COVID-19 VACCINE MODERNA	Potential	Possible	Causality of the event assessed as possible due to temporal association with TTO of 10 days after 3rd dose, BAT positive for Moderna and Pfizer, confounded by COVID-19 infection approximately one month after onset of urticaria; no known allergies; however limited information on medical history, concomitant medications and clinical course preclude robust case and casuality assessment.	10	#3	
	Skin reaction, Urticaria chronic	43.00	Female	Atopy(C); Asthma(C)	COVID-19 Vaccine Moderna; RELVAR	Definite	Possible	Causality of the event assessed as possible due to temporal association with TTO of 7 days after 3rd dose confounded by history of atopiy and asthma treated with fluticasone furoate and vilanterol trifenatate.	7	#3	
	Mechanical urticaria, Skin reaction, Urticaria chronic	59.00	Male			Definite	Possible	Causality of the event assessed as possible due to temporal correlation between vaccination and event onset (vaccination and event occurred within the same month but dates were unreported ; however, missing/unreported information regarding medical history, concomitant medications and clinical course	Unreported (spikevax vaccine and booster dose temporal correlation is noted, however, no	#3	

Case ID	ALL PTs	Age	Sex	Medical History	Concomitant Medications	Diagnostic certainty	WHO-UMC Causality	Causality Justification	TTO per Med Review	Dose per Med Review	WW Identifier
[redacted]								precludes robust case and causality assessment.	dates of vaccination and event onset, while both occurred in the same month, TTO could be from 0 up to 30 days)		[redacted]
[redacted]	Mechanical urticaria, Skin reaction, Urticaria chronic	49.00	Female			Potential	Possible	Causality of the event assessed as possible due to temporal association with TTO of 10 days after 3rd dose; however, missing/unreported information regarding medical history, concomitant medications and clinical course precludes robust case and causality assessment.	10	#3	[redacted]
[redacted]	Mechanical urticaria, Skin reaction, Urticaria chronic	39.00	Female			Potential	Possible	Causality of the event assessed as possible due to temporal association with TTO of 12 days after 3rd dose; however, lack of information regarding medical history, concomitant medication and clinical course preclude robust case and causality assessment.	12	#3	[redacted]
[redacted]	Angioedema, Skin reaction, Urticaria chronic	39.00	Male	Drug hypersensitivity		Potential	Possible	Causality of the event assessed as possible due to temporal association with TTO of 11 days after administration of 2rd dose, confounded by history of drug allergy; however, lack of information regarding medical history, concomitant medication and clinical course preclude robust case and causality assessment.	11	#3	[redacted]
[redacted]	Mechanical urticaria, Pruritus, Skin reaction, Urticaria chronic	62.00	Female			Potential	Possible	Causality of the event assessed as possible due to temporal association with TTO of 14 days after administration of 3rd dose, no history of atopy.	14	#3	[redacted]
[redacted]	Mechanical urticaria, Skin reaction, Urticaria chronic	48.00	Male	SPIKEVAX; SPIKEVAX; Seasonal allergy		Potential	Possible	Causality of the event assessed as possible due to temporal association with TTO of 21 days after administration of 3rd dose, taking to consideration a history of pollinosis and missing information of concomitant medications as potential attributable confounders.	21	#3	[redacted]
[redacted]	Dermatitis atopic, Eczema asteatotic, Mechanical urticaria, Skin reaction, Urticaria chronic	56.00	Female	Atopy(C); MODERNA COVID-19 VACCINE; MODERNA COVID-19 VACCINE		Definite	Possible	Causality of the event assessed as possible due to temporal association with TTO of 15 days after administration of 3rd dose, confounded by a history of atopy.	15	#3	[redacted]

Case ID	ALL PTs	Age	Sex	Medical History	Concomitant Medications	Diagnostic certainty	WHO-UMC Causality	Causality Justification	TTO per Med Review	Dose per Med Review	WW Identifier
[redacted]	Peripheral swelling, Pruritus, Urticaria chronic	35.00	Male			Definite	Possible	Causality of the event assessed as possible due to temporal association with TTO of 12 days after administration of 3rd dose, no reported skin allergy history; however, missing information of medical history,concomitant medications, and clinical assessment/details precludes a robust case and causality assessment.	12	#3	[redacted]
	Chronic spontaneous urticaria, Rash	22.00	Female	Autoimmune thyroiditis(C)		Definite	Possible	Causality of the event assessed as possible due to temporal association with TTO of 12 days after 3rd dose in a patient with Hashimoto's thyroiditis as a possible attributable confounder.	12	#3	
	Chronic spontaneous urticaria, Rash	30.00	Female	Drug hypersensitivity; Coeliac disease(C)		Potential	Possible	Causality of the event assessed as possible due to temporal association with TTO of 13 days after 3rd dose in a patient with drug allergies and celiac disease as possible attributable confounders.	13	#3	
	Angioedema, Urticaria chronic	42.00	Male	SPIKEVAX; SPIKEVAX		Potential	Possible	Causality of the event assessed as possible due to temporal association with TTO of 10 days after administration of 3rd dose, taking to consideration missing information of medical history and concomitant medications as potential attributable confounders	10	#3	
	Pruritus, Urticaria chronic	35.00	Female	Seasonal allergy	COVID-19 Vaccine Moderna	Potential	Possible	Causality of the event assessed as possible due to temporal association with TTO of 10 days after 3rd dose in a patient with pollen allergies as possible attributable confounders.	10	#3	
	Chronic spontaneous urticaria	24.00	Female			Definite	Possible	Causality of the event assessed as possible due to temporal association with TTO of 10 days after administration of mRNA vaccine, taking to consideration missing information of relevant medical history and concomitant medications as potential attributable confounders.	10	unreported	
	Chronic spontaneous urticaria, Rash	52.00	Male			Definite	Possible	Causality of the event assessed as possible due to temporal association with event onset on the day of administration of 3rd dose, taking to consideration missing information of medical history and concomitant medications as potential attributable confounders.	0	#3	
	Mechanical urticaria, Skin reaction, Urticaria chronic	61.00	Female			Definite	Possible	Causality of the event assessed as possible due to temporal association with TTO of 15 days following administration 3rd dose of vaccine, taking to consideration missing information of medical history and	15	#3	

Case ID	ALL PTs	Age	Sex	Medical History	Concomitant Medications	Diagnostic certainty	WHO-UMC Causality	Causality Justification	TTO per Med Review	Dose per Med Review	WW Identifier
								concomitant medications as potential attributable confounders.			
[redacted]	Angioedema, Asthma, Mechanical urticaria, Skin reaction, Urticaria chronic	48.00	Male	Cardiomyopathy(H); Type IIa hyperlipidaemia(H); Myocardial ischaemia(C); Stent placement	COVID-19 Vaccine Moderna; COVID-19 Vaccine Moderna; PRALUENT; CRESTOR; EZETROL; ASPIRIN CARDIO; PANTOZOLE	Definite	Possible	Causality of the event assessed as possible due to temporal association with TTO of 10 days after administration of 3rd dose of vaccine in a patient with no known allergy history and medical history of cardiovascular disease with hypercholesterolemia with administration of concomitant nedications (Alirocumab, rosuvastatin and acetylsalicylic acid).	10	#3	[redacted]
	Skin reaction, Urticaria chronic	44.00	Male	Seasonal allergy	COVID-19 VACCINE MODERNA; COVID-19 VACCINE MODERNA	Definite	Unlikely	Temporal relationship of 33 days seems remote; patient's pollen allergy could be a confounder, .	33	#3	
	Skin reaction, Urticaria chronic	31.00	Female	Seasonal allergy; Atopy		Definite	Possible	Causality of the event assessed as possible due to temporal association with TTO of 7 days after administration of 3rd dose of vaccine in a setting of known history of pollinosis and atopic that could be considered plausible confounders of the event.	7	#3	
	Skin reaction, Urticaria chronic	46.00	Male		ODEFSEY; KALCIPOS; VI-DE 3; PROLIA; COVID-19 VACCINE MODERNA	Definite	Possible	Causality of the event assessed as possible due to temporal association with TTO 12 days after administration of a dose of mRNA-1273 vaccine, taking to consideration missing information of medical history and concomitant medications as potential attributable confounders.	12	unreported	

Appendix 11.20b Chronic Urticaria: Case Narratives for "Definite" cases of Chronic Urticaria (N=35)

CASE NARRATIVES FOR "DEFINITE" CASES OF CHRONIC URTICARIA (N=35)

Case ID	WW Identifier	Narrative (Complete)
[redacted]		This literature-non-study case was reported in a literature article and describes the occurrence of ANGIOEDEMA (Swelling of her upper lip) in a 74-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. LITERATURE REFERENCE: Alflen C, Birch K, Shilian R, Wu SS, HostofferJr, R. Two cases of well controlled chronic spontaneous urticaria triggered by the moderna COVID-19 vaccine. Allergy Rhinol. 2021;12:1-3 The patient's past medical history included Allergic rhinitis, Chronic spontaneous urticaria (The patient's CSU symptoms include angioedema of the upper lip.) in 1973 and Angioedema in 1973. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On an unknown date, after starting mRNA-1273 (Moderna COVID-19 Vaccine), the patient experienced ANGIOEDEMA (Swelling of her upper lip) (seriousness criterion medically significant) and CHRONIC SPONTANEOUS URTICARIA (relapse of Chronic spontaneous urticaria). At the time of the report, ANGIOEDEMA (Swelling of her upper lip) and CHRONIC SPONTANEOUS URTICARIA (relapse of Chronic spontaneous urticaria) had resolved. mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosing remained unchanged. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Past medication included first generation H1 antihistamine to control Chronic spontaneous urticaria (CSU). No concomitant medication was reported. Treatment medication not provided. Company comment: Based on the current available information which shows a temporal association between the use of mRNA-1273 and the onset of the reported events, a causal relationship cannot be excluded This case was linked to [redacted] (Patient Link). Most recent FOLLOW-UP information incorporated above includes: On 12-Jul-2021: Date Initial received by safety should be 13-Jul-2021. Secondary authors captured as reporters were deleted. Primary reporter address corrected per source. Journal and title were updated per conventions. On 15-Jul-2021: Follow up received by safety 15-Jul-2021 included no new information.
[redacted]		This case was received via European Medicines Agency (Reference number: [redacted] on 15-Oct-2021 and was forwarded to Moderna on 15-Oct-2021. This regulatory authority case was reported by a consumer and describes the occurrence of URTICARIA CHRONIC (History of chronic urticaria), PRURITUS (Flares-ups of hives (burning, itching patches over 70% of body lasting three weeks)), CONDITION AGGRAVATED (Flares-ups of hives (burning, itching patches over 70% of body lasting three weeks)), URTICARIA (Flares-ups of hives (burning, itching patches over 70% of body lasting three weeks)), INJECTION SITE REACTION (Reaction at the injection site) and ANGIOEDEMA (Flares-ups of hives (burning, itching patches over 70% of body lasting three weeks)) in a 36-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. Concurrent medical conditions included Chronic urticaria and Hemophilia A (Type A hemophilia). Concomitant products included BILASTINE (BELLOZAL) for an unknown indication. On 12-Jun-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 14-Jun-2021, the patient experienced URTICARIA CHRONIC (History of chronic urticaria) (seriousness criterion disability), PRURITUS (Flares-ups of hives (burning, itching patches over 70% of body lasting three weeks)) (seriousness criterion disability), CONDITION AGGRAVATED (Flares-ups of hives (burning, itching patches over 70% of body lasting three weeks)) (seriousness criterion disability), URTICARIA (Flares-ups of hives (burning, itching patches over 70% of body lasting three weeks)) (seriousness criterion disability), INJECTION SITE REACTION (Reaction at the injection site) (seriousness criterion disability) and ANGIOEDEMA (Flares-ups of hives (burning, itching patches over 70% of body lasting three weeks)) (seriousness criteria disability and medically significant). On 04-Jul-2021, URTICARIA CHRONIC (History of chronic urticaria), PRURITUS (Flares-ups of hives (burning, itching patches over 70% of body lasting three weeks)), CONDITION AGGRAVATED (Flares-ups of hives (burning, itching patches over 70% of body lasting three weeks)), URTICARIA (Flares-ups of hives (burning, itching

CASE NARRATIVES FOR "DEFINITE" CASES OF CHRONIC URTICARIA (N=35)

Case ID	WW Identifier	Narrative (Complete)
		patches over 70% of body lasting three weeks)), INJECTION SITE REACTION (Reaction at the injection site) and ANGIOEDEMA (Flares-ups of hives (burning, itching patches over 70% of body lasting three weeks)) had resolved. No treatment information was provided. It was reported that evolution of adverse drug reaction recovered. History of chronic urticaria flareups of hives (burning, itching patches over 70 percent of body lasting three weeks). Company comment This case concerns a 36 year-old, female patient with a history of Chronic urticaria, who experienced the serious (due to disability) unexpected events of Urticaria chronic, Urticaria, Pruritus, Condition aggravated, Injection site reaction and Angioedema. The events occurred approximately 3 days after the first dose of Spikevax. The rechallenge was unknown since the events occurred after the first dose and no information has been provided regarding second dose. The medical history, of Chronic urticaria, remains a confounder. The benefit-risk relationship of Spikevax is not affected by this report. Event seriousness assessed as per Regulatory Authority reporting, however there was no information in the source document supporting that the events resulted in a persistent or permanent incapacity. The event chronic urticaria was reported as history of chronic urticaria, it´s retained as an event as reported by regulatory authority but it is consistent with relevant medical history. Most recent FOLLOW-UP information incorporated above includes: On 15-Oct-2021: Translated document received on 19-Oct-2021 and patient concurrent condition and event verbatim added.
[redacted]		This case was received via European Medicines Agency (Reference number: [redacted] on 14-Dec-2021 and was forwarded to Moderna on 14-Dec-2021. This regulatory authority case was reported by a consumer and describes the occurrence of the first episode of ANGIOEDEMA [redacted] and the second episode of ANGIOEDEMA [redacted] in a 55-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3002913) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 09-Jun-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 03-Jul-2021, the patient experienced the first episode of ANGIOEDEMA [redacted] (seriousness criterion medically significant), the second episode of ANGIOEDEMA [redacted] (seriousness criterion medically significant), URTICARIA [redacted] and CHRONIC SPONTANEOUS URTICARIA [redacted]. On 28-Jul-2021, last episode of ANGIOEDEMA [redacted] URTICARIA [redacted] and CHRONIC SPONTANEOUS URTICARIA [redacted] had not resolved. Concomitant product was not provided by the reporter. Patient suffer from a chronic. spont. Urticaria since 2012 with severe intermittent impairments due to angioedema of the tongue, lips and throat. It was reported that to prevent swelling, patient has only been eating food from an extremely restricted food pool of 10-12 selected, long-tested and previously rel. safely functioning foods for Years. About 3 weeks ago, patient unexpectedly had puffiness from bread and rolls that he ate for many years without problems. Since both wheat and rye products were equally affected, he assumed that the cause was manufacturing, but this denied. The nature of

CASE NARRATIVES FOR "DEFINITE" CASES OF CHRONIC URTICARIA (N=35)

Case ID	WW Identifier	Narrative (Complete)
		swelling has changed, they begin with severe burning in the mouth, build up in minutes instead of hours. Achieving the maximum at night was unchanged, associated with swallowing problems. He was able to switch to 2-3 replacement products from another manufacturer, which was also tested by him over a longer period of time and which he could eat easily at first. 3 days ago (since 24-Jul-2021) patient suddenly got swelling from the new manufacturer's rye bread. Little by little, all other substitutes were affected and he could no longer eat any cereal products since yesterday. This means eliminating his entire food base, as bread and rolls account for about 2/3 of his daily food intake. There was a temporal link between the appearance of swelling after previously unsuspected foods and his covid vaccinations: Problems with the first manufacturer's baking products occurred around 3 weeks after primary vaccination (09-Jun-2021). In the meantime, patient successfully used the replacement products. A week after the second vaccination (this was on 20-Jul-2021 and had severe flu-like side effects and a large skin rash 2 days later), swelling began in all other cereal products as well. Treatment product was not provided by the reporter. Company comment: This case concerns a 55-year-old male patient with relevant medical history of chronic spontaneous urticaria with severe intermittent impairments due to angioedema of the tongue, lips and throat, who developed serious unexpected events of Angioedema (Lip angioedema and Angioedema aggravated), Urticaria and Chronic spontaneous urticaria which occurred 25 days after the administration of the first dose of the mRNA-1273 vaccine. Reportedly, the patient had severe deterioration of chronic spontaneous urticaria due to unexpected and constant occurrence of angioedema of lips, throat, tongue after eating previously unsuspected foods (event description was described above). It was stated that week after the second vaccination, swelling began in all other cereal products as well. At the time of this report, all events were reported as not resolved/not recovered, even though the stop dates for the events was also provided. Major confounding factor for the reported events is the fact that the patient already had chronic spontaneous urticaria in his medical history. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report. Event seriousness assessed as per Regulatory Authority reporting.
[redacted]		This case was received via European Medicines Agency (Reference number: [redacted] on 20-Dec-2021 and was forwarded to Moderna on 20-Dec-2021. This regulatory authority case was reported by a consumer and describes the occurrence of URTICARIA CHRONIC (Urticaria chronic) and DISEASE RECURRENCE (Disease recurrence) in a 46-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The patient's past medical history included Chronic urticaria. On 07-May-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On an unknown date, the patient experienced URTICARIA CHRONIC (Urticaria chronic) and DISEASE RECURRENCE (Disease recurrence). At the time of the report, URTICARIA CHRONIC (Urticaria chronic) and DISEASE RECURRENCE (Disease recurrence) had resolved. 46 year old woman who had a surge of her chronic urticaria 24 h after vaccination with SPIKEVAX. Recurrence of the effect when recalled by COMIRNATY. No concomitant medication were provided No treatment details were provide This case was linked to [redacted] (E2B Linked Report).
[redacted]		This case was received via European Medicines Agency (Reference number: [redacted] 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 URTICARIA CHRONIC (Worsening of symptoms of existing chronic urticaria. More rash, more itching, significantly more antihistamines needed.) and CONDITION AGGRAVATED (Worsening of symptoms of existing chronic urticaria. More rash, more itching, significantly more antihistamines needed.) in a 24-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 3004218) for COVID-19 vaccination. No Medical History information was reported. On 09-Jul-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 16-Jul-2021, the patient experienced URTICARIA CHRONIC (Worsening of symptoms of existing chronic urticaria. More rash, more itching, significantly more antihistamines needed.) and CONDITION AGGRAVATED (Worsening of symptoms of existing chronic urticaria. More rash, more itching, significantly more antihistamines needed.). At the

CASE NARRATIVES FOR "DEFINITE" CASES OF CHRONIC URTICARIA (N=35)

Case ID	WW Identifier	Narrative (Complete)
		time of the report, URTICARIA CHRONIC (Worsening of symptoms of existing chronic urticaria. More rash, more itching, significantly more antihistamines needed.) and CONDITION AGGRAVATED (Worsening of symptoms of existing chronic urticaria. More rash, more itching, significantly more antihistamines needed.) had resolved. The action taken with mRNA-1273 (Spikevax) (Unknown) was unknown. No concomitant medication was reported by reporter. Reporter's comment: treatment included increased antihistamine administration. After a few weeks, the condition was almost as before vaccination. This case was linked to [redacted] (E2B Linked Report).
[redacted]		This case was received via European Medicines Agency (Reference number: [redacted] on 24-Dec-2021 and was forwarded to Moderna on 24-Dec-2021. This regulatory authority case was reported by a consumer and describes the occurrence of URTICARIA CHRONIC (worsening of symptoms of existing chronic urticaria. More rash, more itching, significantly more antihistamines needed.) and CONDITION AGGRAVATED (worsening of symptoms of existing chronic urticaria. More rash, more itching, significantly more antihistamines needed.) in a 23-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 3004218) for COVID-19 vaccination. Previously administered products included for Drug use for unknown indication: COVID-19 Vaccine Moderna on 09-Jul-2021. Past adverse reactions to the above products included Chronic urticaria with COVID-19 Vaccine Moderna. On 06-Aug-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 13-Aug-2021, the patient experienced URTICARIA CHRONIC (worsening of symptoms of existing chronic urticaria. More rash, more itching, significantly more antihistamines needed.) and CONDITION AGGRAVATED (worsening of symptoms of existing chronic urticaria. More rash, more itching, significantly more antihistamines needed.). At the time of the report, URTICARIA CHRONIC (worsening of symptoms of existing chronic urticaria. More rash, more itching, significantly more antihistamines needed.) and CONDITION AGGRAVATED (worsening of symptoms of existing chronic urticaria. More rash, more itching, significantly more antihistamines needed.) had not resolved. No concomitant medications were reported. No treatment medications were reported. Increased antihistamine administration. After a few weeks, the condition almost returned to the same condition before vaccination. Occurred again after double vaccination, 3 months later slowly returned to original state and close to original dose of antihistamines. This case was linked to [redacted] (E2B Linked Report).
[redacted]		This case was received via an unknown source (no reference has been entered for a health authority or license partner) on 28-Dec-2021 and was forwarded to Moderna on 28-Dec-2021. This regulatory authority case was reported by a consumer and describes the occurrence of CHRONIC SPONTANEOUS URTICARIA (Chronic Urticaria Spontaneous occurring after the 2nd injection Moderna on 15.06.2021 (3 weeks later). UCS treated with antihistamines for several months. Improvement of...) in a 39-year-old female patient who received mRNA-1273 (COVID-19 Vaccine Moderna) (batch no. 3002186) for an unknown indication. No Medical History information was reported. On 16-Apr-2021, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (unknown route) 1 dosage form. On 21-May-2021, received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (unknown route) dosage was changed to 1 dosage form. On 15-Jun-2021, after starting mRNA-1273 (COVID-19 Vaccine Moderna), the patient experienced CHRONIC SPONTANEOUS URTICARIA (Chronic Urticaria Spontaneous occurring after the 2nd injection Moderna on 15.06.2021 (3 weeks later). UCS treated with antihistamines for several months. Improvement of...) (seriousness criterion medically significant). At the time of the report, CHRONIC SPONTANEOUS URTICARIA (Chronic Urticaria Spontaneous occurring after the 2nd injection Moderna on 15.06.2021 (3 weeks later). UCS treated with antihistamines for several months. Improvement of..) had not resolved.

CASE NARRATIVES FOR "DEFINITE" CASES OF CHRONIC URTICARIA (N=35)

Case ID	WW Identifier	Narrative (Complete)
		Concomitant product use was not provided by the reporter. Treatment information was not provided. Company comment This case concerns a 39-year-old female patient, with no reported medical history, who experienced the unexpected serious event of CHRONIC SPONTANEOUS URTICARIA. The event occurred approximately 3 weeks after the administration of the second dose of mRNA-1273 vaccine. At the time of report, event had not resolved. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.
[redacted]		This spontaneous case was reported by a consumer and describes the occurrence of CHEST PAIN (ER 4 weeks after due to chest pain) and ANGIOEDEMA (Angioedema) in a 49-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 071F21A, 036821A and 0462a21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Herpes zoster (No recent change) since 2003. On 03-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 28-Apr-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 03-Nov-2021, received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 08-Nov-2021 at 4:00 PM, the patient experienced ANGIOEDEMA (Angioedema) (seriousness criterion medically significant), URTICARIA CHRONIC (spontaneous urticaria,broke out in hives with dermographia/The itch progreed to full on hives outbreak the next day with hands and feet on fire/ the hives continue/ chronic urticaria) and MECHANICAL URTICARIA (hives with dermographia). On 09-Nov-2021, the patient experienced BURNING SENSATION (hands and feet on fire/ body continues to feel like it is on fire (milder) and the hives continue). In November 2021, the patient experienced ERYTHEMA (began to see red marks running across body - principally arms, legs and back/ arms have deep red swelling), IMPAIRED QUALITY OF LIFE (It was life changing/quit job due to this) and FATIGUE (physically and mentally exhausting to deal). On an unknown date, the patient experienced CHEST PAIN (ER 4 weeks after due to chest pain) (seriousness criterion hospitalization), CHEST DISCOMFORT (Chest tightness), DYSPHAGIA (Difficulty swallowing) and PARAESTHESIA (Prickling/Tingling). The patient was hospitalized from 13-Dec-2021 to 13-Dec-2021 due to CHEST PAIN. The patient was treated with PREDNISONE at a dose of UNK UNK, bid for 5 days; CETIRIZINE HYDROCHLORIDE (ZYRTEC [CETIRIZINE HYDROCHLORIDE]) ongoing from 11-Sep-2021 at a dose of 10 milligram AM and DIPHENHYDRAMINE HYDROCHLORIDE (BENADRYL [DIPHENHYDRAMINE HYDROCHLORIDE]) ongoing from 11-Sep-2021 at a dose of 5 milligram PM. At the time of the report, CHEST PAIN (ER 4 weeks after due to chest pain), ANGIOEDEMA (Angioedema), URTICARIA CHRONIC (spontaneous urticaria,broke out in hives with dermographia/The itch progreed to full on hives outbreak the next day with hands and feet on fire/ the hives continue/ chronic urticaria), MECHANICAL URTICARIA (hives with dermographia), BURNING SENSATION (hands and feet on fire/ body continues to feel like it is on fire (milder) and the hives continue), IMPAIRED QUALITY OF LIFE (It was life changing/quit job due to this) and FATIGUE (physically and mentally exhausting to deal) had not resolved and CHEST DISCOMFORT (Chest tightness), ERYTHEMA (began to see red marks running across body - principally arms, legs and back/ arms have deep red swelling), DYSPHAGIA (Difficulty swallowing) and PARAESTHESIA (Prickling/Tingling) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Blood test: normal (normal) normal/unremarkable. On an unknown date, Electrocardiogram: normal (normal) normal/unremarkable. No Concomitant medication was reported. The ER doctor has given to patient an injectable steroid . The doctor recommended to continue anti histamine. The patient experienced spontaneous urticaria, broke out in hives with dermographia. This was going on for 8 weeks. She went to the ER 4 weeks after the booster dose because she was experiencing chest pain. Patient had long red streaks that would run across legs or back but there was no pain. They would come and go in about ten minutes. Patient's arms have deep red swelling that makes me feel like body is hemmorging. The hives continued along with chest pain that would last for 5-7 minutes. The prednisone helped but did not resolve the symptoms. Patient also wound up having a herpes outbreak after the prednisone.

CASE NARRATIVES FOR "DEFINITE" CASES OF CHRONIC URTICARIA (N=35)

Case ID	WW Identifier	Narrative (Complete)
		Company Comment - This spontaneous case concerns a 49 year old female patient with no relevant medical history, who experienced the serious (hospitalization) unexpected events of chest pain and angioedema. The event occurred 5 days after the third dose of mRNA-1273 vaccine while the event chest pain occurred 4 weeks after receiving the booster dose. The rechallenge was not applicable as there are no plans for future dosing. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report. This case was linked to [redacted] (Patient Link). Most recent FOLLOW-UP information incorporated above includes: On 07-Jan-2022: Added new events, Updated reporter's address,Patient Demographics, lab data, Dosage of treatment drugs, event outcome for angioedema and urticaria.
[redacted]		This case was initially received via [redacted] (Reference number: [redacted]) on 30-Jan-2022. The most recent information was received on 27-Mar-2022 and was forwarded to Moderna on 27-Mar-2022. This regulatory authority case was reported by a consumer and describes the occurrence of PAIN IN EXTREMITY (Painful arm), RASH PRURITIC (Itchy rash), PYREXIA (Fever chills), PYREXIA (High temperature), LOSS OF CONSCIOUSNESS (Passed out) and URTICARIA CHRONIC (Urticaria chronic) in a 41-year-old female patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) (batch nos. 3003607 and 3002332) for COVID-19 vaccination. The patient's past medical history included In vitro fertilization (In November, patient was on an IVF long-protocol, which was cancelled.). Concurrent medical conditions included Deaf (I'm deaf, but this is unrelated). Concomitant products included MENOTROPHIN (MERIOFERT) for Assisted fertilisation, BUSERELIN ACETATE (SUPRECUR) for an unknown indication. On 28-May-2021, the patient received first dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 16-Jul-2021, received second dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 18-Dec-2021, received third dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 21-Dec-2021, the patient experienced RASH PRURITIC (Itchy rash) (seriousness criteria disability and medically significant). On an unknown date, the patient experienced PAIN IN EXTREMITY (Painful arm) (seriousness criteria disability and medically significant), PYREXIA (Fever chills) (seriousness criteria disability and medically significant), PYREXIA (High temperature) (seriousness criteria disability and medically significant), LOSS OF CONSCIOUSNESS (Passed out) (seriousness criteria disability and medically significant) and URTICARIA CHRONIC (Urticaria chronic) (seriousness criteria disability and medically significant). At the time of the report, PAIN IN EXTREMITY (Painful arm), PYREXIA (Fever chills), PYREXIA (High temperature) and LOSS OF CONSCIOUSNESS (Passed out) had resolved and RASH PRURITIC (Itchy rash) and URTICARIA CHRONIC (Urticaria chronic) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 27-Jan-2022, 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. Patient reported that the GP and dermatologist diagnosed the condition as chronic spontaneous urticaria (although originally diagnosed it as scabies). However, it had onset a couple of days after the booster shot. The medical description of urticaria and images did not match with what patient was experiencing. Patient had been on antihistamine since 23rd December, just over a month, now on fexofenadine via the GP. It's started to become less effective. Initially supported for 24h, now the itchy rash appear after 9h. The symptoms had two types: 1. a rash which was very itchy, looked a little like line-writing, and sometimes pimple dots, raised. It appeared on neck, ears, chest, arms, back, stomach, legs, feet. jaw, chin. Each rash lasts for around 30 mins, then disappears, it was constantly appearing around the body. 2. less often, patient had areas which start with more of a bundle of raised bumps around 10cm total. These then merge, and the area was hot like an infection, and itchy, there was no cut nearby. This lasts slightly longer, then disappears without a trace. Happened on left arm, and left leg. Patient still had the symptoms when the antihistamine prescribed, had worn off. (March 25th, 2022). Patient found two case studies and a group of people (~1000) who all have developed a type of chronic urticaria which seems connected to the vaccine.

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		Patient was not enrolled in clinical trial. Patient did not had symptoms associated with COVID-19. Patient was not currently breastfeeding. Company Comment:This regulatory case concerns a 41-year-old, female patient with no relevant medical history, who experienced the serious (disability and medically significant) unexpected events of loss of consciousness, urticaria chronic, pain in extremity, rash pruritic, pyrexia and fever chills. The patient received first and second dose of mRNA 1273 COVID-19 vaccine with 49 days interval in between doses and a third dose of mRNA 1273 vaccine 5 months after second dose. Three days after third dose of mRNA-1273 vaccine, patient had rash pruritic, while other events started on unknown date. Patient had a very itchy raised rash that appears on neck, ears, chest, arms, back, stomach, legs, feet, jaw and chin which lasts around 30 minutes and disappears and would constantly appear throughout her body. Occasionally, she would also have a bundle of raised bumps which are hot and itchy and would stay a bit longer. She was prescribed with fexofenadine by her general physician. 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 27-Mar-2022: Significant Follow up received. Medical history of the patient, suspect drug information, events and narrative updated.
[redacted]		This case was received via European Medicines Agency (Reference number: [redacted] on 14-Feb-2022 and was forwarded to Moderna on 14-Feb-2022. This regulatory authority case was reported by a consumer and describes the occurrence of URTICARIA CHRONIC (Chronic hives) in a 37-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. Allergies included Hay fever (early bloomers, hazel, Alder & Birch), Amoxicillin - hives was diagnosed about 20 years ago, but was successfully treated without any discomfort. Intake of magnesium, silicea and urtica [redacted]H. Pre-existing conditions included allergic asthma. On 11-May-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 10-Jun-2021, the patient experienced URTICARIA CHRONIC (Chronic hives). On 16-Aug-2021, URTICARIA CHRONIC (Chronic hives) had resolved with sequelae. The action taken with mRNA-1273 (Spikevax) (Unknown) was unknown. No relevant concomitant medications were reported. The patient experienced multiple hives which relapsed daily, itchy red skin. Treatment included four Aerius tablets daily.
[redacted]		This case was received via [redacted] (Reference number: [redacted] on 17-Feb-2022 and was forwarded to Moderna on 17-Feb-2022. This regulatory authority case was reported by a consumer and describes the occurrence of ERYTHEMA (redness), FATIGUE (tiredness), BURNING SENSATION (burning sensation), URTICARIA CONTACT (contact urticaria), PRURITUS (itching) and CHRONIC SPONTANEOUS URTICARIA (Chronic idiopathic urticaria) in a 61-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for an unknown indication. The patient's past medical history included Chronic idiopathic urticaria (re auto immune response following jellyfish stings in 2008 resulting Chronic Idiopathic Urticaria.) in 2008 and Jellyfish sting (re auto immune response following jellyfish stings) in 2008. Concurrent medical conditions included Immunodeficiency (Has an illness or condition, not listed above, which reduces the immune response (e.g. immunodef...). Concomitant products included INFLUENZA VACCINE (INFLUENZA VIRUS) from 03-Nov-2021 to an unknown date for an unknown indication. On 29-Nov-2021, the patient received third dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 02-Dec-2021, the patient experienced CHRONIC SPONTANEOUS URTICARIA (Chronic idiopathic urticaria) (seriousness criterion medically significant). On an unknown date, the patient experienced ERYTHEMA (redness) (seriousness criterion medically significant), FATIGUE (tiredness) (seriousness criterion medically significant), BURNING SENSATION (burning sensation) (seriousness criterion medically significant), URTICARIA CONTACT (contact urticaria) (seriousness criterion medically significant) and PRURITUS (itching) (seriousness criterion medically significant). At the time of the report, ERYTHEMA (redness), FATIGUE (tiredness), BURNING SENSATION (burning sensation), URTICARIA CONTACT (contact urticaria) and PRURITUS (itching) was resolving and CHRONIC SPONTANEOUS URTICARIA (Chronic idiopathic urticaria) had not resolved.

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Case ID	WW Identifier	Narrative (Complete)
		DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 23-Nov-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. Patient has not tested positive for COVID-19 since having the vaccine, patient was not enrolled in clinical trial and patient has not had symptoms associated with COVID-19. It was reported that started with redness and inflammation of the face, ears and hands. Contacted urticaria from clothing. Some pain discomfort burning sensation. Acid reflux indigestion and tiredness. This appears to be a re-occurrence of a chronic Idiopathic urticarial condition similar to that from 2008 following toxin from thimble Jellyfish. That episode took 8 years to dissipate. Treated at that time with steroids (initially) then and 180 mg fexofenadine antihistamine daily for 8 years. Following this occurrence that patient believed was triggered by the moderna vaccine. Patient consulted general practitioner and requested antihistamines to alleviate symptoms. General practitioner also prescribed one week dose of prednisolone steroids 8x5 mg daily. Still experiencing all symptoms after 12 weeks. Additional symptoms include, itching, tiredness, swelling of the face and lips and keratitis in the cornea left eye. Report not related to possible inflammation of the heart. Company comment This regulatory authority case concerns a 61-year-old male patient, with medical history of Chronic idiopathic urticaria and Immunodeficiency, who experienced the unexpected serious (medically significant) events of ERYTHEMA, FATIGUE, BURNING SENSATION, URTICARIA CONTACT, PRURITUS and CHRONIC SPONTANEOUS URTICARIA, which occurred approximately 3 days after receiving third dose of mRNA-1273 vaccine. General practitioner prescribed antihistamines and one week dose of prednisolone steroids. Still experiencing all symptoms after 12 weeks. The mentioned medical history remains as a confounder. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.
[redacted]		This case was received via [redacted] Reference number [redacted] on 20-Feb-2022 and was forwarded to Moderna on 20-Feb-2022. This regulatory authority case was reported by a consumer and describes the occurrence of URTICARIA CHRONIC (Chronic urticaria) and URTICARIA (Hives) in a 26-year-old female patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) (batch no. 3005686) for an unknown indication. No Medical History information was reported. On 16-Dec-2021, the patient received dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 26-Dec-2021, after starting mRNA-1273 (Moderna CoviD-19 Vaccine), the patient experienced URTICARIA CHRONIC (Chronic urticaria) (seriousness criterion medically significant). On an unknown date, the patient experienced URTICARIA (Hives) (seriousness criterion medically significant). At the time of the report, URTICARIA CHRONIC (Chronic urticaria) had not resolved and URTICARIA (Hives) outcome was unknown. Concomitant medications were not provided by the reporter. 10 days after Moderna booster, patient woke up with chronic urticaria and hives all over the body. Now its mid February and the reaction was still ongoing. Patient did research into this and it seems it was more common than you would think. This reaction did not occur as a result of a mistake made in the administration of the vaccine. Treatment information was not provided. Company Comment: This case refers to a 26-year-old female patient with no reported medical history who experienced the unexpected event of Urticaria chronic approximately 10 days after a dose of mRNA-1273 vaccine while the event of Urticaria occurred after an unspecified number of days post exposure to the vaccine. The benefit-risk relationship of mRNA-1273 is not affected by this report. Events seriousness assessed as per Regulatory Authority reporting.
[redacted]		This spontaneous case was reported by a consumer and describes the occurrence of MAST CELL ACTIVATION SYNDROME (Mast cell release syndrome) in a 30-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient had no previous history of allergic/hypersensitivity reactions to vaccines.

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Case ID	WW Identifier	Narrative (Complete)
		In March 2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. In April 2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 19-Dec-2021, received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On an unknown date, the patient experienced MAST CELL ACTIVATION SYNDROME (Mast cell release syndrome) (seriousness criterion medically significant) and CHRONIC SPONTANEOUS URTICARIA (Chronic spotaneous uticaria,Mechanical urticaria,Feeling abnormal,Pruritus,Scar,Blister,Urticaria). The patient was treated with FEXOFENADINE HYDROCHLORIDE (ALLEGRA [FEXOFENADINE HYDROCHLORIDE]) for Adverse event, at a dose of UNK UNK, qid. At the time of the report, MAST CELL ACTIVATION SYNDROME (Mast cell release syndrome) and CHRONIC SPONTANEOUS URTICARIA (Chronic spotaneous uticaria,Mechanical urticaria,Feeling abnormal,Pruritus,Scar,Blister,Urticaria) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Blood test: normal (normal) All bloodwork has come back normal.. No concomitant medication was reported. Treatment medication included daily Antihistamines that controlled itching. Without antihistamines the patient gets extremely itchy hives on various body parts that worsened if the patient scratched them and then spread. The patient had been and was still, honestly, a torturous experience. The patient reported that they received Moderna booster on 19-Dec-2021 and 10 days later, the patient broke out in full body hives. The patient had no history of allergies. The patient had Chronic hives for 12+ weeks (10 days delayed onset). Reportedly, the patient was since diagnosed with chronic spontaneous urticaria and dermatographia, with the diagnosis of mast cell release syndrome. Company comment: This spontaneous case concerns a 30-year-old, female patient with no reported medical history, who experienced the unexpected serious (medically significant) event of Mast cell activation syndrome, that occurred after receiving the third (booster) dose of mRNA-1273 COVID-19 Vaccine. There were no adverse events reported after receiving the previous doses of mRNA-1273 vaccine. Patient experienced dermatographia and generalized urticaria 10 days after receiving the third dose of mRNA-1273 vaccine.; wherein, urticaria persisted for more than 12 weeks. All blood tests were normal, however, details on the specific laboratory tests were not provided in the report. She was further diagnosed to have Mass cell release syndrome, Dermatographia and Chronic spontaneous urticaria and was treated with Fexofenadine hydrochloride. As of this report, the skin lesions have turned into healing scars like insect bites. The benefit-risk relationship of mRNA-1273 is not affected by this report. This case was linked to [redacted](Patient Link). Most recent FOLLOW-UP information incorporated above includes: On 05-Apr-2022: Follow up received containing significant information: Updated reporter information and patient demographics. The patient's medical history information and lab data were added. Updated the start date of the suspect drug to 19-Dec-2021 from previously captured 23-Dec-2021. Treatment medication information was added. Added new events Mast cell activation syndrome, and Chronic spontaneous urticaria. The case upgraded to serious, and narrative was also updated.
[redacted]		This case was initially received via [redacted](Reference number: [redacted] on 05-Mar-2022. The most recent information was received on 06-May-2022 and was forwarded to Moderna on 06-May-2022. This regulatory authority case was reported by a consumer and describes the occurrence of CHILLS (chills), FATIGUE (fatigue), PYREXIA (fever), PRURITUS (itchy scalp) and URTICARIA (Hives) in a 35-year-old female patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) (batch no. 00005017) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Patient had no allergies, never used hormonal contraception, never suffered from hives. Patient had no hormonal imbalances and good blood pressure and cholesterol. . Concomitant products included mRNA-1273 (Moderna CoviD-19 Vaccine) and mRNA-1273 (Moderna CoviD-19 Vaccine) for COVID-19. On 18-Feb-2022, the patient received third dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 18-Feb-2022, the patient experienced FATIGUE (fatigue). On 19-Feb-2022, the patient experienced CHILLS (chills), PYREXIA (fever) and MYALGIA (Muscle ache). On 27-Feb-2022, the patient experienced PRURITUS (itchy scalp) and URTICARIA (Hives). On an unknown date, the patient experienced CHRONIC SPONTANEOUS URTICARIA (Chronic spontaneous urticaria), MECHANICAL URTICARIA (Dermatographia),

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Case ID	WW Identifier	Narrative (Complete)
		ARTHRALGIA (Joint pain) and ABNORMAL WEIGHT GAIN (Unintentional weight gain). The patient was treated with CETIRIZINE at a dose of 1 dosage form. On 19-Feb-2022, CHILLS (chills), PYREXIA (fever) and MYALGIA (Muscle ache) had resolved. At the time of the report, FATIGUE (fatigue) and PRURITUS (itchy scalp) was resolving and URTICARIA (Hives), CHRONIC SPONTANEOUS URTICARIA (Chronic spontaneous urticaria), MECHANICAL URTICARIA (Dermatographia), ARTHRALGIA (Joint pain) and ABNORMAL WEIGHT GAIN (Unintentional weight gain) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, SARS-CoV-2 test: negative (Negative) Negative COVID-19 test. The action taken with mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown) was unknown. Patient had received dose 3a of the vaccine. Patient suffered fatigue on the day vaccine and the next day had a fever, muscle aches and chills that resolved within a day. 9 days after Moderna boosters patient broke out in hives all over body (arms, thighs, legs, bum, lower back, neck and have a very itchy scalp) that are itchy and red constantly. Patient never had hives or an allergic reaction to anything and did not come into contact with any new materials or allergens that could have caused this. It was reported that the patient was still suffering from the condition and it was now a chronic spontaneous urticaria and had been over two months. The treatment drug Cetirizine was not able to stop the dermatographia and hives completely and the treatment drug leaves the patient feeling fatigued. It was also reported that the hives/histamines had caused weight gain and joint pain. The patient stated that it had reduced her quality of life from a healthy person with no allergies or need for medication to someone taking medication everyday. Patient did not test positive for COVID-19 since having the vaccine. Patient was not enrolled in clinical trial. Patient's report did not relate to possible inflammation of the heart (myocarditis or pericarditis). Patient had regular periods. Patient did not have symptoms associated with COVID-19. Patient was not pregnant and was not currently breastfeeding. Most recent FOLLOW-UP information incorporated above includes: On 06-May-2022: Treatment drug added, Event onset and stop dates added, Outcome of events updated, New events added and I-narrative supplement updated.
[redacted]		This case was initially received via European Medicines Agency (Reference number: [redacted] on 28-Mar-2022. The most recent information was received on 13-May-2022 and was forwarded to Moderna on 13-May-2022. This regulatory authority case was reported by a consumer and describes the occurrence of ASTHMA (After 3 doses of vaccine: spontaneous urticaria now chronic exceeded 6 weeks with itchy wheals on face and body, angioedema, bronchial asthma and esophageal heartburn with reflux.), ANGIOEDEMA (After 3 doses of vaccine: spontaneous urticaria now chronic exceeded 6 weeks with itchy wheals on face and body, angioedema, bronchial asthma and esophageal heartburn with reflux.), GASTROOESOPHAGEAL REFLUX DISEASE (After 3 doses of vaccine: spontaneous urticaria now chronic exceeded 6 weeks with itchy wheals on face and body, angioedema, bronchial asthma and esophageal heartburn with reflux.), URTICARIA (After 3 doses of vaccine: spontaneous urticaria now chronic exceeded 6 weeks with itchy wheals on face and body, angioedema, bronchial asthma and esophageal heartburn with reflux.), URTICARIA CHRONIC (After 3 doses of vaccine: spontaneous urticaria now chronic exceeded 6 weeks with itchy wheals on face and body, angioedema, bronchial asthma and esophageal heartburn with reflux.) and DYSPEPSIA (After 3 doses of vaccine: spontaneous urticaria now chronic exceeded 6 weeks with itchy wheals on face and body, angioedema, bronchial asthma and esophageal heartburn with reflux.) in a 52-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 3005689) for COVID-19 vaccination. No Medical History information was reported. On 24-Jan-2022, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 24-Jan-2022, the patient experienced ASTHMA (After 3 doses of vaccine: spontaneous urticaria now chronic exceeded 6 weeks with itchy wheals on face and body, angioedema, bronchial asthma and esophageal heartburn with reflux.) (seriousness criterion disability), ANGIOEDEMA (After 3 doses of vaccine: spontaneous urticaria now chronic exceeded 6 weeks with itchy wheals on face and body, angioedema, bronchial asthma and esophageal heartburn with reflux.) (seriousness criterion disability), GASTROOESOPHAGEAL REFLUX DISEASE (After 3 doses of vaccine: spontaneous urticaria now chronic exceeded 6 weeks with itchy wheals on face and body, angioedema, bronchial asthma and esophageal heartburn with reflux.) (seriousness criterion disability), URTICARIA (After 3 doses of vaccine: spontaneous urticaria now chronic exceeded 6 weeks with itchy wheals on face and body, angioedema, bronchial asthma and esophageal heartburn with reflux.) (seriousness criterion disability), URTICARIA CHRONIC

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		(After 3 doses of vaccine: spontaneous urticaria now chronic exceeded 6 weeks with itchy wheals on face and body, angioedema, bronchial asthma and esophageal heartburn with reflux.) (seriousness criterion disability) and DYSPEPSIA (After 3 doses of vaccine: spontaneous urticaria now chronic exceeded 6 weeks with itchy wheals on face and body, angioedema, bronchial asthma and esophageal heartburn with reflux.) (seriousness criterion disability). At the time of the report, ASTHMA (After 3 doses of vaccine: spontaneous urticaria now chronic exceeded 6 weeks with itchy wheals on face and body, angioedema, bronchial asthma and esophageal heartburn with reflux.), ANGIOEDEMA (After 3 doses of vaccine: spontaneous urticaria now chronic exceeded 6 weeks with itchy wheals on face and body, angioedema, bronchial asthma and esophageal heartburn with reflux.), GASTROOESOPHAGEAL REFLUX DISEASE (After 3 doses of vaccine: spontaneous urticaria now chronic exceeded 6 weeks with itchy wheals on face and body, angioedema, bronchial asthma and esophageal heartburn with reflux.), URTICARIA (After 3 doses of vaccine: spontaneous urticaria now chronic exceeded 6 weeks with itchy wheals on face and body, angioedema, bronchial asthma and esophageal heartburn with reflux.), URTICARIA CHRONIC (After 3 doses of vaccine: spontaneous urticaria now chronic exceeded 6 weeks with itchy wheals on face and body, angioedema, bronchial asthma and esophageal heartburn with reflux.) and DYSPEPSIA (After 3 doses of vaccine: spontaneous urticaria now chronic exceeded 6 weeks with itchy wheals on face and body, angioedema, bronchial asthma and esophageal heartburn with reflux.) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 23-Mar-2022, Alpha 2 globulin abnormal: 0,86 gram(s) 0,80/0,50 0,86 GRAM(S) 0,80/0,50. On 23-Mar-2022, Blood fibrinogen increased (150-450): 463 ug (microgram) (High) 463 ug (microgram). On 23-Mar-2022, C-reactive protein increased: 0,88 milligram(s) 0,80/0,00 0,88 MILLIGRAM(S) 0,80/0,00. On 23-Mar-2022, Helicobacter test negative: negative percent (Negative) NEGATIVE PERCENT. No concomitant medications were reported. No treatment information was provided. Company Comment: This is a regulatory case concerning a 52-year-old female patient with no reported medical history, who experienced the unexpected serious (disability) events of Asthma, Angioedema, Gastrooesophageal reflux disease, Urticaria, Urticaria chronic and Dyspepsia, which occurred on the same day after receiving a dose of mRNA-1273 vaccine. No other information was provided for any other COVID-19 vaccination except for the verbatim that mentions there had been 3 doses of vaccines received by the patient. It is reported that there were an abnormal Alpha 2 globulin with 0,86 gram(s) 0,80/0,50, increased Blood fibrinogen (150-450): 463 microgram, increased C-reactive protein: 0,88 milligram(s), and a negative Helicobacter test, approximately 2 months after mRNA-1273 vaccination. No further details about the treatments were provided. Patient reported that the events were not yet resolved. 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 13-May-2022: Follow-up received include : Lab test updated.
[redacted]		This case was received via European Medicines Agency (Reference number: [redacted] on 07-Apr-2022 and was forwarded to Moderna on 07-Apr-2022. This regulatory authority case was reported by a physician and describes the occurrence of URTICARIA CHRONIC (Chronic urticaria. Tendency to urticaria through 3 months since 4/1-2022. Activity with nettles and itching every day as well as dermatographic urticaria) in a 29-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 3004959) for COVID-19 vaccination. No Medical History information was reported. On 26-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 04-Jan-2022, after starting mRNA-1273 (Spikevax), the patient experienced URTICARIA CHRONIC (Chronic urticaria. Tendency to urticaria through 3 months since 4/1-2022. Activity with nettles and itching every day as well as dermatographic urticaria). At the time of the report, URTICARIA CHRONIC (Chronic urticaria. Tendency to urticaria through 3 months since 4/1-2022. Activity with nettles and itching every day as well as dermatographic urticaria) had not resolved. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medications were reported. No treatment medications were reported.

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Case ID	WW Identifier	Narrative (Complete)
[redacted]		This regulatory authority case was reported by a physician and describes the occurrence of SKIN REACTION (Delayed skin reaction), URTICARIA CHRONIC (Chronic urticaria) and URTICARIA CHOLINERGIC (Cholinergic urticaria) in a 41-year-old female patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination. Concomitant products included CEFALORIDINE (CERAZETTE [CEFALORIDINE]) from 2017 to an unknown date for Birth control pill, mRNA-1273 (COVID-19 Vaccine Moderna) and mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination. On 18-Jan-2022, the patient received third dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form once a day. On 28-Jan-2022, the patient experienced SKIN REACTION (Delayed skin reaction) and URTICARIA CHOLINERGIC (Cholinergic urticaria). 28-Jan-2022, the patient experienced URTICARIA CHRONIC (Chronic urticaria). The patient was treated with BILASTINE (BILAXTEN) for Adverse event, at a dose of 20 milligram three times a day. At the time of the report, SKIN REACTION (Delayed skin reaction), URTICARIA CHRONIC (Chronic urticaria) and URTICARIA CHOLINERGIC (Cholinergic urticaria) had not resolved. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered SKIN REACTION (Delayed skin reaction), URTICARIA CHRONIC (Chronic urticaria) and URTICARIA CHOLINERGIC (Cholinergic urticaria) to be possibly related. Patient never had COVID infection. Previous vaccination with SpikeVax was well tolerated. Chronic urticaria had lasted for more than 6 weeks as of now. Patient responded poorly to antihistamines. Reporter's comment included Post vaccine urticaria.
[redacted]		This regulatory authority case was reported by a physician and describes the occurrence of URTICARIA CHRONIC (Urticaria chronic), SKIN REACTION (Delayed skin reaction) and MECHANICAL URTICARIA (Dermographism) in a 35-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination. No known medical history of major pathologies. On 17-Aug-2021, the patient received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) dosage was changed to 1 dosage form once a day. On an unknown date, the patient received dose of mRNA-1273 (COVID-19 Vaccine Moderna) (unknown route) 1 dosage form. On 31-Aug-2021, the patient experienced URTICARIA CHRONIC (Urticaria chronic), SKIN REACTION (Delayed skin reaction) and MECHANICAL URTICARIA (Dermographism). The patient was treated with DESLORATADINE (AERIUS [DESLORATADINE]) at a dose of 5 milligram three times a day. At the time of the report, URTICARIA CHRONIC (Urticaria chronic), SKIN REACTION (Delayed skin reaction) and MECHANICAL URTICARIA (Dermographism) was resolving. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered URTICARIA CHRONIC (Urticaria chronic), SKIN REACTION (Delayed skin reaction) and MECHANICAL URTICARIA (Dermographism) to be possibly related. No concomitant product use was reported. On 17-Aug-2021, he took second dose with Spikevax Moderna (previously received a dose of the same vaccine, well tolerated). On 31-Aug-2021, the patient manifested widespread itchy symptomatology (so on 12-Sep-2021 he accessed emergency room, as a result of which the patient was not hospitalized, but discharged to his home in good general conditions, with the indication to use mild soap, to continue antihistamine therapy for 10 consecutive days, and to carry out any dermatological evaluation in accordance with the curant). This was followed by the appearance of urticaria (wheals, migrants, itchy) with dermographism. At the time of the report (on 22-Mar-2022) the skin manifestation was still present, configuring a picture of chronic urticaria. Partial benefit from ongoing high-dose antihistamine therapy (Aerius 5 mg x 3/ day). Further courses were not known. It was reported that the causal link was considered, between the adverse reaction chronic urticaria, delayed skin reaction and dermographism and the administration of Spikevax, as possible in consideration of the chronological plausibility between vaccination and the onset of symptoms, notoriety and the possible existence of other plausible causes for their onset.
[redacted]		This regulatory authority case was reported by a physician and describes the occurrence of SKIN REACTION (Delayed skin reaction) and URTICARIA CHRONIC (Chronic urticaria) in a 48-year-old female patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination.

CASE NARRATIVES FOR "DEFINITE" CASES OF CHRONIC URTICARIA (N=35)

Case ID	WW Identifier	Narrative (Complete)
		No contact with positive people to Covid-19 in recent months. Concurrent medical conditions included Primary biliary cholangitis. Concomitant products included mRNA-1273 (COVID-19 Vaccine Moderna) and mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination. On 22-Dec-2021, the patient received third dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form once a day. On 01-Jan-2022, the patient experienced SKIN REACTION (Delayed skin reaction) and URTICARIA CHRONIC (Chronic urticaria). At the time of the report, SKIN REACTION (Delayed skin reaction) and URTICARIA CHRONIC (Chronic urticaria) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Basophil degranulation test: positive (Positive) Positive for Moderna, Pfizer and Polysorbate 80. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered SKIN REACTION (Delayed skin reaction) and URTICARIA CHRONIC (Chronic urticaria) to be possibly related. It showed a late and chronicized urticaria (lasted for >6 weeks) that at the time of the report (on 21-MAR-.2022) had not yet been resolved. In treatment with antihistamines.
[redacted]		This regulatory authority case was reported by a physician and describes the occurrence of URTICARIA CHRONIC (Chronic urticaria) and SKIN REACTION (Delayed skin reaction) in a 43-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination. Patient had no major clinical history. In July 2021, the patient received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (unknown route) 1 dosage form. In July 2021, received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (unknown route) dosage was changed to 1 dosage form. On 13-Jan-2022, received third dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) dosage was changed to 1 dosage form once a day. On 24-Jan-2022, the patient experienced URTICARIA CHRONIC (Chronic urticaria) and SKIN REACTION (Delayed skin reaction). The patient was treated with BILASTINE (BILAXTEN) for Chronic urticaria, at an unspecified dose and frequency. At the time of the report, URTICARIA CHRONIC (Chronic urticaria) and SKIN REACTION (Delayed skin reaction) was resolving. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered URTICARIA CHRONIC (Chronic urticaria) and SKIN REACTION (Delayed skin reaction) to be possibly related. No concomitant medication was reported by reporter. Patient had temperature and tachycardia after 1st injection, but 2nd injection was well tolerated. Patient took booster and Immediately after got itching problems. Patient was treated with Bilaxten 1-0-1. At the specialist visit of 2.3 always Urticaria but in the process of attenuation. Bilaxten 1-0-0 was proposed. Chronic urticaria had been persisted for more than 6 weeks No investigation was done.
[redacted]		This regulatory authority case was reported by a physician and describes the occurrence of URTICARIA CHRONIC (Chronic urticaria), SKIN REACTION (Delayed skin reaction) and MECHANICAL URTICARIA (Dermographism) in a 51-year-old female patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination. No known medical history of major pathologies. On 17-Dec-2021, the patient received third dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) dosage was changed to 1 dosage form once a day. 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. On 30-Dec-2021, the patient experienced URTICARIA CHRONIC (Chronic urticaria), SKIN REACTION (Delayed skin reaction) and MECHANICAL URTICARIA (Dermographism). At the time of the

CASE NARRATIVES FOR "DEFINITE" CASES OF CHRONIC URTICARIA (N=35)

Case ID	WW Identifier	Narrative (Complete)
		report, URTICARIA CHRONIC (Chronic urticaria), SKIN REACTION (Delayed skin reaction) and MECHANICAL URTICARIA (Dermographism) had not resolved. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered URTICARIA CHRONIC (Chronic urticaria), SKIN REACTION (Delayed skin reaction) and MECHANICAL URTICARIA (Dermographism) to be possibly related. No concomitant product use was reported. On 17-Dec-2021, the patient performed booster dose with Spikevax Moderna (previously received two doses of the same vaccine, which were well tolerated). On 30-Dec-2021, the patient manifested urticaria (wheals, migrants, itchy) with dermographism. At the time of the report (On 14-Mar-2022) the skin manifestation was still present, configuring a picture of chronic urticaria. Partial benefit from ongoing antihistamine therapy. Further course not known. It was reported that the causal link considered, between the adverse reaction chronic urticaria, delayed skin reaction and dermographism and the administration of Spikevax, as possible in consideration of the chronological plausibility between vaccination and the onset of symptoms, notoriety and the possible existence of other plausible causes for their onset
[redacted]		This regulatory authority case was reported by a physician and describes the occurrence of URTICARIA CHRONIC (Chronic urticaria) and SKIN REACTION (Delayed skin reaction) in a 53-year-old female patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination. The patient's past medical history included COVID-19 PCR test positive on 07-Jan-2022. On 06-Jan-2022, the patient received dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form once a day. On 16-Jan-2022, the patient experienced URTICARIA CHRONIC (Chronic urticaria) and SKIN REACTION (Delayed skin reaction). At the time of the report, URTICARIA CHRONIC (Chronic urticaria) and SKIN REACTION (Delayed skin reaction) was resolving. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered URTICARIA CHRONIC (Chronic urticaria) and SKIN REACTION (Delayed skin reaction) to be possibly related. Concomitant medications details were not reported by the reporter. Reportedly, Patient was in good condition not atopic precedents. No medication intake. Spikevax vaccine. First dose (June 2021) with no problems, second dose temperature and joint pain for three days. 6-Jan-2022 Spike Vax Booster. The next day PCR buffer feedback positive. COVID with few symptoms but develop after 10 days of urticaria conjunctivitis and itching. Treatment with Cortisone 30 mg to scale and Tavegyl. Transient improvement but 28-Jan-22 with relapse of symptomatology requiring new cortisone treatment given by the attending physician in addition to Zaditen. Stop cortisone on 20-Feb-2022. Only Zaditen. Seen on 4-Mar-2022. The situation is improving. Proposed stop Zaditen (asthenia) and prescribed Telfast. There was currently an increase in late urticaria notifications reported after booster vaccination (boosters), particularly with Spikevax, which occur in different parts of the body. after a latency period ranging from a few days to 1 to 2 weeks after vaccination, sometimes relapsing. It was therefore considered the causal link between the urticaria and the booster dose of Spikevax as possible, not being able to exclude also that the virus itself contributed to the skin problem (urticarie after COVID-19 infection are known).
[redacted]		This regulatory authority case was reported by a physician and describes the occurrence of URTICARIA CHRONIC (Chronic urticaria) and SKIN REACTION (Delayed skin reaction) in a 43-year-old female patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination. Concurrent medical conditions included Atopic and Asthma. Concomitant products included mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination, FLUTICASONE FUROATE, VILANTEROL TRIFENATATE (RELVAR) for an unknown indication. On 04-Jan-2022, the patient received third dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form once a day. On 11-Jan-2022, the patient experienced URTICARIA CHRONIC (Chronic urticaria) and SKIN REACTION (Delayed skin reaction). At the time of the report, URTICARIA CHRONIC (Chronic urticaria) and SKIN REACTION (Delayed skin reaction) was resolving. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered URTICARIA CHRONIC (Chronic urticaria) and SKIN REACTION (Delayed skin reaction) to be possibly related.

CASE NARRATIVES FOR "DEFINITE" CASES OF CHRONIC URTICARIA (N=35)

Case ID	WW Identifier	Narrative (Complete)
		Patient never did CoviD. Patient administered two first doses Spikevax in january 2021 without problems. Boster Spikevax on 4.1.2022. After 7 days Urticaria patient got Telfastin at the pharmacy. No effect. Doctor on the city guard. Prednisone and Tavegyl Meglio in 4 days At the visit to the specialist on 21.02, healthy outbreaks persisted. No treatment were reported. patient still light outbursts that did not need treatment. Further treatment not known. It was reported that late and chronic urticaria (present for >6 weeks) arose in time correlation with the Spikevax booster dose in a known atopic and asthmatic patient.
[redacted]		This regulatory authority case was reported by a physician and describes the occurrence of URTICARIA CHRONIC (Chronic urticaria), SKIN REACTION (Delayed skin reaction) and MECHANICAL URTICARIA (Dermographism) in a 59-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination. No Medical History information was reported. In December 2021, the patient received dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form once a day. In December 2020, the patient experienced URTICARIA CHRONIC (Chronic urticaria). In December 2021, the patient experienced SKIN REACTION (Delayed skin reaction) and MECHANICAL URTICARIA (Dermographism). The patient was treated with BILASTINE (BILAXTEN) for Urticaria, at a dose of bid. At the time of the report, URTICARIA CHRONIC (Chronic urticaria), SKIN REACTION (Delayed skin reaction) and MECHANICAL URTICARIA (Dermographism) had not resolved. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered URTICARIA CHRONIC (Chronic urticaria), SKIN REACTION (Delayed skin reaction) and MECHANICAL URTICARIA (Dermographism) to be possibly related. No concomitant medication was reported. Urticaria still presents in March 2022 (chronic since it lasts for more than 6 weeks). Treated with Bilaxten 2x/day. Clinically wheals on the shoulders, urticarioid dermographism, important skin xerosis in the hands. It was recommended to increase the treatment with Bilaxten to 3x/day. Late and chronic urticaria (present for >6 weeks) with dermographism that arose in temporal correlation with the Spikevax vaccine Booster dose. The adverse reactions reported were limited to skin, in the absence of systemic manifestations. The hypothesized etiopathogenesis involves T cells, stimulated by a previous infection with SARS-CoV-2 or certain components/excipients of the vaccine. There is currently an increase in late urticaria notifications reported after booster vaccination (boosters), particularly with Spikevax, which occur in different parts of the body after a latency period ranging from a few days to 1 to 2 weeks after vaccination, sometimes relapsing.
[redacted]		This regulatory authority case was reported by a physician and describes the occurrence of URTICARIA CHRONIC (Chronic urticaria), SKIN REACTION (Delayed skin reaction), MECHANICAL URTICARIA (Dermographism), DERMATITIS ATOPIC (Dermatitis atopic) and ECZEMA ASTEATOTIC (Eczema asteatotic) in a 56-year-old female patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination. Previously administered products included for Product used for unknown indication: Moderna and Moderna. Past adverse reactions to the above products included No adverse event with Moderna and Moderna. Concurrent medical conditions included Atopic. On 30-Dec-2021, the patient received third dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form once a day. On 14-Feb-2022, the patient experienced URTICARIA CHRONIC (Chronic urticaria), SKIN REACTION (Delayed skin reaction), MECHANICAL URTICARIA (Dermographism), DERMATITIS ATOPIC (Dermatitis atopic) and ECZEMA ASTEATOTIC (Eczema asteatotic). The patient was treated with BILASTINE (BILAXTEN) for Dermographism, at a dose of 1 CPR in evening; UREA (NUTRAPLUS) for Eczema asteatotic, at a dose of UNK, bid and POLIDOCANOL, UREA (OPTIDERM F) for Eczema asteatotic, at an unspecified dose and frequency. At the time of the report, URTICARIA CHRONIC (Chronic urticaria), SKIN REACTION (Delayed skin reaction), MECHANICAL URTICARIA (Dermographism), DERMATITIS ATOPIC (Dermatitis atopic) and ECZEMA ASTEATOTIC (Eczema asteatotic) had not resolved. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered URTICARIA CHRONIC (Chronic urticaria), SKIN REACTION (Delayed skin reaction), MECHANICAL URTICARIA (Dermographism), DERMATITIS ATOPIC (Dermatitis atopic) and ECZEMA ASTEATOTIC (Eczema asteatotic) to be possibly related. It was reported that the patient had the first two vaccinations that had been performed with the same vaccine (Moderna) without any problems. It was reported that the causes of urticaria were clearly multiple, COVID-19

CASE NARRATIVES FOR "DEFINITE" CASES OF CHRONIC URTICARIA (N=35)

Case ID	WW Identifier	Narrative (Complete)
		infections and viral diseases were a trigger that the patient at least anamnestic ally denies, they had not found others in medical history. Linked if not a basic atopy and the Booster as a possible trigger. No concomitant medications were reported. On 30-Dec-2022, 14 days after the Spikevax vaccine booster received the patient had a skin lesion compatible with a urticaria. The patient had not contracted COVID-19 at that time. It was reported that with Bilaxten 1 CPR therapy in the evening there was a marked improvement in symptomatology and to date (mid-March 2022) dermographism was only minimally urticarioid. As for bust injuries, the patient described how stretch marks were compared with eczema craquelé in atopic patients and for this reason they prescribed Nutraplus cream 2 times per day if bad. The patient endured because it burned too much and would be able to apply Optiderm F cream: asteatotic eczema in atopic patient/exacerbation of dermatitis atopic. Further course of treatment was not known for rest events. It was reported from the senders comments that the late and chronic urticaria (present for more than 6 weeks) with dermographism arised in temporal correlation with the Spikevax vaccine Booster dose. Causal correlation was therefore judged possible. Asteatotic eczema and dermatitis atopic were not reported among adverse events following the administration of Spikevax. The literature described the appearance of generalized eczematous skin reactions in atopic subjects and the exacerbation of dermatitis atopic (including during therapy, e.g., Dupilumab) a follow-up to vaccination with COVID-19 mRNA vaccines. Even if other causes could not be ruled out, the causal correlation was judged as possible.
[redacted]		This case was initially received via European Medicines Agency (Reference number: [redacted] on 09-May-2022. The most recent information was received on 11-May-2022 and was forwarded to Moderna on 11-May-2022. This regulatory authority case was reported by an attorney and describes the occurrence of PERIPHERAL SWELLING (Chronic urticaria itching and swelling after Modern booster), URTICARIA CHRONIC (Chronic urticaria itching and swelling after Modern booster) and PRURITUS (Chronic urticaria itching and swelling after Modern booster) in a 35-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. No Medical History information was reported. On 16-Feb-2022, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 28-Feb-2022, the patient experienced PERIPHERAL SWELLING (Chronic urticaria itching and swelling after Modern booster) (seriousness criterion medically significant), URTICARIA CHRONIC (Chronic urticaria itching and swelling after Modern booster) (seriousness criterion medically significant) and PRURITUS (Chronic urticaria itching and swelling after Modern booster) (seriousness criterion medically significant). At the time of the report, PERIPHERAL SWELLING (Chronic urticaria itching and swelling after Modern booster), URTICARIA CHRONIC (Chronic urticaria itching and swelling after Modern booster) and PRURITUS (Chronic urticaria itching and swelling after Modern booster) had not resolved. Patient never had skin or allergies. No concomitant medications were reported. Patient experienced symptoms after 2 months after taking vaccine. The patient's rash, dermography and itching for so many months had been devastating on a mental level. No treatment medications were reported. Company comment:This is a regulatory authority case concerning a 35-year-old, male patient with no reported medical history who experienced the unexpected serious (medically significant) events of Peripheral swelling, Urticaria chronic and Pruritus which occurred 12 days after receiving the third dose of mRNA-1273 vaccine. Information about the two previous doses of COVID-19 vaccine was not provided. Patient never had medical history of any skin rash or allergy. The events have persisted for months and has affected his daily functions. The clinical course, diagnostic evaluation and treatment details were not reported in the case. The benefit-risk relationship of mRNA-1273 is not affected by this report. Events' seriousness was assessed as per regulatory authority's report. Most recent FOLLOW-UP information incorporated above includes: On 09-May-2022: Follow-up contains received contains no new information. On 11-May-2022: Suspect vaccine Start date updated and Reporter's comment updated.
[redacted]		This case was received via European Medicines Agency (Reference number: [redacted] on 09-May-2022 and was forwarded to Moderna on 09-May-2022. This regulatory authority case was reported by a consumer and describes the occurrence of CHRONIC SPONTANEOUS URTICARIA (Chronic spontaneous urticaria + symptomatic demographism) and RASH (Chronic

CASE NARRATIVES FOR "DEFINITE" CASES OF CHRONIC URTICARIA (N=35)

Case ID	WW Identifier	Narrative (Complete)
		spontaneous urticaria + symptomatic demographism) in a 22-year-old female patient who received mRNA-1273 (Spikevax) (batch no. LOT 214022) for COVID-19 vaccination. The patient had no allergies. Concurrent medical conditions included Hashimoto's thyroiditis. On 04-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 16-Dec-2021, the patient experienced CHRONIC SPONTANEOUS URTICARIA (Chronic spontaneous urticaria + symptomatic demographism) and RASH (Chronic spontaneous urticaria + symptomatic demographism). The patient was treated with CETIRIZINE at a dose of 40 milligram once a day; EBASTINE at a dose of 20 milligram once a day and PREDNISOLONE at a dose of 40 milligram once a day. On 26-Mar-2022, CHRONIC SPONTANEOUS URTICARIA (Chronic spontaneous urticaria + symptomatic demographism) and RASH (Chronic spontaneous urticaria + symptomatic demographism) had not resolved. No concomitant medications were reported. 12 days after third COVID-19 vaccination with Moderna occurrence of hives with wheals, Swelling and itching that had been going on ever since. By touch or Wheals continued to develop from scratching. Under therapy with various antihistamines in maximum dosage but no improvement. None Taking medication after vaccination iSv ASS or ibuprofen. None other allergies or intolerances.
[redacted]		This case was received via European Medicines Agency (Reference number: [redacted] on 19-May-2022 and was forwarded to Moderna on 19-May-2022. This regulatory authority case was reported by a physician and describes the occurrence of CHRONIC SPONTANEOUS URTICARIA (On 18Mar2022: Currently severe chronic spontaneous urticaria after the 3rd vaccination) and ANGIOEDEMA (Angioedema aggravated. On 18Mar2022: Currently angioedema after the 3rd vaccination) in a 37-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3005697) for COVID-19 vaccination. Previously administered products included for COVID-19 immunisation: SPIKEVAX in 2021 and SPIKEVAX in 2021. Past adverse reactions to the above products included No adverse event with SPIKEVAX and SPIKEVAX. Concurrent medical conditions included Chronic spontaneous urticaria ((type 2B) with angioedema. On/off outbreaks i 2-year cycles. Treated w. prednisolone, disabling) since 1999 and Angioedema (Spontaneous angioedema in relation w. urticaria. Swelling of eyes, lips, gums, tongue.) since 1999. Concomitant products included MONTELUKAST from 31-Jul-2017 to an unknown date for Urticaria. On 07-Feb-2022, the patient received third dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 12-Feb-2022, the patient experienced CHRONIC SPONTANEOUS URTICARIA (On 18Mar2022: Currently severe chronic spontaneous urticaria after the 3rd vaccination) (seriousness criterion disability) and ANGIOEDEMA (Angioedema aggravated. On 18Mar2022: Currently angioedema after the 3rd vaccination) (seriousness criterion disability). The patient was treated with PREDNISOLONE at an unspecified dose and frequency. At the time of the report, CHRONIC SPONTANEOUS URTICARIA (On 18Mar2022: Currently severe chronic spontaneous urticaria after the 3rd vaccination) and ANGIOEDEMA (Angioedema aggravated. On 18Mar2022: Currently angioedema after the 3rd vaccination) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In 2022, Physical examination: angioedema involving eyes, lips, gums, tongue (abnormal) angioedema involving eyes, lips, gums, tongue. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. CC: This is a regulatory case concerning a 37-year-old male patient, with a relevant history of Chronic spontaneous urticaria with angioedema treated with prednisolone, who experienced the unexpected, serious (disability) events of CHRONIC SPONTANEOUS URTICARIA and ANGIOEDEMA, which occurred 5 days after receiving the third dose of mRNA-1273 vaccine. Upon physical examination, patient had angioedema involving eyes, lips, gums, and tongue. Underlying history of history of Chronic spontaneous urticaria with angioedema treated with prednisolone could be a confounder for the events. The outcome of the events was reported as unknown. The benefit-risk relationship of mRNA-1273 is not affected by this report. Event retained as serious as per Regulatory Authority.

CASE NARRATIVES FOR "DEFINITE" CASES OF CHRONIC URTICARIA (N=35)

Case ID	WW Identifier	Narrative (Complete)
[redacted]		This case was initially received via European Medicines Agency (Reference number: [redacted] on 20-May-2022. The most recent information was received on 20-May-2022 and was forwarded to Moderna on 20-May-2022. This regulatory authority case was reported by a consumer and describes the occurrence of CHRONIC SPONTANEOUS URTICARIA (On 3 January2022 I did the modern Covid vaccine and on 13 January I started to have spontaneous chronic urticaria that still persists after 4 months.) in a 24-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 030G21A) for COVID-19 vaccination. No Medical History information was reported. On 03-Jan-2022, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 13-Jan-2022, after starting mRNA-1273 (Spikevax), the patient experienced CHRONIC SPONTANEOUS URTICARIA (On 3 January2022 I did the modern Covid vaccine and on 13 January I started to have spontaneous chronic urticaria that still persists after 4 months.). At the time of the report, CHRONIC SPONTANEOUS URTICARIA (On 3 January2022 I did the modern Covid vaccine and on 13 January I started to have spontaneous chronic urticaria that still persists after 4 months.) had not resolved. The action taken with mRNA-1273 (Spikevax) (Intramuscular) was unknown. No relevant concomitant medications were reported. No treatment information was provided. Most recent FOLLOW-UP information incorporated above includes: On 20-May-2022: Significant Follow up: Action taken updated.
[redacted]		This case was received via European Medicines Agency (Reference number: [redacted] on 27-May-2022 and was forwarded to Moderna on 27-May-2022. This regulatory authority case was reported by a consumer and describes the occurrence of CHRONIC SPONTANEOUS URTICARIA (CSU) and RASH (CSU) in a 52-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. No Medical History information was reported. On 06-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 06-Dec-2021, the patient experienced CHRONIC SPONTANEOUS URTICARIA (CSU) and RASH (CSU). On 13-Jan-2022, CHRONIC SPONTANEOUS URTICARIA (CSU) and RASH (CSU) had not resolved. No concomitant medication were reported. Patient experienced daily urticaria with hives (hives), no cause found by dermatologist No treatment information was provided by the reporter.
[redacted]		This regulatory authority case was reported by a physician and describes the occurrence of URTICARIA CHRONIC (Chronic urticaria), SKIN REACTION (Delayed skin reaction) and MECHANICAL URTICARIA (Dermographism) in a 61-year-old female patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination. No Medical History information was reported. On 27-Dec-2021, the patient received third dose of mRNA-1273 (COVID-19 Vaccine Moderna) (unknown route) dosage was changed to 1 dosage form once a day. On an unknown date, the patient received dose of mRNA-1273 (COVID-19 Vaccine Moderna) (unknown route) 1 dosage form. On an unknown date, received dose of mRNA-1273 (COVID-19 Vaccine Moderna) (unknown route) dosage was changed to 1 dosage form. On 11-Jan-2022, the patient experienced URTICARIA CHRONIC (Chronic urticaria), SKIN REACTION (Delayed skin reaction) and MECHANICAL URTICARIA (Dermographism). At the time of the report, URTICARIA CHRONIC (Chronic urticaria), SKIN REACTION (Delayed skin reaction) and MECHANICAL URTICARIA (Dermographism) was resolving.

CASE NARRATIVES FOR "DEFINITE" CASES OF CHRONIC URTICARIA (N=35)

Case ID	WW Identifier	Narrative (Complete)
		For mRNA-1273 (COVID-19 Vaccine Moderna) (Unknown), the reporter considered URTICARIA CHRONIC (Chronic urticaria), SKIN REACTION (Delayed skin reaction) and MECHANICAL URTICARIA (Dermographism) to be possibly related. A booster dose with Spikevax (R) Moderna was administered to the patient. Patient had previously received two doses of the same vaccine, which were well tolerated. No concomitant medications information was reported. It was reported that there was partial benefit from ongoing anti-histamine therapy. It was reported that urticaria manifested as wheals, migrants, and pruritic. At the time of the report 05-May-2022, the skin manifestation was still present, configuring a picture of chronic urticaria.
[redacted]		This regulatory authority case was reported by a physician and describes the occurrence of SKIN REACTION (Delayed skin reaction), URTICARIA CHRONIC (Chronic urticaria), MECHANICAL URTICARIA (Dermographism), ANGIOEDEMA (Angioedema in the hands) and ASTHMA (Asthma bronchial) in a 48-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination. The patient's past medical history included Cardiomyopathy, Familial hypercholesterolaemia and Stent placement (previous pose of 2 stents). Concurrent medical conditions included Ischemic heart disease. Concomitant products included mRNA-1273 (COVID-19 Vaccine Moderna) and mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination, ALIROCUMAB (PRALUENT), ROSUVASTATIN CALCIUM (CRESTOR), EZETIMIBE (EZETROL), ACETYLSALICYLIC ACID (ASPIRIN CARDIO) and PANTOPRAZOLE (PANTOZOLE) for an unknown indication. On 03-Jan-2022, the patient received dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form once a day. On 13-Jan-2022, the patient experienced SKIN REACTION (Delayed skin reaction), URTICARIA CHRONIC (Chronic urticaria), MECHANICAL URTICARIA (Dermographism), ANGIOEDEMA (Angioedema in the hands) and ASTHMA (Asthma bronchial). The patient was treated with LEVOCETIRIZINE DIHYDROCHLORIDE (XYZAL) for Urticaria, at a dose of one tablet in the evening and MONTELUKAST SODIUM (LUKAIR) for Bronchial asthma, at an unspecified dose and frequency. In January 2022, ANGIOEDEMA (Angioedema in the hands) had resolved. At the time of the report, SKIN REACTION (Delayed skin reaction), URTICARIA CHRONIC (Chronic urticaria), MECHANICAL URTICARIA (Dermographism) and ASTHMA (Asthma bronchial) had not resolved. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered SKIN REACTION (Delayed skin reaction), URTICARIA CHRONIC (Chronic urticaria), MECHANICAL URTICARIA (Dermographism), ANGIOEDEMA (Angioedema in the hands) and ASTHMA (Asthma bronchial) to be possibly related. Patient had no known allergic history. It was reported that it does not report SARS-CoV-2 infections. On 13-Jan-2022 patient manifested an angioedema in the hands and forearms, a urticaria with severe dermographism (in the form of migrant and itchy ovarian lesions, with scratching lesions on the thumbs) and an asthma Nocturnal bronchial, for which patient goes to the emergency room. Absence of other symptoms (fever, respiratory, gastrointestinal symptoms). Treatment medications included oral antihistamine and cortisone therapy. At the time of the report on 09-May-2022, or after about 4 months from the onset, the urticaria is still present. Company comment: This is a regulatory case concerning a 48 year-old, male patient with no relevant medical history and concomitant use of Alirocumab, rosuvastatin and acetylsalicylic acid, who experienced the non-serious unexpected, events of urticaria chronic, mechanical urticaria, angioedema (reported as angioedema in the hands) and asthma, approximately 10 days after the booster dose of mRNA-1273 vaccine. The patient visited the emergency department due to the symptoms reported and treatment prescribed included oral levocetirizine dihydrochloride, montelukast sodium and cortisone therapy. The outcome of the events urticaria chronic, mechanical urticaria, angioedema and asthma was reported as not recovered. The company causality for the events is considered as related to the vaccine. The mentioned concomitant medication could be confounding factors. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Case is reported as non serious by regulatory authority
[redacted]		This regulatory authority case was reported by a consumer and describes the occurrence of URTICARIA CHRONIC (All-body urticaria, chronic) and SKIN REACTION (Delayed skin reaction) in a 44-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination.

CASE NARRATIVES FOR "DEFINITE" CASES OF CHRONIC URTICARIA (N=35)

Case ID	WW Identifier	Narrative (Complete)
		Concurrent medical conditions included Pollen allergy. Concomitant products included ELASOMERAN (COVID-19 VACCINE MODERNA) and ELASOMERAN (COVID-19 VACCINE MODERNA) from 28-Jul-2021 to 28-Jul-2021 for COVID-19 vaccination. On 28-Dec-2021, the patient received third dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form once a day. On 30-Jan-2022, the patient experienced URTICARIA CHRONIC (All-body urticaria, chronic) (seriousness criterion hospitalization) and SKIN REACTION (Delayed skin reaction) (seriousness criterion hospitalization). At the time of the report, URTICARIA CHRONIC (All-body urticaria, chronic) and SKIN REACTION (Delayed skin reaction) had not resolved. No treatment medication was provided. Company comment. This regulatory case concerns a 44 – year – old, male patient with allergy as concurrent condition (pollen allergy), who experienced the unexpected, serious (due to hospitalization) events of urticaria chronic and skin reaction. The events approximately one month after the administration of the third dose of mRNA-1273 vaccine. The report stated that the patient experienced late urticaria throughout the body, which chromicizes, and was still present 4 months later. No further information such as hospitalization dates, clinical course or treatment details were provided for medical review. Patient's mentioned medical history could be confounder for the events. The company causality for the events is considered as related to the vaccine. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. All-body urticaria, chronic.
[redacted]		This regulatory authority case was reported by a physician and describes the occurrence of SKIN REACTION (Delayed skin reaction) and URTICARIA CHRONIC (Chronic urticaria) in a 31-year-old female patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination. Concurrent medical conditions included Pollinosis and Atopic. On 06-Jan-2022, the patient received third dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form once a day. On 13-Jan-2022, the patient experienced SKIN REACTION (Delayed skin reaction) and URTICARIA CHRONIC (Chronic urticaria). At the time of the report, SKIN REACTION (Delayed skin reaction) and URTICARIA CHRONIC (Chronic urticaria) had not resolved. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered SKIN REACTION (Delayed skin reaction) and URTICARIA CHRONIC (Chronic urticaria) to be possibly related. No concomitant medications were reported. After 7 days after the onset dose of urticaria Booster treated by the dermatologist with corticosteroids and antihistamines, then only with antihistamines. For two months, there have been occasional seizures treated with antihistamine when needed. No treatment medications were reported. Allergic reaction to the Booster
[redacted]		This regulatory authority case was reported by a physician and describes the occurrence of URTICARIA CHRONIC (Chronic urticaria) and SKIN REACTION (Delayed skin reaction) in a 46-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination. Concomitant products included ELASOMERAN (COVID-19 VACCINE MODERNA) for COVID-19 vaccination, EMTRICITABINE, RILPIVIRINE HYDROCHLORIDE, TENOFOVIR ALAFENAMIDE FUMARATE (ODEFSEY), CALCIUM CARBONATE (KALCIPOS), COLECALCIFEROL (VI-DE 3) and DENOSUMAB (PROLIA) for an unknown indication. On 16-Jan-2022, the patient received dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form once a day. On 28-Jan-2022, the patient experienced URTICARIA CHRONIC (Chronic urticaria) and SKIN REACTION (Delayed skin reaction). The patient was treated with BILASTINE (BILAXTEN) for Generalized

CASE NARRATIVES FOR "DEFINITE" CASES OF CHRONIC URTICARIA (N=35)

Case ID	WW Identifier	Narrative (Complete)
		urticaria, at an unspecified dose and frequency. At the time of the report, URTICARIA CHRONIC (Chronic urticaria) and SKIN REACTION (Delayed skin reaction) had not resolved. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered URTICARIA CHRONIC (Chronic urticaria) and SKIN REACTION (Delayed skin reaction) to be possibly related. 1975 patient received Spikevax in May 2021 and Jun 2021, booster on 16-Jan-2022. The patient took Odefsey, Kalcipros, ViDe 3, Prolia at home. On 28-Jan-2022 there was a generalized urticaria in need of Bilaxten antihistamine which the patient was still taking in April 2022 on a regular basis. Further course was not known. Spikevax' s[redacted]monograph mentioned among the possible ADRs the (common) rash without additional specifications, as also reported in the EMA/FDA monographs. UptoDate instead specifically reported 'Delayed urticarial reactions' among the adverse events reported post-marketing for mRNA vaccines. PubMed contained several publications concerning urticaria following anti-Covid-19 vaccination with mRNA vaccines, both again and re-exacerbation in patients already known for urticaria, including type late [1-8]. Causal correlation therefore was judged as possible. Most recent FOLLOW-UP information incorporated above includes: On 10-Jun-2022: Translated document received on 14-Jun-2022 contains non-significant information- updated case narrative.

CASE NARRATIVES FOR "POTENTIAL" CASES OF CHRONIC URTICARIA (N=64)

Case ID	WW Identifier	Narrative (Complete)
[redacted]		This spontaneous case was reported by a physician and describes the occurrence of URTICARIA CHRONIC (Chronic urticaria) in a 62-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for Prevention. No Medical History information was reported. On 09-Jan-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) .5 milliliter. On 06-Feb-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to .5 milliliter. On 10-Jul-2021, the patient experienced URTICARIA CHRONIC (Chronic urticaria). The patient was treated with PREDNISONE for Chronic urticaria, at an unspecified dose and frequency and MONTELUKAST SODIUM (SINGULAIR) for Chronic urticaria, at an unspecified dose and frequency. At the time of the report, URTICARIA CHRONIC (Chronic urticaria) had not resolved. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Concomitant medications was not reported. Treatment medication included antihistamines.
[redacted]		This case was received via European Medicines Agency (Reference number: [redacted] on 04-Sep-2021 and was forwarded to Moderna on 04-Sep-2021. This regulatory authority case was reported by a physician and describes the occurrence of URTICARIA CHRONIC ([redacted]) in a 61-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The patient's past medical history included Graves' disease. Concurrent medical conditions included Ear pruritus (Nickel allergy) and Nickel sensitivity (Nickel allergy). Concomitant products included LEVOTHYROXINE SODIUM (LEVAXIN) for an unknown indication. On 27-Apr-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 03-May-2021, after starting mRNA-1273 (Spikevax), the patient experienced URTICARIA CHRONIC ([redacted] (seriousness criterion medically significant). At the time of the report, URTICARIA CHRONIC ([redacted]) had not resolved. The action taken with mRNA-1273 (Spikevax) (Unknown) was unknown. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. Treatment information was not provided. Company comment: Based on the current available information and temporal association between the use of the product and the onset of the event, a causal relationship cannot be excluded. Most recent FOLLOW-UP information incorporated above includes: On 04-Sep-2021: Translation received on 07 Sep 2021 included relevant medical history and concomitant medication dosage details.
[redacted]		This case was received via European Medicines Agency (Reference number: [redacted] on 29-Sep-2021 and was forwarded to Moderna on 29-Sep-2021. This regulatory authority case was reported by a consumer and describes the occurrence of [redacted], OEDEMA PERIPHERAL [redacted], URTICARIA CHRONIC [redacted] and PYREXIA [redacted] in a 59-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 3002188) for COVID-19 vaccination. The patient's past medical history included Nettle rash (Nettle rash from penicillin 20 years ago and/or 1985 and from omeprazole 5 years ago). Concurrent medical conditions included Penicillin allergy, Celiac disease and Sjogren's syndrome. On 25-May-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 01-Jun-2021, the patient experienced URTICARIA CHRONIC [redacted] (seriousness criterion disability). In July 2021, the patient experienced ANGIOEDEMA

CASE NARRATIVES FOR "POTENTIAL" CASES OF CHRONIC URTICARIA (N=64)

Case ID	WW Identifier	Narrative (Complete)
		[redacted] (seriousness criteria disability and medically significant), OEDEMA PERIPHERAL [redacted] (seriousness criterion disability) and PYREXIA [redacted] (seriousness criterion disability). In July 2021, PYREXIA [redacted] had resolved with sequelae. At the time of the report, ANGIOEDEMA [redacted] OEDEMA PERIPHERAL [redacted] and URTICARIA CHRONIC [redacted] had not resolved. The action taken with mRNA-1273 (Spikevax) (Unknown) was unknown. There was no concomitant medication reported. Patient reported that she experienced angioedema, swelling on the lips and eyes, edema in feet, wrists, Severe hives that have become chronic urticaria. There was no treatment medication reported. Company Comment: A 59-year-old female, with history of Sjogren's syndrome, celiac disease, and drug hypersensitivity, presented with serious unexpected events of angioedema, edema peripheral, urticaria chronic, and pyrexia. Latency 8 days after first dose mRNA-1273. Events ongoing. Rechallenge unknown. Reporter causality not provided. Causality possible based on temporal association. Events consistent with known profile of mRNA-1273. The benefit-risk relationship of mRNA-1273 is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 29-Sep-2021: Translated document received on 01-oct-21 includes dosage form.
[redacted]		This case was received via European Medicines Agency (Reference number: [redacted] on 07-Oct-2021 and was forwarded to Moderna on 07-Oct-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of URTICARIA CHRONIC (Chronic urticaria appeared after the administration of the sars cov2 (Moderna) vaccine) and PRURITUS (Chronic urticaria appeared after the administration of the sars cov2 (Moderna) vaccine) in a 50-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 3002545) for SARS-CoV-2 immunisation. Concurrent medical conditions included Hashimoto's thyroiditis, Arthralgia and Drug allergy. Concomitant products included COLECALCIFEROL (DIBASE) for an unknown indication. On 24-May-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 50 microgram in total. On 24-May-2021, the patient experienced URTICARIA CHRONIC (Chronic urticaria appeared after the administration of the sars cov2 (Moderna) vaccine) (seriousness criterion hospitalization) and PRURITUS (Chronic urticaria appeared after the administration of the sars cov2 (Moderna) vaccine) (seriousness criterion hospitalization). At the time of the report, URTICARIA CHRONIC (Chronic urticaria appeared after the administration of the sars cov2 (Moderna) vaccine) and PRURITUS (Chronic urticaria appeared after the administration of the sars cov2 (Moderna) vaccine) had not resolved. The action taken with mRNA-1273 (Spikevax) (Intramuscular) was unknown. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Treatment information was not provided. The patient had chronic urticaria appeared after the administration of the sars cov2 vaccine. Company Comment: This case concerns a 50-year-old, female with a history of drug allergy and Hashimoto´s thyroiditis, who experienced the unexpected serious (by hospitalization) event of urticaria chronic and pruritus. The events occurred approximately 1 day after the reported dose of mRNA-1273 Moderna vaccine (Spikevax). The dose of vaccine reported is under the recommended dosage for primary series doses and no specification regarding being a booster has been provided. The rechallenge is not applicable since no information regarding other doses has been provided. The medical history of drug allergy and Hashimoto´s thyroiditis could be a potential confounder for the events. The Benefit-risk relationship of mRNA-1273 Moderna vaccine in not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 07-Oct-2021: Translation received on 10-OCT-2021 contains updated narrative

CASE NARRATIVES FOR "POTENTIAL" CASES OF CHRONIC URTICARIA (N=64)

Case ID	WW Identifier	Narrative (Complete)
		On 08-Oct-2021: Follow-up received contains no new information.
[redacted]		This case was received via European Medicines Agency (Reference number: [redacted]) on 14-Oct-2021 and was forwarded to Moderna on 14-Oct-2021. This regulatory authority case was reported by a physician and describes the occurrence of URTICARIA (pronounced urticaria. Now chronic urticaria), HYPERSENSITIVITY (pronounced urticaria. Now chronic urticaria), DRUG HYPERSENSITIVITY (pronounced urticaria. Now chronic urticaria) and URTICARIA CHRONIC (pronounced urticaria. Now chronic urticaria) in a 48-year-old male patient who received mRNA-1273 (Spikevax) for Vaccination. The patient's past medical history included Urticaria. Concurrent medical conditions included Allergy. On 10-Jun-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 13-Jun-2021, the patient experienced URTICARIA (pronounced urticaria. Now chronic urticaria) (seriousness criterion medically significant) and URTICARIA CHRONIC (pronounced urticaria. Now chronic urticaria) (seriousness criterion medically significant). In 2021, the patient experienced HYPERSENSITIVITY (pronounced urticaria. Now chronic urticaria) (seriousness criterion medically significant) and DRUG HYPERSENSITIVITY (pronounced urticaria. Now chronic urticaria) (seriousness criterion medically significant). At the time of the report, URTICARIA (pronounced urticaria. Now chronic urticaria), HYPERSENSITIVITY (pronounced urticaria. Now chronic urticaria), DRUG HYPERSENSITIVITY (pronounced urticaria. Now chronic urticaria) and URTICARIA CHRONIC (pronounced urticaria. Now chronic urticaria) was resolving. The action taken with mRNA-1273 (Spikevax) (Intramuscular) was unknown. For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered URTICARIA (pronounced urticaria. Now chronic urticaria) and URTICARIA CHRONIC (pronounced urticaria. Now chronic urticaria) to be possibly related. No further causality assessments were provided for HYPERSENSITIVITY (pronounced urticaria. Now chronic urticaria) and DRUG HYPERSENSITIVITY (pronounced urticaria. Now chronic urticaria). No concomitant medications were not provided. No treatment medications were not provided. Company comment: This case concerns a 48-year-old, male patient with a history of urticaria and allergy, who experienced the unexpected serious events of urticaria, hypersensitivity, drug hypersensitivity and urticaria chronic. The events occurred approximately 4 days after the first dose of Spikevax. The rechallenge was unknown since no information about the second dose was available. The medical history of urticaria and allergy remains a confounder. The benefit-risk relationship of Spikevax is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 14-Oct-2021: Translation received 18-OCT-2021, event verbatim translated to English.
[redacted]		This case was received via [redacted] (Reference number: [redacted] on 19-Oct-2021 and was forwarded to Moderna on 19-Oct-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of CHRONIC SPONTANEOUS URTICARIA (Chronic spontaneous urticaria), URTICARIA (Urticaria), CONTUSION (Contusion) and PERIPHERAL SWELLING (Peripheral swelling) in a 57-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 026L20A) for COVID-19 vaccination. The patient's past medical history included Anemia (Pre-anemia). Concurrent medical conditions included Asthma, Benign prostatic hyperplasia, Allergy to chemicals (Allergy to Sulfur) and Allergy to nuts. Concomitant products included CETIRIZINE HYDROCHLORIDE (ZYRTEC [CETIRIZINE HYDROCHLORIDE]), BUDESONIDE;FORMOTEROL FUMARATE DIHYDRATE, MULTIVITAMIN IRON, FLUTICASONE PROPIONATE (FLONASE [FLUTICASONE PROPIONATE]) and TADALAFIL for an unknown indication. On 26-Mar-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 26-Mar-2021, the patient experienced CHRONIC SPONTANEOUS URTICARIA (Chronic spontaneous urticaria) (seriousness criterion disability), URTICARIA (Urticaria) (seriousness criterion disability), CONTUSION (Contusion) (seriousness criterion disability) and PERIPHERAL SWELLING (Peripheral swelling) (seriousness criterion disability). The patient was treated with PREDNISONE for Urticaria, at an unspecified dose and frequency; OMALIZUMAB (XOLAIR) at an unspecified dose and frequency; CROMOLYN [CROMOGLICIC ACID] at an unspecified dose and frequency; FAMOTIDINE (PEPCID [FAMOTIDINE]) at an unspecified dose and frequency and DIPHENHYDRAMINE HYDROCHLORIDE (BENADRYL [DIPHENHYDRAMINE HYDROCHLORIDE]) at an unspecified dose and frequency. At the time of the report, CHRONIC SPONTANEOUS

CASE NARRATIVES FOR "POTENTIAL" CASES OF CHRONIC URTICARIA (N=64)

Case ID	WW Identifier	Narrative (Complete)
		URTICARIA (Chronic spontaneous urticaria), URTICARIA (Urticaria), CONTUSION (Contusion) and PERIPHERAL SWELLING (Peripheral swelling) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 26-Mar-2021, Biopsy skin: abnormal (abnormal) abnormal. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Treatment medications also included unspecified antihistamines. The patient had broke out in hives a few hours later around 8:00 pm. Hand swollen with bruising, left arms started with hives than moved all over body and didn't go away. Company comment: This case concerns a 57-year-old male patient, with medical history of Asthma and Allergies, who experienced the serious unexpected events of CHRONIC SPONTANEOUS URTICARIA, URTICARIA, CONTUSION and PERIPHERAL SWELLING. The events occurred on the same day of the administration of the second dose of Moderna COVID-19 Vaccine. The rechallenge was not applicable. Patient's medical history of Asthma and Allergies, remains a confounder. The benefit-risk relationship of Moderna COVID-19 Vaccine is not affected by this report.
[redacted]		This case was received via European Medicines Agency (Reference number: [redacted] on 20-Oct-2021 and was forwarded to Moderna on 20-Oct-2021. This regulatory authority case was reported by a consumer and describes the occurrence of IMPAIRED WORK ABILITY (NOW UNABLE TO WORK), CHRONIC SPONTANEOUS URTICARIA (CRONIC SPONTANEOUS URTICARIA), PAIN (I AM IN AGONY) and ARTHRALGIA (JOINT PAIN) in a 40-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 3003652) for COVID-19 immunisation. No Medical History information was reported. On 19-Jun-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 15-Jul-2021, received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. On 27-Jul-2021, after starting mRNA-1273 (Spikevax), the patient experienced CHRONIC SPONTANEOUS URTICARIA (CRONIC SPONTANEOUS URTICARIA) (seriousness criteria disability and medically significant). On 07-Aug-2021, the patient experienced ARTHRALGIA (JOINT PAIN) (seriousness criteria disability and medically significant). On an unknown date, the patient experienced IMPAIRED WORK ABILITY (NOW UNABLE TO WORK) (seriousness criteria disability and medically significant) and PAIN (I AM IN AGONY) (seriousness criteria disability and medically significant). At the time of the report, IMPAIRED WORK ABILITY (NOW UNABLE TO WORK), CHRONIC SPONTANEOUS URTICARIA (CRONIC SPONTANEOUS URTICARIA), PAIN (I AM IN AGONY) and ARTHRALGIA (JOINT PAIN) had not resolved. Concomitant product use was not provided by the reporter. Treatment information was not provided. Company Comment: This case concerns a 40-year-old, female patient with no relevant medical history, who experienced the unexpected events of impaired work ability, chronic spontaneous urticaria, pain and arthralgia. The event chronic spontaneous urticaria occurred 12 days after administration of the second dose of Spikevax; the event arthralgia occurred 23 days after administration of the second dose of Spikevax. The start date of the events impaired work ability and pain were not provided. The rechallenge was not applicable as no additional dosing will be given. The benefit-risk relationship of Spikevax is not affected by this report. Seriousness of the events were assessed as per Regulatory Authority reporting; however, there was no information in the source document supporting that the events resulted in a persistent or permanent incapacity, nor are these events medically significant.
[redacted]		This case was received via [redacted] (Reference number: [redacted] on 01-Nov-2021 and was forwarded to Moderna on 01-Nov-2021. This regulatory authority case was reported by a consumer and describes the occurrence of URTICARIA CHRONIC (chronic urticaria) and URTICARIA (Urticaria) in a 44-year-old female patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) (batch no. 3001659) for COVID-19 vaccination. No Medical History information was reported.

CASE NARRATIVES FOR "POTENTIAL" CASES OF CHRONIC URTICARIA (N=64)

Case ID	WW Identifier	Narrative (Complete)
		On 30-Apr-2021, the patient received first dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 21-May-2021, the patient experienced URTICARIA (Urticaria) (seriousness criterion medically significant). On an unknown date, the patient experienced URTICARIA CHRONIC (chronic urticaria) (seriousness criterion medically significant). At the time of the report, URTICARIA CHRONIC (chronic urticaria) was resolving and URTICARIA (Urticaria) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, SARS-CoV-2 test: no - negative covid-19 test (Negative) negative. The action taken with mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown) was unknown. Last menstrual period date - 27-OCT-2021. Concomitant medication was provided as COVID-19 VACCINE MODERNA with start date 2-JUL-2021. It was mentioned in the report that the patient's urticaria first started coming up just over 2 weeks after the first jab. She has never had it before, aside for 1 day over 10 years ago. It went down again but then after the 2nd jab it came up in August on and off, then came back on the 5th of September, and has been up every single day since. It has affected the patient's mood, general well-being, mental health, work and life in general. Antihistamines and steroids have not helped. She had to pay for a nutritional therapist and is 3 days into a very restrictive diet with supplements. She had seen many more similar accounts of chronic urticaria documented in the internet. Company Comment: This case concerns a 44-year-old, female patient with no relevant medical history, who experienced the unexpected events of urticaria and chronic urticaria. The event urticaria occurred 3 weeks after administration of the first dose of the Moderna COVID-19 Vaccine. The start date of the event chronic urticaria was not provided. The rechallenge was not applicable as the events occurred after the first dose. The benefit-risk relationship of the Moderna COVID-19 Vaccine is not affected by this report.
[redacted]		This case was initially received via European Medicines Agency (Reference number:[redacted] on 08-Nov-2021. The most recent information was received 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 URTICARIA (Urticaria: Present daily until now and tried to suppress with prednisone without success, now on a daily basis Cetrizine and soon an appointment with allergist/dermatologist. Itching all over the body due to urticaria including dermography), MECHANICAL URTICARIA (Dermography: Present daily until now and tried to suppress with prednisone without success, now on a daily basis Cetrizine Itching all over the body due to urticaria including dermography.) and CHRONIC SPONTANEOUS URTICARIA (Urticaria and dermography: Present daily to date. Itching throughout the body through urticaria including dermography. Allergist: CSU with Cin.du (symptomatic dermographism)) in a 30-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 3002537) for COVID-19 vaccination. The patient's past medical history included Disease risk factor. Previously administered products included for Product used for unknown indication: Moderna vaccin (Spikevax)COVID-19 VACCIN MODERNA [redacted]0 and5MLCOVID-19 VACCIN MODERNA [redacted] on 10-May-2021. Past adverse reactions to the above products included No adverse event with Moderna vaccin (Spikevax)COVID-19 VACCIN MODERNA [redacted] 0 and5MLCOVID-19 VACCIN MODERNA[redacted] Concomitant products included ETHINYLESTRADIOL, LEVONORGESTREL (ETHINYLESTRADIOL/LEVONORGESTREL) for an unknown indication. On 10-Jun-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 23-Jun-2021, the patient experienced URTICARIA (Urticaria: Present daily until now and tried to suppress with prednisone without success, now on a daily basis Cetrizine and soon an appointment with allergist/dermatologist. Itching all over the body due to urticaria including dermography) and MECHANICAL URTICARIA (Dermography: Present daily until now and tried to suppress with prednisone without success, now on a daily basis Cetrizine Itching all over the body due to urticaria including dermography.). 23-Jun-2021, the patient experienced CHRONIC SPONTANEOUS URTICARIA (Urticaria and dermography: Present daily to date. Itching throughout the body through urticaria including dermography. Allergist: CSU with Cin.du (symptomatic dermographism)). At the time of the report, URTICARIA (Urticaria: Present daily until now and tried to suppress with prednisone without success, now on a daily basis Cetrizine and soon an appointment with allergist/dermatologist. Itching all over the body due to urticaria including dermography), MECHANICAL URTICARIA (Dermography: Present daily until now and tried to suppress with prednisone without success, now on a daily basis Cetrizine Itching all over the body due to urticaria including dermography.) and CHRONIC SPONTANEOUS URTICARIA (Urticaria and dermography: Present daily

CASE NARRATIVES FOR "POTENTIAL" CASES OF CHRONIC URTICARIA (N=64)

Case ID	WW Identifier	Narrative (Complete)
		to date. Itching throughout the body through urticaria including dermography. Allergist: CSU with Cin.du (symptomatic dermographism)) had not resolved. No treatment medications were reported. Most recent FOLLOW-UP information incorporated above includes: On 08-Nov-2021: Translation received on 09-Nov-2021- event verbatim was updated. On 24-Nov-2021: Follow-up information included no new information. On 23-Dec-2021: Significant Follow up received one event was added.
[redacted]		This case was received via European Medicines Agency (Reference number: [redacted] on 29-Nov-2021 and was forwarded to Moderna on 29-Nov-2021. This regulatory authority case was reported by a consumer and describes the occurrence of URTICARIA CHRONIC (Chronic urticaria) in a 29-year-old female patient who received mRNA-1273 (Spikevax) for Vaccination. Co-suspect product included non-company product TOZINAMERAN (COMIRNATY) for Vaccination. Concomitant products included CANDESARTAN from 04-Nov-2020 to an unknown date for Prevention and Migraine. On 01-Jul-2021 at 6:35 PM, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 25-Aug-2021 at 12:05 PM, the patient started TOZINAMERAN (COMIRNATY) (Intramuscular) Dose no. in series: 2 Vaccination site: LeftArm. In July 2021, the patient experienced URTICARIA CHRONIC (Chronic urticaria). At the time of the report, URTICARIA CHRONIC (Chronic urticaria) had not resolved. The action taken with mRNA-1273 (Spikevax) (Intramuscular) was unknown. Doctor prescribed antihistamine pill daily. If the patient forgets to take a pill in the morning, urticaria appears during the day. The rash spreads and occurs all over the body. Most often stomach / back and scalp. Also spread to chest, neck, face and legs. Most recent FOLLOW-UP information incorporated above includes: On 29-Nov-2021: Translation received on 01-Dec-2021 contains drug information, concomitant information and event verbatim translated.
[redacted]		This case was received via [redacted] (Reference number: [redacted] on 21-Dec-2021 and was forwarded to Moderna on 21-Dec-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of URTICARIA CHRONIC (Urticaria chronic) in a 54-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 003B21A) for an unknown indication. No Medical History information was reported. On 22-Mar-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 24-Mar-2021, the patient experienced URTICARIA CHRONIC (Urticaria chronic) (seriousness criterion disability). At the time of the report, URTICARIA CHRONIC (Urticaria chronic) had not resolved. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Other medications were not reported. Reported chronic urticaria (hives).Patient had to take 5 different allergy medications (Allegra in the morning, Zyrtec, Pepcid, and Singular in the evening and when hives are extreme had to take prednisone to try to control the daily hives. Have been hospitalized several times when the hives could not be controlled. Was given epinephrine when hospital visit was necessary.
[redacted]		This spontaneous case was reported by a consumer and describes the occurrence of ANAPHYLACTIC REACTION (Anaphylaxis/ anaphylactic type reaction) in a 30-year-old female patient who received mRNA-1273 (Moderna

CASE NARRATIVES FOR "POTENTIAL" CASES OF CHRONIC URTICARIA (N=64)

Case ID	WW Identifier	Narrative (Complete)
	[redacted]	COVID-19 Vaccine) (batch nos. 031M20A and 041L20A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Dermatitis, Ex-smoker (Former smoker, 0.75 years of tobacco smoking, never used electronic cigarettes.), Recreational drug use ([redacted] x 1 experienced) and Birth control. Previously administered products included for Chronic urticaria: Zyrtec (10 mg QD); for Product used for unknown indication: Benadryl (25mg 8x every 2-3 days during a reaction), Omeprazole (20 mg BID) and Flu shot (Took flu shot this year). Past adverse reactions to the above products included No adverse event with Benadryl, Flu shot, Omeprazole and Zyrtec. Family history included Diabetes mellitus (Maternal grandmother has diabetes mellitus) since an unknown date and Hypertension (Mother and sister has hypertensive disorder) since an unknown date. Concurrent medical conditions included Allergy to nuts (Pistachio nut allergy) and Alcohol use (Moderate alcohol consumption). Concomitant products included ETHINYLESTRADIOL, NORGESTIMATE (TRI-SPRINTEC) for Birth control, SPIRONOLACTONE and SERTRALINE for an unknown indication. On 30-Jan-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 20-Feb-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 20-Feb-2021, the patient experienced INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (Patient took first dose on 30-Jan-2021 and second dose on 20-Feb-2021, timeframe was 22 days). In 2021, the patient experienced ANAPHYLACTIC REACTION (Anaphylaxis/ anaphylactic type reaction) (seriousness criterion medically significant). On 19-Oct-2021, the patient experienced URTICARIA CHRONIC (Chronic urticaria/Hives). The patient was treated with CETIRIZINE HYDROCHLORIDE (ZYRTEC [CETIRIZINE HYDROCHLORIDE]) (oral) on 19-Oct-2021 for Chronic urticaria, at a dose of 20-30 mg; CETIRIZINE HYDROCHLORIDE (ZYRTEC [CETIRIZINE HYDROCHLORIDE]) for Chronic urticaria, at a dose of 20 mg qpm, PRN; CETIRIZINE HYDROCHLORIDE (ZYRTEC [CETIRIZINE HYDROCHLORIDE]) (oral) for Chronic urticaria, at a dose of 10 milligram once a day; FAMOTIDINE (PEPCID [FAMOTIDINE]) (oral) for Chronic urticaria, at a dose of 20 milligram at bedtime and EPINEPHRINE (EPIPEN) for Chronic urticaria, at an unspecified dose and frequency. At the time of the report, ANAPHYLACTIC REACTION (Anaphylaxis/ anaphylactic type reaction) and URTICARIA CHRONIC (Chronic urticaria/Hives) had resolved and INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (Patient took first dose on 30-Jan-2021 and second dose on 20-Feb-2021, timeframe was 22 days) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 19-Oct-2021, Body temperature: 97.7 97.7 F (36.5 C) at 09:25 am. On 19-Oct-2021, Heart rate: 85 85 bpm at 09:28 am. On 19-Oct-2021, Oxygen saturation: 99 99% at 09:28 am. On 16-Nov-2021, Body temperature: 98.6 98.6 F (37 C) at 04:00 pm. On 16-Nov-2021, Heart rate: 85 85 bpm at 04:01 pm. On 16-Nov-2021, Oxygen saturation: 99 99% at 04:00 pm. On an unknown date, Blood test: cu index result pending CU index result pending. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter considered URTICARIA CHRONIC (Chronic urticaria/Hives) to be related. No further causality assessments were provided for ANAPHYLACTIC REACTION (Anaphylaxis/ anaphylactic type reaction) and INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (Patient took first dose on 30-Jan-2021 and second dose on 20-Feb-2021, timeframe was 22 days). Company comment: This spontaneous case concerns a 30 year old female patient with relevant medical history of dermatitis , allergy to peanuts (pistachio) , vaccinated with Influenza vaccine(date) with the following concomitant medications spironolactone, birth control pills , sertraline trispentec indication not reported, who experienced Serious (medically significant) , expected event of anaphylactic reaction and serious , unexpected event of urticaria (Chronic) which occurred on an unknown date after vaccination with the 2nd dose of mRNA-1273 vaccine It was reported that this patient experienced pruritus on the hands and feet three week after receiving the 1st dose of the mRNA -1273 vaccine. This patient consulted at a hospital due to her urticaria and occurrence of anaphylactic reaction every 2-3 days. These symptoms have improved since she discontinued spironolactone, Trispentec (birth control pills) and Sertaline . There were no identifiable triggers. She is taking omeprazole, cetirizine and diphenhydramine as treatment medications. Assessment at the hospital was Chronic urticaria and she was advised to do Chronic Urtricaria index and urticaria lab panel (results not reported) and as medication s Cetirizine 20-30 mg daily ,Epipen at hand and Pepcid . It was also reported that patient had Adverse reaction to Covid 19 mRNA-1273 vaccine by the physician. Event of Inappropriate Schedule of Product administration occurred. At the time of this report the events were reported as resolved with maintenance medications. The history of dermatitis and allergy to peanuts plus the

CASE NARRATIVES FOR "POTENTIAL" CASES OF CHRONIC URTICARIA (N=64)

Case ID	WW Identifier	Narrative (Complete)
		other concomitant medications the patient was taking as mentioned above are confounders for this case. The benefit - risk relationship of mRNA -1273 (Moderna Covid 19 Vaccine) is not affected by this report. This case was linked to [redacted] (Patient Link). Most recent FOLLOW-UP information incorporated above includes: On 23-Mar-2022: Follow up received included, updated medical history information in narrative.
[redacted]		This spontaneous case was reported by a consumer and describes the occurrence of ECZEMA (eczema), MECHANICAL URTICARIA (Dermatographia), INSOMNIA (Little to no sleep), CHRONIC SPONTANEOUS URTICARIA (Chronic Spontaneous Urticaria) and URTICARIA (Still developing itchy welts/light itch to skin) in a 55-year-old female patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) (batch nos. 052C21A and 300233I) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 12-May-2021 at 1:20 PM, the patient received first dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (Intramuscular) 1 dosage form. On 13-Jul-2021 at 1:20 PM, received second dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 15-Jul-2021, after starting mRNA-1273 (Moderna CoviD-19 Vaccine), the patient experienced RASH (Patch of rash on lower back/Scalp and 1/2 of back covered in rash and persistent itchy bumps). On 28-Aug-2021, the patient experienced ECZEMA (eczema). 28-Aug-2021, the patient experienced INSOMNIA (Little to no sleep). On 06-Oct-2021, the patient experienced MECHANICAL URTICARIA (Dermatographia). 06-Oct-2021, the patient experienced CHRONIC SPONTANEOUS URTICARIA (Chronic Spontaneous Urticaria). On an unknown date, the patient experienced URTICARIA (Still developing itchy welts/light itch to skin), ERYTHEMA (small red pinhead sized red itchy dots that stay for a few days/Areas of my skin, especially my back, seem to have a memory itch/sensitivity where large patches once were), SUNBURN (At times my skin almost feels like a sunburn itch - sore but itchy) and PAIN (it hurts to touch). The patient was treated with HYDROCORTISONE for Adverse event, at an unspecified dose and frequency; LORATADINE (CLARITIN [LORATADINE]) for Adverse event, at an unspecified dose and frequency; BETAMETHASONE DIPROPIONATE, GENTAMICIN SULFATE (BETADERM [BETAMETHASONE DIPROPIONATE;GENTAMICIN SULFATE]) for Adverse event, at an unspecified dose and frequency; CLOBETASOL PROPIONATE (CLOBETASOL 0.05%) for Adverse event, at an unspecified dose and frequency; PREDNISONE for Adverse event, at a dose of 50mg x 6 days and BILASTINE ([redacted]) for Adverse event, at a dose of 20 mg 2 tabs. At the time of the report, ECZEMA (eczema), MECHANICAL URTICARIA (Dermatographia), URTICARIA (Still developing itchy welts/light itch to skin) and RASH (Patch of rash on lower back/Scalp and 1/2 of back covered in rash and persistent itchy bumps) had not resolved and INSOMNIA (Little to no sleep), CHRONIC SPONTANEOUS URTICARIA (Chronic Spontaneous Urticaria), ERYTHEMA (small red pinhead sized red itchy dots that stay for a few days/Areas of my skin, especially my back, seem to have a memory itch/sensitivity where large patches once were), SUNBURN (At times my skin almost feels like a sunburn itch - sore but itchy) and PAIN (it hurts to touch) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 03-Nov-2021, Blood test: results not reported (Inconclusive) T/B Cell Blood Testing. For mRNA-1273 (Moderna CoviD-19 Vaccine) (Intramuscular), the reporter considered ECZEMA (eczema), MECHANICAL URTICARIA (Dermatographia), INSOMNIA (Little to no sleep), CHRONIC SPONTANEOUS URTICARIA (Chronic Spontaneous Urticaria), URTICARIA (Still developing itchy welts/light itch to skin), ERYTHEMA (small red pinhead sized red itchy dots that stay for a few days/Areas of my skin, especially my back, seem to have a memory itch/sensitivity where large patches once were), SUNBURN (At times my skin almost feels like a sunburn itch - sore but itchy), PAIN (it hurts to touch) and RASH (Patch of rash on lower back/Scalp and 1/2 of back covered in rash and persistent itchy bumps) to be related. On 28 August 2021 the patient attended ER as skin was raw, itchy and covered most of back, neck and scalp.Sheets and clothing unbearable and change of laundry soap, shampoo, etc., produced no change. Concomitant medications contains D Drops 1000 Ix pd. On Oct 14, 2021 patient said each hive remained 3 days to 6 weeks even with steroid cream. Prescribed: Eurcrisa. Dec 13, 2021 Began low histamine diet. On 13 Jan, 2022 Low histamine diet had some effect, but patient still cannot do without the Clobetasol to keep it under control and Quecetin. Clothing seams and bands have felt like glass shards against the skin for about 5 months now. Scalp could feel like it has fire ants all over it. This case was linked to [redacted] (Patient Link). Most recent FOLLOW-UP information incorporated above includes: On 01-Feb-2022: Follow-up document contains no additional information.

CASE NARRATIVES FOR "POTENTIAL" CASES OF CHRONIC URTICARIA (N=64)

Case ID	WW Identifier	Narrative (Complete)
[redacted]	[redacted]	This case was received via [redacted] (Reference number: [redacted]) on 06-Feb-2022 and was forwarded to Moderna on 06-Feb-2022. This regulatory authority case was reported by a consumer and describes the occurrence of RASH PRURITIC (itchy rash), IDIOPATHIC URTICARIA (idiopathic urticaria), MAST CELL ACTIVATION SYNDROME (Mast cell activation syndrome) and CHRONIC SPONTANEOUS URTICARIA (Chronic idiopathic urticaria) in a 37-year-old female patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) (batch no. 3005287) for an unknown indication. Concomitant products included ELASOMERAN (COVID-19 VACCINE MODERNA) and ELASOMERAN (COVID-19 VACCINE MODERNA) for an unknown indication. On 12-Dec-2021, the patient received third dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 20-Dec-2021, the patient experienced MAST CELL ACTIVATION SYNDROME (Mast cell activation syndrome) (seriousness criterion medically significant) and CHRONIC SPONTANEOUS URTICARIA (Chronic idiopathic urticaria) (seriousness criterion medically significant). On an unknown date, the patient experienced RASH PRURITIC (itchy rash) (seriousness criterion medically significant) and IDIOPATHIC URTICARIA (idiopathic urticaria) (seriousness criterion medically significant). At the time of the report, RASH PRURITIC (itchy rash) and IDIOPATHIC URTICARIA (idiopathic urticaria) was resolving and MAST CELL ACTIVATION SYNDROME (Mast cell activation syndrome) and CHRONIC SPONTANEOUS URTICARIA (Chronic idiopathic urticaria) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, SARS-CoV-2 test: negative (Negative) No - Negative COVID-19 test. The action taken with mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown) was unknown. Patient stated that the rash was migrating, it appeared in one place for about half an hour and then disappeared to appear elsewhere. The skin appeared normal after rash disappeared. Patient consulted GP twice and had seen an allergist, The allergist suggested this could be due to the vaccine shot had taken just about a week before the symptoms first appeared. Patient took fexofenadine currently on high dose to tried to control it. It controlled about 90 percent and even with the medication, still had the rash appearing in places. Patient had not tested positive for COVID-19 since having the vaccine, Patient was not enrolled in clinical trial, Patient had not had symptoms associated with COVID-19. Reporter mentioned No possible inflammation of the heart, myocarditis or pericarditis. Company Comment : This is a regulatory authority case concerning a 37-year-old, female patient with no reported medical history and with vaccine history of receiving 2 previous doses of mRNA-1273 vaccine, who experienced the unexpected serious events of itchy rash, idiopathic urticaria, mast cell activation syndrome and chronic idiopathic urticaria. The events itchy rash, idiopathic urticaria, mast cell activation syndrome and chronic idiopathic urticaria occurred 8 days after the third dose of mRNA-1273 vaccine administration. The events were described as, 8 days after the third dose of mRNA-1273 vaccine administration patient started having a very itchy rash all over her body. The rash is migrating, it appears in one place for about half an hour and then disappears to appear elsewhere. The skin appears normal after rash disappears. Patient consulted GP twice and have seen an allergist - they believe this is a case of idiopathic urticaria, chronic (it's about 6 weeks in duration now) and is due to mast cell overactivity. The allergist suggested this could be due to the vaccine shot I have just about a week before the symptoms first appeared. The rash is still ongoing and the patient is currently on high dose of fexofenadine to try to control it. It controls it about 90% and even with the medication I still have the rash appearing in places. The outcome of the events itchy rash and idiopathic urticaria were resolving while the events mast cell activation syndrome and chronic idiopathic urticaria the outcome were not resolved from the time of last observation. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.
[redacted]	[redacted]	This spontaneous case was reported by a consumer and describes the occurrence of URTICARIA CHRONIC (massive hives everywhere including her side, upper ribs, hip, around her back, arms, legs, thighs, and buttocks/welts/chronic systemic urticaria), VACCINATION COMPLICATION (A severe reaction from the Moderna booster), RASH PRURITIC (hives were thick, and terribly itchy with a rash, but different from her first rash), PURPURA (hive came back to different places, were sometimes a red flatter thing, sometimes purpura) and TREMOR (Shaking) in a 73-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 027D21A, 016M20A and 025L20A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below.

CASE NARRATIVES FOR "POTENTIAL" CASES OF CHRONIC URTICARIA (N=64)

Case ID	WW Identifier	Narrative (Complete)
		No Medical History information was reported. On 22-Jan-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 19-Feb-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 03-Nov-2021, received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to .25 milliliter. On 10-Nov-2021, the patient experienced URTICARIA CHRONIC (massive hives everywhere including her side, upper ribs, hip, around her back, arms, legs, thighs, and buttocks/welts/chronic systemic urticaria). In November 2021, the patient experienced VACCINATION COMPLICATION (A severe reaction from the Moderna booster), RASH PRURITIC (hives were thick, and terribly itchy with a rash, but different from her first rash), PURPURA (hive came back to different places, were sometimes a red flatter thing, sometimes purpura), TREMOR (Shaking), SKIN BURNING SENSATION (her skin burns at night), MUSCULOSKELETAL STIFFNESS (stiff around her face and mouth), ERYTHEMA (sometimes solid red portions, red flatter thing/fingertips are very red for a while then have a purplish color), SKIN DISCOLOURATION (her eyelids have a dark color around them particularly on the right side/ her hands look like a picture of Reynaud's syndrome and are white up), FEELING ABNORMAL (She feels her life is not normal and that it is not normal to have "serious symptoms" for months after receiving a vaccine), HYPOAESTHESIA (numb fingers, hands and feet) and FATIGUE (fatigue). The patient was treated with LORATADINE (CLARITIN [LORATADINE]) at an unspecified dose and frequency and PARACETAMOL (TYLENOL [PARACETAMOL]) at an unspecified dose and frequency. At the time of the report, URTICARIA CHRONIC (massive hives everywhere including her side, upper ribs, hip, around her back, arms, legs, thighs, and buttocks/welts/chronic systemic urticaria) had not resolved and VACCINATION COMPLICATION (A severe reaction from the Moderna booster), RASH PRURITIC (hives were thick, and terribly itchy with a rash, but different from her first rash), PURPURA (hive came back to different places, were sometimes a red flatter thing, sometimes purpura), TREMOR (Shaking), SKIN BURNING SENSATION (her skin burns at night), MUSCULOSKELETAL STIFFNESS (stiff around her face and mouth), ERYTHEMA (sometimes solid red portions, red flatter thing/fingertips are very red for a while then have a purplish color), SKIN DISCOLOURATION (her eyelids have a dark color around them particularly on the right side/ her hands look like a picture of Reynaud's syndrome and are white up), FEELING ABNORMAL (She feels her life is not normal and that it is not normal to have "serious symptoms" for months after receiving a vaccine), HYPOAESTHESIA (numb fingers, hands and feet) and FATIGUE (fatigue) outcome was unknown. Patient height was reported as 5 1.5 No concomitant medications were reported. Treatment medication also includes Anti-histamines It was reported that, the patient administered the last dose in the vial for a booster dose of the vaccine but did not think there was anything wrong with her dose or the vaccine. 7 days after receiving the booster dose. portions. She spoke to a healthcare professional who stated her "urticaria" may possibly have developed into chronic systemic urticaria.All these symptoms had occurred every day starting 1 week after receiving the booster. Patient stated that her hands look like a picture of Reynaud's syndrome and are white up until the first knuckle at the top while the inside of her hands. The patient continued to take unspecified antihistamines. She was concerned for blood dis orders, inflammation, and autoimmune disorders because of the vaccine. The patient was never previously been diagnosed with COVID-19. She had never experienced any of these symptoms prior to receiving the vaccine. This case was linked to [redacted] (Patient Link). Most recent FOLLOW-UP information incorporated above includes: On 14-Feb-2022: Updated reporter's details, patient's height, suspected product details and route of administration, treatment medications, additional events were added added and narrative updated.
[redacted]		This spontaneous case was reported by a consumer and describes the occurrence of URTICARIA CHRONIC (Chronic Urticaria) and INSOMNIA (he cannot sleep because it itched too much/Difficulty sleeping) in a 28-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 027H21B, 032B21A and 003C21A) for COVID-19 vaccination. No Medical History information was reported. On 10-Dec-2021, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form.

CASE NARRATIVES FOR "POTENTIAL" CASES OF CHRONIC URTICARIA (N=64)

Case ID	WW Identifier	Narrative (Complete)
		On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On an unknown date, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 20-Dec-2021, the patient experienced URTICARIA CHRONIC (Chronic Urticaria) and INSOMNIA (he cannot sleep because it itched too much/Difficulty sleeping). The patient was treated with CETIRIZINE at a dose of 1 dosage form once a day. At the time of the report, URTICARIA CHRONIC (Chronic Urticaria) had not resolved and INSOMNIA (he cannot sleep because it itched too much/Difficulty sleeping) outcome was unknown. Patient had rashes all over his body and had itched too much. Patient then consulted an allergologist who advised the patient had chronic urticaria. Treatment medications included antihistamines to be taken for months.
[redacted]		This spontaneous case was reported by a patient family member or friend and describes the occurrence of URTICARIA CHRONIC (Chronic urticaria) in a 21-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 041J21A, 030B21A and 036B21A) for COVID-19 vaccination. The patient's past medical history included COVID-19 (Symptoms: Cough(for 5 days), Headache(for 5 days), Nasal congestion/runny nose(for 9 days), tiredness(For 8 days)) on 28-Nov-2021. Concurrent medical conditions included Lactose intolerance (diarrhea, bloating) since 2002 and Inflammatory bowel disease (Worse constipation because of the medication that she is taking for the hives. Increased issues with constipation. Must use additional over the counter medication, laxative, to address.) since 2018. Concomitant products included LINACLOTIDE (LINZESS) from 2020 to an unknown date and MENTHA X PIPERITA OIL (IBGARD) from August 2021 to an unknown date for Irritable bowel syndrome. On 09-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 13-May-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 27-Dec-2021, received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 07-Jan-2022 at 9:00 PM, the patient experienced URTICARIA CHRONIC (Chronic urticaria). The patient was treated with FEXOFENADINE HYDROCHLORIDE (ALLEGRA [FEXOFENADINE HYDROCHLORIDE]) (oral) from 07-Jan-2022 to 08-Jan-2022 for Hives, at a dose of 2 tablets; CETIRIZINE HYDROCHLORIDE (ZYRTEC [CETIRIZINE HYDROCHLORIDE]) for Hives, at an unspecified dose and frequency; HYDROCORTISONE on 27-Jan-2022 for Hives, at an unspecified dose and frequency and DIPHENHYDRAMINE HYDROCHLORIDE (BENADRYL [DIPHENHYDRAMINE HYDROCHLORIDE]) (oral) from 07-Jan-2022 to 08-Jan-2022 for Hives, at a dose of 2 tablets. At the time of the report, URTICARIA CHRONIC (Chronic urticaria) had not resolved. Initially, patient consulted to a doctor and they administered Hydrocortisone cream and a dose of Benadryl and it went away after 3 hours. However they were coming back all the time, mostly when she took a shower and they appeared on different parts of her body. She was currently still experiencing hives and it has not been better. The hives were not consistent and switch places, they were then appearing also on her face. She was currently taking Allegra and Zyrtec for her symptoms. Reported patient race was Chinese. Symptoms experienced by the patient included Redness/erythema- Local, Itching/pruritus- generalized, Hives/urticaria- local. Treatment provided for SARS-CoV-2 infection was over the counter cold meds for every 4 hr as indicated oral route from 28 Nov 2021 to 2 Dec 2021 Patient was taking a 24-hr allergy pill 2-3x week which seems to help lessen the severity of the hives. They often appear as raised welts, 2-3 inches in length. Otherwise, they appear as a redness. They do not consistently appear in the same location at each attack. Each attack is accompanied by itchiness basically all over the body. Until Feb 13, the hives never appeared on her face. Starting Feb 13, they now appear on her face as well as extremities randomly. The hives can also appear during the day but random and not often. The hives and accompanying itchiness always disappear in hours. Ice packs and a cold shower tend to reduce the welts and itchiness. Hot showers tend to aggravate or start the attack. Also a warm environment can trigger an attack (e.g. roommate turns up heat in apartment). Patient had changed laundry detergent, soap, tested several different foods (eliminated from diet) with no success. It was reported that the allergy meds may be causing negative effects - specifically constipation, which is aggravating the IBS-C unfortunately. Patient was scheduled to see an allergist in [redacted]

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Case ID	WW Identifier	Narrative (Complete)
		This case was linked to [redacted] Patient Link). Most recent FOLLOW-UP information incorporated above includes: On 21-Feb-2022: Follow up contains significant information. Reporter information added, new events added, event description and medical history were added.
[redacted]		This regulatory authority case was reported by a pharmacist and describes the occurrence of URTICARIA CHRONIC (Chronic Urticaria factitia), COVID-19 (COVID-19) and VACCINATION FAILURE (Vaccination failure) in a 40-year-old female patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination. No Medical History information was reported. On 04-May-2021, the patient received dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 50 microgram. On 09-Dec-2021, received dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) dosage was changed to 50 microgram. On 22-Dec-2021, after starting mRNA-1273 (COVID-19 Vaccine Moderna), the patient experienced URTICARIA CHRONIC (Chronic Urticaria factitia) (seriousness criterion medically significant). On an unknown date, the patient experienced COVID-19 (COVID-19) (seriousness criterion medically significant) and VACCINATION FAILURE (Vaccination failure) (seriousness criterion medically significant). At the time of the report, URTICARIA CHRONIC (Chronic Urticaria factitia) had not resolved and COVID-19 (COVID-19) and VACCINATION FAILURE (Vaccination failure) outcome was unknown. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered URTICARIA CHRONIC (Chronic Urticaria factitia), COVID-19 (COVID-19) and VACCINATION FAILURE (Vaccination failure) to be possibly related. Concomitant product was not provided by the reporter Treatment information was not provided On an unknown date, Unknown test: 1 week after occurrence: small blood count unremarkable, tryptase normal. CRP not increased.. Company comment: This regulatory authority case concerns a 40-year-old female patient with no reported medical history who experienced serious unexpected event of urticaria chronic, vaccination failure and AESI COVID-19. The event of chronic urticaria occurred 13 days after the 3rd dose of mRNA-1273 whereas the exact time to onset for vaccination failure and COVID-19 were not provided. The events were assessed as related to the vaccine by the reporter. Based on the current available information, the mRNA-1273 does not contain a virus capable of causing COVID-19 infection after vaccination. The benefit-risk relationship of mRNA-1273 is not affected by this report. The seriousness assessment retained as per regulatory authority reporting.
[redacted]		This case was received via European Medicines Agency (Reference number: [redacted]) on 09-Mar-2022 and was forwarded to Moderna on 09-Mar-2022. This regulatory authority case was reported by a physician and describes the occurrence of CHRONIC SPONTANEOUS URTICARIA (Urticaria chronica - 1 week after 2. vaccination against COVID-19, Moderna, developed spontaneous autoimmun chronic urticaria.) in a 39-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. No Medical History information was reported. In August 2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. In August 2021, the patient experienced CHRONIC SPONTANEOUS URTICARIA (Urticaria chronica - 1 week after 2. vaccination against COVID-19, Moderna, developed spontaneous autoimmun chronic urticaria.). At the time of the report, CHRONIC SPONTANEOUS URTICARIA (Urticaria chronica - 1 week after 2. vaccination against COVID-19, Moderna, developed spontaneous autoimmun chronic urticaria.) had not resolved. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. Concomitant product use was not provided by the reporter. No treatment information was provided.
[redacted]		This case was initially received via European Medicines Agency (Reference number: [redacted] on 11-Mar-2022. The most recent information was received on 23-Mar-2022 and was forwarded to Moderna on 23-Mar-2022.

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Case ID	WW Identifier	Narrative (Complete)
		This regulatory authority case was reported by a consumer and describes the occurrence of URTICARIA CHRONIC (Chronic urticaria) in a 62-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 3005843) for COVID-19 vaccination. Concurrent medical conditions included Hip arthrosis. On 11-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 13-Dec-2021, after starting mRNA-1273 (Spikevax), the patient experienced URTICARIA CHRONIC (Chronic urticaria) (seriousness criterion medically significant). At the time of the report, URTICARIA CHRONIC (Chronic urticaria) was resolving. No concomitant medications were provided by the reporter. No treatment information was provided by the reporter. Company comment: This is a regulatory authority case concerning a 62-year-old female patient with no relevant medical history, who experienced the unexpected serious (medically significant) event of chronic urticaria. The event occurred approximately 2 days after the third dose of mRNA-1273 vaccine administration. No other details surrounding the event was reported. The outcome of the event was resolving. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Event seriousness assessed as per Regulatory Authority reporting. Most recent FOLLOW-UP information incorporated above includes: On 23-Mar-2022: Significant follow-up received, Medical history added.
[redacted]		This case was received via European Medicines Agency (Reference number: [redacted] on 11-Mar-2022 and was forwarded to Moderna on 11-Mar-2022. This regulatory authority case was reported by a physician and describes the occurrence of URTICARIA CHRONIC (Urticaria chronic) in a 35-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 immunisation. No Medical History information was reported. On 14-Jul-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 28-Sep-2021, after starting mRNA-1273 (Spikevax), the patient experienced URTICARIA CHRONIC (Urticaria chronic). At the time of the report, URTICARIA CHRONIC (Urticaria chronic) had not resolved. The action taken with mRNA-1273 (Spikevax) (Intramuscular) was unknown. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Dosage text: dose 1 No concomitant drug details were reported. No treatment details were reported.
[redacted]		This regulatory authority case was reported by a consumer and describes the occurrence of URTICARIA CHRONIC (Urticaria chronic) and MECHANICAL URTICARIA (Dermographism) in a 35-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination. No Medical History information was reported. On 12-Dec-2021, the patient received third dose of mRNA-1273 (COVID-19 Vaccine Moderna) (unknown route) 1 dosage form. On 23-Dec-2021, the patient experienced URTICARIA CHRONIC (Urticaria chronic) (seriousness criterion medically significant) and MECHANICAL URTICARIA (Dermographism) (seriousness criterion medically significant). At the time of the report, URTICARIA CHRONIC (Urticaria chronic) and MECHANICAL URTICARIA (Dermographism) had not resolved.

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Case ID	WW Identifier	Narrative (Complete)
		No concomitant medications were provided. It was reported that the patient received COVID-19 Vaccine Moderna (Spikevax) 3rd vaccination. Dosage text included: Dose 3c. No treatment information was provided. Company comment: This regulatory authority case concerns a 35-year-old male patient, with no medical history reported, who experienced the unexpected events of urticaria chronic and mechanical urticaria, which were considered as medically significant. The events occurred approximately 11 days after the third dose of mRNA-1273 and, as reported, had not resolved. The benefit-risk relationship of mRNA-1273 is not affected by this report. Event seriousness was assessed as per Regulatory Authority reporting.
[redacted]		This case was received via [redacted] (Reference number: [redacted] on 18-Mar-2022 and was forwarded to Moderna on 18-Mar-2022. This regulatory authority case was reported by a consumer and describes the occurrence of ANGIOEDEMA (angioedema), IDIOPATHIC URTICARIA (idiopathic urticaria) and CHRONIC SPONTANEOUS URTICARIA (Chronic idiopathic urticaria) in a 35-year-old female patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for an unknown indication. No Medical History information was reported. On 23-May-2021, the patient received first dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 30-May-2021, the patient experienced CHRONIC SPONTANEOUS URTICARIA (Chronic idiopathic urticaria) (seriousness criterion medically significant). On an unknown date, the patient experienced ANGIOEDEMA (angioedema) (seriousness criterion medically significant) and IDIOPATHIC URTICARIA (idiopathic urticaria) (seriousness criterion medically significant). At the time of the report, ANGIOEDEMA (angioedema) and IDIOPATHIC URTICARIA (idiopathic urticaria) outcome was unknown and CHRONIC SPONTANEOUS URTICARIA (Chronic idiopathic urticaria) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, SARS-CoV-2 test: negative (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 last menstrual period date was on 15-MAR-2022. Patient had no symptoms associated with COVID-19. Patient was not pregnant and was not breastfeeding. The patient had quite severe urticaria and angioedema. Patient had been seen by general practitioner and allergist and given diagnosis in Aug. Patient had not tested positive for COVID-19 since having the vaccine and was not enrolled in clinical trial. Patient's report was not related to possible myocarditis or pericarditis. No treatment information was provided. Company comment: This case concerns a 35-year-old female patient with no medical history reported, who experienced the unexpected, serious (medically significant) events of angioedema and chronic spontaneous urticaria 7 days after the first dose of mRNA-1273. The patient reports that she had a diagnosis after being seen by her general practitioner and allergist. The benefit-risk relationship of mRNA-1273 is not affected by this report.
[redacted]		This case was received via an unknown source (no reference has been entered for a health authority or license partner) on 16-Mar-2022 and was forwarded to Moderna on 16-Mar-2022. This regulatory authority case was reported by a consumer and describes the occurrence of URTICARIA CHRONIC (Urticaria chronic) in a 27-year-old female patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination. Concurrent medical conditions included Celiac disease (celiac disease) and Allergic reaction to bee sting (bee stings). Concomitant products included ELASOMERAN (COVID-19 VACCINE MODERNA) from 13-Feb-2021 to 13-Mar-2021 for COVID-19 vaccination. On 29-Nov-2021, the patient received dose of mRNA-1273 (COVID-19 Vaccine Moderna) (unknown route) 1 dosage form. On 08-Dec-2021, the patient experienced URTICARIA CHRONIC (Urticaria chronic) (seriousness criterion medically significant). At the time of the report, URTICARIA CHRONIC (Urticaria chronic) had not resolved.

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		The patient received COVID-19 Vaccine Moderna (Spikevax) 3rd vaccination (COVID-19 vaccine), unknown dosage. No treatment details were reported. Company comment: This regulatory authority case concerns a 27-year-old female patient with medical history (Celiac disease and Allergic reaction to bee sting), who experienced the serious unexpected event of Urticaria chronic. The event started occurring approximately within (9 days) after the dose of mRNA-1273, Moderna COVID-19 Vaccine. The benefit-risk relationship of mRNA-1273, Moderna COVID-19 Vaccine is not affected by this report.
[redacted]		This spontaneous case was reported by a patient and describes the occurrence of URTICARIA CHRONIC (Chronic urticaria) and INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (2nd dose administered more than 35 days after initial dose) in a 34-year-old female patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) (batch nos. 093D21A and 3002538) for COVID-19 vaccination. Patient did not have history of the following medical conditions; anaphylaxis, asthma, hypersensitivity reactions, hay fever, hiver/urticaria. No previous history of allergic/ hypersensitivity reactions to vaccines or other allergic/hypersensitivity reactions (medications, foods, environmental, etc). No acute illnesses at the time of vaccination and up to one month before or any chronic/long-standing health conditions. Patient did not take prescriptions, over-the-counter medications, dietary supplements, or herbal remedies at time of vaccination. On 29-May-2021, the patient received first dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (Intramuscular) .5 milliliter. On 17-Jul-2021, received second dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (Intramuscular) dosage was changed to .5 milliliter. On 17-Jul-2021, after starting mRNA-1273 (Moderna CoviD-19 Vaccine), the patient experienced INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (2nd dose administered more than 35 days after initial dose). On 01-Aug-2021, the patient experienced URTICARIA CHRONIC (Chronic urticaria). At the time of the report, URTICARIA CHRONIC (Chronic urticaria) had not resolved and INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (2nd dose administered more than 35 days after initial dose) outcome was unknown. No concomitant medications was provided by the reporter. Patient experienced swelling of face, felt like patient was in a boxing match, itching everywhere, red round patches on the skin and dermatographia, 15 days after administration of 2nd dose. Due to event patient seek medical care and visited physician office. Patient took Antihistamine to control the symptom as the symptoms got worsen once patient stopped. This case was linked to [redacted] (Patient Link). Most recent FOLLOW-UP information incorporated above includes: On 08-Apr-2022: Follow-up information received includes primary reporter details, patient demographics and patient's negative history were updated.
[redacted]		This spontaneous case was reported by an other health care professional and describes the occurrence of ANGIOEDEMA (Angioedema) in a 34-year-old female patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) (batch nos. 019J21A, 093D21A and 3002538) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Patient has no medical history for following conditions: Anaphylaxis, Asthma, Hay Fever, Hypersensitivity reactions, Hives/urticaria. On 29-May-2021, the patient received first dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (Intramuscular) .5 milliliter. On 17-Jul-2021, received second dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) dosage was changed to .5 milliliter. On 16-Jan-2022, received third dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) dosage was changed to .25 milliliter. On 27-Jan-2022, the patient experienced ANGIOEDEMA (Angioedema) (seriousness

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		criterion medically significant) and CHRONIC SPONTANEOUS URTICARIA (Chronic urticaria/swelling of face, felt like the patient was in a boxing match, itching everywhere, red round patches on the skin and dermatographia/CHRONIC SPONTANEOUS URTICARIA). On 31-Jan-2022, the patient experienced CONDITION AGGRAVATED (symptoms worsened). At the time of the report, ANGIOEDEMA (Angioedema), CHRONIC SPONTANEOUS URTICARIA (Chronic urticaria/swelling of face, felt like the patient was in a boxing match, itching everywhere, red round patches on the skin and dermatographia/CHRONIC SPONTANEOUS URTICARIA) and CONDITION AGGRAVATED (symptoms worsened) had not resolved. For mRNA-1273 (Moderna CoviD-19 Vaccine) (Intramuscular), the reporter considered ANGIOEDEMA (Angioedema) and CHRONIC SPONTANEOUS URTICARIA (Chronic urticaria/swelling of face, felt like the patient was in a boxing match, itching everywhere, red round patches on the skin and dermatographia/CHRONIC SPONTANEOUS URTICARIA) to be related. No further causality assessment was provided for CONDITION AGGRAVATED (symptoms worsened). No concomitant medications were taken by patient. The patient had received the booster dose of the vaccine. Patient received treatment Antihistamines on 27-JAN-2022 dose was 40mg per day then 20mg per day. It was reported that the patient's adverse events had worsened and had to take antihistamine to control the symptoms and if it was stopped, the symptoms returned. It was reported that the patient had no past medical history of acute or chronic illnesses, allergies or urticaria and never had COVID disease. The patient had not taken any other vaccines within 1 month prior to taking Moderna COVID-19 vaccine. Symptoms of event included generalized itching/pruritis, generalized hives/urticaria, rash, redness/erythema, Swelling of upper airway (lips, tongue, throat, uvula, or larynx), Angioedema. It was stated that there were no other potential causes. This is a spontaneous case concerning a 34-year-old, female patient with no relevant medical history, who experienced the unexpected serious (medically significant) event of Angioedema and unexpected non-serious events of Chronic spontaneous urticaria, Condition aggravated. The event Angioedema and Chronic spontaneous urticaria occurred 11 days after the third dose of mRNA-1273 COVID 19 Vaccine. While the vent condition aggravated occurred 15 days after the third dose mRNA-1273 COVID 19 Vaccine. Patient treated with Antihistamine of unknown generic name, with dosage of 40mg /day then 20mg /day. The events were reported as not resolved. The rechallenge was positive since patient experienced the same symptoms after the second dose. The benefit-risk relationship of mRNA-1273 COVID 19 Vaccine, is not affected by this report. This case was linked to [redacted] (Patient Link). Most recent FOLLOW-UP information incorporated above includes: On 08-Apr-2022: Significant follow-up: reporter details, patient details, event details were updated.
[redacted]		This spontaneous case was reported by a consumer and describes the occurrence of HEART RATE INCREASED (Elevated heart rate or work load), ERYTHEMA (Redness/erythema Generalized), CHRONIC SPONTANEOUS URTICARIA (Chronic spontaneous urticaria), PRURITUS (Itching/pruritus) and PARAESTHESIA (Prickling/Tingling sensation) in a 62-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 069h21a, 032bz1a and 047a21a) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concomitant products included ROSUVASTATIN from 01-Jan-2012 to an unknown date, METOPROLOL from 01-Jan-2012 to an unknown date and CLOPIDOGREL from 01-Jan-2012 to an unknown date for an unknown indication. On 14-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 11-Apr-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 06-Jan-2022, received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 10-Feb-2022, the patient experienced ERYTHEMA (Redness/erythema Generalized), PRURITUS (Itching/pruritus), PARAESTHESIA (Prickling/Tingling sensation), URTICARIA (noticed hives on stomach/Hives/urticaria/but has increased to other parts of body like thighs, neck, hands and face) and RASH (Rash Generalized). On an unknown date, the patient experienced HEART RATE INCREASED (Elevated heart rate or work

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		load) and CHRONIC SPONTANEOUS URTICARIA (Chronic spontaneous urticaria). At the time of the report, HEART RATE INCREASED (Elevated heart rate or work load) outcome was unknown and ERYTHEMA (Redness/erythema Generalized), CHRONIC SPONTANEOUS URTICARIA (Chronic spontaneous urticaria), PRURITUS (Itching/pruritus), PARAESTHESIA (Prickling/Tingling sensation), URTICARIA (noticed hives on stomach/Hives/urticaria/but has increased to other parts of body like thighs, neck, hands and face) and RASH (Rash Generalized) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 07-Mar-2022, Full blood count: all within range (normal) all within range. On 07-Mar-2022, Metabolic function test: all within range (normal) all within range. On an unknown date, Heart rate: elevated (High) elevated. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter considered HEART RATE INCREASED (Elevated heart rate or work load), ERYTHEMA (Redness/erythema Generalized), CHRONIC SPONTANEOUS URTICARIA (Chronic spontaneous urticaria), PRURITUS (Itching/pruritus), PARAESTHESIA (Prickling/Tingling sensation), URTICARIA (noticed hives on stomach/Hives/urticaria/but has increased to other parts of body like thighs, neck, hands and face) and RASH (Rash Generalized) to be related. The patient had no new medications or shots taken in last 5 years and had never had hives before this issue. No new soaps or lotions. The patient had the same diet as in last 5 years and was living in same house-area for the last 25 years. The patient had no hives experience after 1st or 2nd Moderna shot. Reportedly, the condition started around 3 weeks after the Moderna booster shot. The first reported issue on stomach but had increased to other parts of body like thighs, neck, hands, and face. It seems to come out after an elevated heart rate or workload. One occurrence happened after shoveling snow without gloves, hives started up on hands. The patient stated that it seemed to be getting worse in the last month. The patient also reported that it normally would happen 4-5 times per week. Treatment medication reported included Antihistamines which the patient was still taking as needed and it was reported that the patient started to taking Antihistamines from 07-Mar-2022.
[redacted]		This case was received via an unknown source (no reference has been entered for a health authority or license partner) on 21-Mar-2022 and was forwarded to Moderna on 21-Mar-2022. This regulatory authority case was reported by a physician and describes the occurrence of URTICARIA CHRONIC (Chronic urticaria) in a 35-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination. No Medical History information was reported. On 17-Dec-2021, the patient received dose of mRNA-1273 (COVID-19 Vaccine Moderna) (unknown route) 1 dosage form. On 27-Dec-2021, the patient experienced URTICARIA CHRONIC (Chronic urticaria) (seriousness criterion medically significant). At the time of the report, URTICARIA CHRONIC (Chronic urticaria) had not resolved. For mRNA-1273 (COVID-19 Vaccine Moderna) (Unknown), the reporter considered URTICARIA CHRONIC (Chronic urticaria) to be possibly related. No concomitant medication were reported. The patient's medical history and concurrent conditions included: no relevant medical history reported. The patient's weight was not reported, and height was not reported. The patient received COVID-19 Vaccine Moderna (Spikevax) 3rd vaccination (COVID-19 vaccine), unknown dosage. No treatment information was provided. Company comment: This regulatory authority case concerns a 35-year-old male patient with no medical history provided, who experienced serious (medically significant) unexpected event of Chronic urticaria. The event occurred 10 days after the patient had received the mRNA-1273 vaccine (as third vaccination). At the time of this report, the event was still ongoing and details regarding the clinical course of the event were not disclosed. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report. Event seriousness assessed as per Regulatory Authority reporting.
[redacted]		This spontaneous case was reported by a consumer and describes the occurrence of CHRONIC SPONTANEOUS URTICARIA (Chronic spontaneous Urticaria), PALPITATIONS (Irregular heart rate/palpitations/Heart rate more than 100 beats per min), FEELING HOT (Feeling hot), CHILLS (Chills) and INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (2nd dose on 27-09-2021 and 3rd dose on 03-02-2022) in a 38-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination.

CASE NARRATIVES FOR "POTENTIAL" CASES OF CHRONIC URTICARIA (N=64)

Case ID	WW Identifier	Narrative (Complete)
		No Medical History information was reported. On 26-Jul-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 27-Sep-2021, received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. On 03-Feb-2022, received third dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. On 03-Feb-2022, the patient experienced INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (2nd dose on 27-09-2021 and 3rd dose on 03-02-2022). On 15-Feb-2022 at 10:00 PM, after starting mRNA-1273 (Spikevax), the patient experienced CHRONIC SPONTANEOUS URTICARIA (Chronic spontaneous Urticaria), PALPITATIONS (Irregular heart rate/palpitations/Heart rate more than 100 beats per min), FEELING HOT (Feeling hot) and CHILLS (Chills). At the time of the report, CHRONIC SPONTANEOUS URTICARIA (Chronic spontaneous Urticaria), PALPITATIONS (Irregular heart rate/palpitations/Heart rate more than 100 beats per min), FEELING HOT (Feeling hot) and CHILLS (Chills) had not resolved and INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (2nd dose on 27-09-2021 and 3rd dose on 03-02-2022) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 15-Feb-2022, Heart rate: >100 (abnormal) Heart rate >100 beats per min. There was no previous history of other allergic/hypersensitivity reactions. Patient reported first observation of reaction as first it started to itch in the armpits. Signs and symptoms include Itching/pruritis, hives/urticaria, generalized redness/erythema, generalized rash, sensation of throat closing, red/itchy eyes, sneezing/runny nose and difficulty breathing. Treatment medications include unspecified antihistamines. Unknown if there were any other potential causes. No Concomitant medication information was reported. This case was linked to [redacted] (Patient Link).
[redacted]		This regulatory authority case was reported by a physician and describes the occurrence of URTICARIA CHRONIC (Chronic urticaria) in a 39-year-old female patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination. No Medical History information was reported. On 02-Jan-2022, the patient received dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form. On 02-Jan-2022, the patient experienced URTICARIA CHRONIC (Chronic urticaria) (seriousness criterion medically significant). At the time of the report, URTICARIA CHRONIC (Chronic urticaria) had not resolved. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered URTICARIA CHRONIC (Chronic urticaria) to be possibly related. No concomitant medications were provided. The patient received COVID-19 Vaccine Moderna (Spikevax) 3rd vaccination (COVID-19 vaccine), unknown dosage. No treatment information was provided. Company comment: This regulatory authority case concerns a 39-year-old female patient, with no medical history reported, who experienced the unexpected event of chronic urticaria which was considered as medically significant. The event occurred on the same day after the third dose of mRNA-1273. The benefit-risk relationship of mRNA-1273 is not affected by this report. Event seriousness was assessed as per Regulatory Authority reporting.
[redacted]		This regulatory authority case was reported by a consumer and describes the occurrence of CHRONIC SPONTANEOUS URTICARIA (Chronic spontaneous urticaria) and PRURITUS (Pruritus) in a 30-year-old female patient who received mRNA-1273 (COVID-19 Vaccine Moderna) (batch nos. 3002541 and 3002918) for COVID-19 vaccination. No Medical History information was reported. On 08-Jun-2021, the patient received dose of mRNA-1273 (COVID-19 Vaccine Moderna) (unknown route) 1 dosage form.

CASE NARRATIVES FOR "POTENTIAL" CASES OF CHRONIC URTICARIA (N=64)

Case ID	WW Identifier	Narrative (Complete)
		On 09-Jul-2021, received dose of mRNA-1273 (COVID-19 Vaccine Moderna) (unknown route) dosage was changed to 1 dosage form. In September 2021, the patient experienced CHRONIC SPONTANEOUS URTICARIA (Chronic spontaneous urticaria) (seriousness criterion medically significant) and PRURITUS (Pruritus) (seriousness criterion medically significant). At the time of the report, CHRONIC SPONTANEOUS URTICARIA (Chronic spontaneous urticaria) and PRURITUS (Pruritus) had not resolved. No concomitant medication was reported. Severe urticaria appeared at the end of September 2021 and became chronic. Patient took antiallergic medication (Bilaxten 20mg 2x/d in the evening) the symptoms were relatively under control, but reappeared extremely strongly when the medication was stopped. Company comment: This is a regulatory case concerning a 30 year-old, female patient with no reported medical history, who experienced the serious (due to medically important condition) unexpected, events of Chronic spontaneous urticaria and pruritus, approximately 2 months after the mRNA-1273 vaccine, dose number not provided (probably second dose case). The outcome of both events was reported as not recovered. Patient received treatment with Bilastine which controlled the symptoms, but they reappeared when the medication was stopped. No further clinical information was available for medical review. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Event's seriousness assessed as reported. This case was linked to [redacted] (E2B Linked Report).
[redacted]		This case was received via European Medicines Agency (Reference number: [redacted] on 28-Mar-2022 and was forwarded to Moderna on 28-Mar-2022. This regulatory authority case was reported by a physician and describes the occurrence of MECHANICAL URTICARIA (Chronic urticaria inducible from physical causes in atopic, sensitized to grasses. Showy stinging dermographism 10 days after vaccination.) and URTICARIA CHRONIC (Chronic urticaria inducible from physical causes in atopic, sensitized to grasses. Showy stinging dermographism 10 days after vaccination.) in a 33-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3005884) for COVID-19 vaccination. Previous vaccination includes 1st dose Spikevax 13-JUN-2021 at 3.50 pm left shoulder Lot: 3002622A expired 05-DEC-2021 and 2nd dose Spikevax 18-JUL-2021 at 12.49 pm left shoulder Lot: 3003655 expires 31-DEC-2021. On 09-Jan-2022, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 19-Jan-2022, the patient experienced MECHANICAL URTICARIA (Chronic urticaria inducible from physical causes in atopic, sensitized to grasses. Showy stinging dermographism 10 days after vaccination.) and URTICARIA CHRONIC (Chronic urticaria inducible from physical causes in atopic, sensitized to grasses. Showy stinging dermographism 10 days after vaccination.). At the time of the report, MECHANICAL URTICARIA (Chronic urticaria inducible from physical causes in atopic, sensitized to grasses. Showy stinging dermographism 10 days after vaccination.) and URTICARIA CHRONIC (Chronic urticaria inducible from physical causes in atopic, sensitized to grasses. Showy stinging dermographism 10 days after vaccination.) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Blood immunoglobulin E: inconclusive (Inconclusive) Inconclusive. On an unknown date, Radioallergosorbent test negative: inconclusive (Inconclusive) Inconclusive. The action taken with mRNA-1273 (Spikevax) (Intramuscular) was unknown. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medication details was reported. No treatment medication details was reported It was reported that Symptoms have onset about 10 days after the 3rd dose covid, the time correlation is modest, I report in any case to the pharmacy. In the event of a risk, there is sufficient antihistamine therapy within 10 days following vaccination.
[redacted]		This case was received via European Medicines Agency (Reference number: [redacted] on 04-Apr-2022 and was forwarded to Moderna on 04-Apr-2022. This regulatory authority case was reported by a physician and describes the occurrence of URTICARIA CHRONIC (Urticaria chronica) in a 31-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. No Medical history was reported.

CASE NARRATIVES FOR "POTENTIAL" CASES OF CHRONIC URTICARIA (N=64)

Case ID	WW Identifier	Narrative (Complete)
		. Concomitant products included MIRABEGRON (BETMIGA) for Attention deficit/hyperactivity disorder, ETHINYLESTRADIOL, LEVONORGESTREL (MICROGYN) for Contraception, METHYLPHENIDATE HYDROCHLORIDE (CONCERTA) for an unknown indication. In December 2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 16-Jan-2022, the patient experienced URTICARIA CHRONIC (Urticaria chronica). At the time of the report, URTICARIA CHRONIC (Urticaria chronica) had not resolved. The action taken with mRNA-1273 (Spikevax) (Intramuscular) was unknown. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No treatment information provided.
[redacted]		This case was received via European Medicines Agency (Reference number: [redacted] on 04-Apr-2022 and was forwarded to Moderna on 04-Apr-2022. This regulatory authority case was reported by a physician and describes the occurrence of URTICARIA CHRONIC (Chronic urticaria) in a 52-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 000004A) for COVID-19 vaccination. No Medical History information was reported. On 16-Jan-2022, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) .25 milliliter. On 26-Jan-2022, after starting mRNA-1273 (Spikevax), the patient experienced URTICARIA CHRONIC (Chronic urticaria). At the time of the report, URTICARIA CHRONIC (Chronic urticaria) had not resolved. The action taken with mRNA-1273 (Spikevax) (Intramuscular) was unknown. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No concomitant drug details were reported. No treatment details were reported.
[redacted]		This case was received via European Medicines Agency (Reference number: [redacted] on 06-Apr-2022 and was forwarded to Moderna on 06-Apr-2022. This regulatory authority case was reported by a consumer and describes the occurrence of URTICARIA CHRONIC (Chronic urticaria. Experienced heavy urticaria since 5 days after booster vaccinatyion against COVID19 and har by a dermatologist gotten notified with chronic urticaria. Has never had urticaria before) in a 51-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The patient had no other reported health issues. On 06-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 11-Dec-2021, after starting mRNA-1273 (Spikevax), the patient experienced URTICARIA CHRONIC (Chronic urticaria. Experienced heavy urticaria since 5 days after booster vaccinatyion against COVID19 and har by a dermatologist gotten notified with chronic urticaria. Has never had urticaria before). At the time of the report, URTICARIA CHRONIC (Chronic urticaria. Experienced heavy urticaria since 5 days after booster vaccinatyion against COVID19 and har by a dermatologist gotten notified with chronic urticaria. Has never had urticaria before) had not resolved. No relevant concomitant medications were reported. Additional information on drug included Previously given: Yes 2 times. Treatment information was unknown.
[redacted]		This case was received via European Medicines Agency (Reference number: [redacted] on 06-Apr-2022 and was forwarded to Moderna on 06-Apr-2022. This regulatory authority case was reported by a consumer and describes the occurrence of URTICARIA CHRONIC (Chronic urticaria.) and SERUM SICKNESS-LIKE REACTION (Serum-Sickness-Like-Reaction) in a 42-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 3005836 and 3002920) for COVID-19 vaccination.

CASE NARRATIVES FOR "POTENTIAL" CASES OF CHRONIC URTICARIA (N=64)

Case ID	WW Identifier	Narrative (Complete)
		No Medical History information was reported. On 09-Jun-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 09-Dec-2021, received third dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. On 15-Jul-2021, the patient experienced URTICARIA CHRONIC (Chronic urticaria.). On 17-Dec-2021, the patient experienced SERUM SICKNESS-LIKE REACTION (Serum-Sickness-Like-Reaction). At the time of the report, URTICARIA CHRONIC (Chronic urticaria.) had not resolved and SERUM SICKNESS-LIKE REACTION (Serum-Sickness-Like-Reaction) had resolved. No concomitant medications was reported. Side effect treatment 1: daily 20 mg Desloratadin treatment side effect 2: 5 g Desloratadin.
[redacted]		This case was received via European Medicines Agency (Reference number [redacted] on 06-Apr-2022 and was forwarded to Moderna on 06-Apr-2022. This regulatory authority case was reported by a physician and describes the occurrence of URTICARIA CHRONIC (Urticaria chronic) in a 64-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. No Medical History information was reported. On 18-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 15-Jan-2022, after starting mRNA-1273 (Spikevax), the patient experienced URTICARIA CHRONIC (Urticaria chronic). At the time of the report, URTICARIA CHRONIC (Urticaria chronic) had not resolved. The action taken with mRNA-1273 (Spikevax) (Unknown) was unknown. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. No concomitant medication was reported. No treatment information was reported.
[redacted]		This case was received via European Medicines Agency (Reference number: [redacted] on 07-Apr-2022 and was forwarded to Moderna on 07-Apr-2022. This regulatory authority case was reported by a physician and describes the occurrence of URTICARIA CHRONIC (Urticaria 1 week after 3rd moderna vaccine) in a 19-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. No Medical History information was reported. On 14-Jan-2022, the patient received third dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 21-Jan-2022, after starting mRNA-1273 (Spikevax), the patient experienced URTICARIA CHRONIC (Urticaria 1 week after 3rd moderna vaccine). At the time of the report, URTICARIA CHRONIC (Urticaria 1 week after 3rd moderna vaccine) had not resolved. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Concomitant medications details were not reported by the reporter. Treatment details was not reported by the reporter.
[redacted]		This case was received via European Medicines Agency (Reference number: [redacted] on 08-Apr-2022 and was forwarded to Moderna on 08-Apr-2022. This regulatory authority case was reported by a physician and describes the occurrence of URTICARIA CHRONIC (Urticaria chronic) in a 34-year-old patient of an unknown gender who received mRNA-1273 (Spikevax) for COVID-19 vaccination. No Medical History information was reported. On 27-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 05-Jan-2022, after starting mRNA-1273 (Spikevax), the patient experienced URTICARIA CHRONIC (Urticaria chronic). At the time of the report, URTICARIA CHRONIC (Urticaria chronic) had not resolved.

CASE NARRATIVES FOR "POTENTIAL" CASES OF CHRONIC URTICARIA (N=64)

Case ID	WW Identifier	Narrative (Complete)
		For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medication was reported. No treatment medication was reported. Additional information on drug previously given: yes 2 times.
[redacted]		This case was initially received via European Medicines Agency (Reference number: [redacted] on 08-Apr-2022. The most recent information was received on 05-May-2022 and was forwarded to Moderna on 05-May-2022. This regulatory authority case was reported by a consumer and describes the occurrence of MECHANICAL URTICARIA (Chronic Spontaneous Urticaria - Dermatographia) and URTICARIA CHRONIC (Chronic Spontaneous Urticaria - Dermatographia) in a 29-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 3005242) for COVID-19 vaccination. The patient had no other reported health issues. Concomitant products included HEPATITIS A VACCINE INACT (VAQTA) from 29-Oct-2020 to an unknown date for Hepatitis A immunisation. On 08-Jan-2022, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 20-Jan-2022, the patient experienced MECHANICAL URTICARIA (Chronic Spontaneous Urticaria - Dermatographia) and URTICARIA CHRONIC (Chronic Spontaneous Urticaria - Dermatographia). At the time of the report, MECHANICAL URTICARIA (Chronic Spontaneous Urticaria - Dermatographia) and URTICARIA CHRONIC (Chronic Spontaneous Urticaria - Dermatographia) had not resolved. No treatment information were provided. Senders comment stated that COMMENT FROM [redacted] (Version 002): Reaction text deleted, no other new information added. Most recent FOLLOW-UP information incorporated above includes: On 14-Apr-2022: Follow up received contains non significant information, senders comments updated. On 05-May-2022: Significant follow up appended contains::Specified Substance term ID updated for concomitant medication and events arranged as per recent source document.
[redacted]		This case was received via European Medicines Agency (Reference number: [redacted] on 08-Apr-2022 and was forwarded to Moderna on 08-Apr-2022. This regulatory authority case was reported by a physician and describes the occurrence of URTICARIA CHRONIC (Urticaria chronic) in a 24-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. No Medical History information was reported. On 14-Jan-2022, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 23-Jan-2022, after starting mRNA-1273 (Spikevax), the patient experienced URTICARIA CHRONIC (Urticaria chronic). At the time of the report, URTICARIA CHRONIC (Urticaria chronic) had not resolved. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. No concomitant information was provided. Additional information on sipkevax was reported as Previously given: Yes 2 times . No treatment information was provided.
[redacted]		This spontaneous case was reported by a consumer and describes the occurrence of URTICARIA CHRONIC (chronic hives) and MECHANICAL URTICARIA (dermatographia) in a 31-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 012H21B, 013L20A and 025J20A) for COVID-19 vaccination. Previously administered products included for Product used for unknown indication: Flu shot (Patient reported that it was more than 1 month prior to the Moderna COVID-19 vaccine). Past adverse reactions to the above products included No adverse event with Flu shot. Concomitant products included MULTIVITAMINS [VITAMINS NOS] for an unknown indication.

CASE NARRATIVES FOR "POTENTIAL" CASES OF CHRONIC URTICARIA (N=64)

Case ID	WW Identifier	Narrative (Complete)
		On 05-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) .5 milliliter. On 17-Mar-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to .5 milliliter. On 26-Nov-2021, received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to .25 milliliter. On 15-Dec-2021, the patient experienced URTICARIA CHRONIC (chronic hives) and MECHANICAL URTICARIA (dermatographia). The patient was treated with PREDNISONE at an unspecified dose and frequency; CETIRIZINE HYDROCHLORIDE (ZYRTEC ALLERGY) at an unspecified dose and frequency; ALUMINIUM HYDROXIDE GEL, DRIED, MAGNESIUM CARBONATE (PEPCID F) at an unspecified dose and frequency; DIPHENHYDRAMINE HYDROCHLORIDE (BENADRYL [DIPHENHYDRAMINE HYDROCHLORIDE]) at an unspecified dose and frequency and FEXOFENADINE HYDROCHLORIDE (ALLEGRA [FEXOFENADINE HYDROCHLORIDE]) for Chronic urticaria, at a dose of since the start of chronic hives. At the time of the report, URTICARIA CHRONIC (chronic hives) and MECHANICAL URTICARIA (dermatographia) had not resolved. No medical history was reported. Patient reported birth control as concomitant medication. Patient stated that the adverse reaction had stayed the same. However, it was probably due to the medications she was taking to treat her symptoms. Patient stated that she was getting better at managing her condition. Patient felt that if not treated herself properly, condition would worsen. Patient had been seeing a Dermatologist monthly since FEB 2022, and her primary care physician twice (JAN 2022 and FEB 2022) for her condition. Patient reported acupuncture as a treatment. This case was linked to [redacted] (Patient Link).
[redacted]		This case was received via European Medicines Agency (Reference number: [redacted] on 14-Apr-2022 and was forwarded to Moderna on 14-Apr-2022. This regulatory authority case was reported by a physician and describes the occurrence of URTICARIA CHRONIC (Urticaria chronic) and URTICARIA (Urticaria) in a 41-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 000080A) for COVID-19 vaccination. Previously administered products included for Product used for unknown indication: Moderna Vaccine (Dose 1,Right Arm, Intramuscular Injection, Lot No 3002616) on 08-Jun-2021, Moderna Vaccine (Dose 2, Right Arm, Intramuscular Injection and Lot No 214009) on 20-Jul-2021. Past adverse reactions to the above products included No adverse event with Moderna Vaccine and Moderna Vaccine. On 06-Jan-2022, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 06-Jan-2022, after starting mRNA-1273 (Spikevax), the patient experienced URTICARIA (Urticaria). On 12-Jan-2022, the patient experienced URTICARIA CHRONIC (Urticaria chronic). At the time of the report, URTICARIA CHRONIC (Urticaria chronic) and URTICARIA (Urticaria) had not resolved. The action taken with mRNA-1273 (Spikevax) (Intramuscular) was unknown. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Suspect product dosage text was R1. No concomitant medication reported. No treatment information was provided.
[redacted]		This case was received via European Medicines Agency (Reference number: [redacted] on 14-Apr-2022 and was forwarded to Moderna on 14-Apr-2022. This regulatory authority case was reported by a consumer and describes the occurrence of URTICARIA CHRONIC (CHRONIC URTICARIA WITH INTENSE PRURITUS AND BLISTERS) in a 51-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. No Medical History information was reported.

CASE NARRATIVES FOR "POTENTIAL" CASES OF CHRONIC URTICARIA (N=64)

Case ID	WW Identifier	Narrative (Complete)
		On 25-May-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 15-Jun-2021, the patient experienced URTICARIA CHRONIC (CHRONIC URTICARIA WITH INTENSE PRURITUS AND BLISTERS) (seriousness criteria disability and medically significant). At the time of the report, URTICARIA CHRONIC (CHRONIC URTICARIA WITH INTENSE PRURITUS AND BLISTERS) had not resolved. No concomitant medications reported. No treatment reported. Company comment: This regulatory authority case concerns a 51-year-old female patient, with no medical history reported, who experienced the serious (disability and medically significant) unexpected event of Urticaria Chronic, which occurred approximately 21 days after the second dose of mRNA-1273. Event outcome was not resolved. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.
[redacted]		This case was received via European Medicines Agency (Reference number: [redacted] on 22-Apr-2022 and was forwarded to Moderna on 22-Apr-2022. This regulatory authority case was reported by a consumer and describes the occurrence of RESTLESSNESS (IT INHIBITS ME FROM FOCUSING & I CANT BE STILL), DISTURBANCE IN ATTENTION (IT INHIBITS ME FROM FOCUSING & I CANT BE STILL), EMOTIONAL DISTRESS (CRONIC URTICARIA, UNCONTROLABLE, VERY DEPRESSING / I'M FINDING IT HARD TO LIVE WITH CONDITION / SO SAD & ANGRY TO HAVE CONTRACTED THIS CONDITION FROM THE VACCINE), URTICARIA CHRONIC (CRONIC URTICARIA, UNCONTROLABLE, VERY DEPRESSING / SEVERE CHRONIC URTICARIA) and IMPAIRED QUALITY OF LIFE (I'M FINDING IT HARD TO LIVE WITH CONDITION) in a 43-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 044G21A) for COVID-19 vaccination. No Medical History information was reported. On 02-Jan-2022, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 05-Jan-2022, the patient experienced RESTLESSNESS (IT INHIBITS ME FROM FOCUSING & I CANT BE STILL) (seriousness criterion medically significant), DISTURBANCE IN ATTENTION (IT INHIBITS ME FROM FOCUSING & I CANT BE STILL) (seriousness criterion medically significant), EMOTIONAL DISTRESS (CRONIC URTICARIA, UNCONTROLABLE, VERY DEPRESSING / I'M FINDING IT HARD TO LIVE WITH CONDITION / SO SAD & ANGRY TO HAVE CONTRACTED THIS CONDITION FROM THE VACCINE) (seriousness criterion medically significant), URTICARIA CHRONIC (CRONIC URTICARIA, UNCONTROLABLE, VERY DEPRESSING / SEVERE CHRONIC URTICARIA) (seriousness criterion medically significant) and IMPAIRED QUALITY OF LIFE (I'M FINDING IT HARD TO LIVE WITH CONDITION) (seriousness criterion medically significant). At the time of the report, RESTLESSNESS (IT INHIBITS ME FROM FOCUSING & I CANT BE STILL), DISTURBANCE IN ATTENTION (IT INHIBITS ME FROM FOCUSING & I CANT BE STILL), EMOTIONAL DISTRESS (CRONIC URTICARIA, UNCONTROLABLE, VERY DEPRESSING / I'M FINDING IT HARD TO LIVE WITH CONDITION / SO SAD & ANGRY TO HAVE CONTRACTED THIS CONDITION FROM THE VACCINE), URTICARIA CHRONIC (CRONIC URTICARIA, UNCONTROLABLE, VERY DEPRESSING / SEVERE CHRONIC URTICARIA) and IMPAIRED QUALITY OF LIFE (I'M FINDING IT HARD TO LIVE WITH CONDITION) had not resolved. No concomitant medications were provided by the reporter. No treatment information was provided by the reporter. Company comment: This regulatory case concerns a 43-year-old male patient, with no reported medical history, who experienced, unexpected, serious (Medically Significant) events of Restlessness, Emotional Distress, Urticaria chronic and Disturbances in attention, 3 days after receiving mRNA-1273 vaccine as a third dose. Impaired Quality of Life is also reported in this case as an additional event. Clinical course and treatment details are not available at this report. The events had not resolved. The benefit-risk relationship of mRNA-1273 is not affected by this report. Event's seriousness was assessed as per Regulatory Authority's report Most recent FOLLOW-UP information incorporated above includes: On 12-May-2022: Follow-up received contains no new information
[redacted]		This case was received via European Medicines Agency (Reference number: [redacted] on 22-Apr-2022 and was forwarded to Moderna on 22-Apr-2022. This regulatory authority case was reported by a physician and describes the occurrence of CHRONIC SPONTANEOUS URTICARIA (Spontaneous chronic urticaria suspected autoimmune pathogenesis) in a 41-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 000033ba) for COVID-19 vaccination.

CASE NARRATIVES FOR "POTENTIAL" CASES OF CHRONIC URTICARIA (N=64)

Case ID	WW Identifier	Narrative (Complete)
		The patient's past medical history included Autoimmune thyroiditis. Previously administered products included for Product used for unknown indication: Moderna vaccine (I dose Moderna vaccine on 8/5/2021 lot 3001943 exp 29/10/2021.) on 08-May-2021 and Moderna vaccine (II dose Moderna vaccine on 7/6/2021 lot 3002917 exp 5/12/2021.) on 29-Oct-2021. Past adverse reactions to the above products included No adverse event with Moderna vaccine and Moderna vaccine. On 28-Jan-2022, the patient received third dose of mRNA-1273 (Spikevax) (Intramuscular) .25 milliliter. On 10-Feb-2022, after starting mRNA-1273 (Spikevax), the patient experienced CHRONIC SPONTANEOUS URTICARIA (Spontaneous chronic urticaria suspected autoimmune pathogenesis). At the time of the report, CHRONIC SPONTANEOUS URTICARIA (Spontaneous chronic urticaria suspected autoimmune pathogenesis) had not resolved. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Chronic spontaneous urticaria (still ongoing) after about 15 days after the Covid19 vaccine booster (Moderna) in a predisposed subject (autoimmune thyroiditis) but unprecedented urticaria. No concomitant medication was reported. No treatment medications was reported.
[redacted]		This case was received via European Medicines Agency (Reference number: [redacted] on 25-Apr-2022 and was forwarded to Moderna on 25-Apr-2022. This regulatory authority case was reported by a consumer and describes the occurrence of MECHANICAL URTICARIA (still present chronic dermographic urticaria started 3 weeks after the Moderna mRNA vaccine booster dose) and URTICARIA CHRONIC (still present chronic dermographic urticaria started 3 weeks after the Moderna mRNA vaccine booster dose) in a 25-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The patient's past medical history included Skin reaction (Patient had episodes of skin reactivity (to creams or sweat) never more than a week). Concurrent medical conditions included Polycystic ovarian syndrome. On 18-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 05-Jan-2022, the patient experienced MECHANICAL URTICARIA (still present chronic dermographic urticaria started 3 weeks after the Moderna mRNA vaccine booster dose) and URTICARIA CHRONIC (still present chronic dermographic urticaria started 3 weeks after the Moderna mRNA vaccine booster dose). At the time of the report, MECHANICAL URTICARIA (still present chronic dermographic urticaria started 3 weeks after the Moderna mRNA vaccine booster dose) and URTICARIA CHRONIC (still present chronic dermographic urticaria started 3 weeks after the Moderna mRNA vaccine booster dose) had not resolved. The action taken with mRNA-1273 (Spikevax) (Intramuscular) was unknown. Concomitant medication included kirocomplex 1.15g tablets 1 every 3 days for PCOS Treatment information was not provided. Patient states that she had no allergies.
[redacted]		This case was received via European Medicines Agency (Reference number: [redacted] on 26-Apr-2022 and was forwarded to Moderna on 26-Apr-2022. This regulatory authority case was reported by a consumer and describes the occurrence of HEADACHE (Headache) and URTICARIA CHRONIC (Chronic urticaria) in a 19-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 3102184) for COVID-19 vaccination. The patient's past medical history included Hashimoto's thyroiditis. Concomitant products included ETHINYLESTRADIOL, LEVONORGESTREL [redacted] for Contraception, LEVOTHYROXINE SODIUM [redacted] for Hypothyroidism. On 12-May-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 14-May-2021, after starting mRNA-1273 (Spikevax), the patient experienced URTICARIA CHRONIC (Chronic urticaria).

CASE NARRATIVES FOR "POTENTIAL" CASES OF CHRONIC URTICARIA (N=64)

Case ID	WW Identifier	Narrative (Complete)
		On an unknown date, the patient experienced HEADACHE (Headache). At the time of the report, HEADACHE (Headache) had resolved and URTICARIA CHRONIC (Chronic urticaria) had not resolved. Treatment details was not reported by the reporter.
[redacted]		This case was received via European Medicines Agency (Reference number: [redacted] on 28-Apr-2022 and was forwarded to Moderna on 28-Apr-2022. This regulatory authority case was reported by a physician and describes the occurrence of URTICARIA CHRONIC (Chronic urticaria) in a 47-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3005242) for COVID-19 vaccination. No Medical History information was reported. On 19-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) .25 milliliter. On 26-Dec-2021, after starting mRNA-1273 (Spikevax), the patient experienced URTICARIA CHRONIC (Chronic urticaria). At the time of the report, URTICARIA CHRONIC (Chronic urticaria) had not resolved. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medication reported. No treatment information was provided.
[redacted]		This case was received via European Medicines Agency (Reference number: [redacted] on 28-Apr-2022 and was forwarded to Moderna on 28-Apr-2022. This regulatory authority case was reported by a consumer and describes the occurrence of URTICARIA CHRONIC (Urticaria chronic) in a 35-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. No Medical History information was reported. On 10-Jan-2022, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 17-Jan-2022, after starting mRNA-1273 (Spikevax), the patient experienced URTICARIA CHRONIC (Urticaria chronic). At the time of the report, URTICARIA CHRONIC (Urticaria chronic) had not resolved. No concomitant medication was reported. No treatment medication was reported. The patient had no other reported health issues. Additional information on drug previously given: Yes 2 times.
[redacted]		This case was received via European Medicines Agency (Reference number: [redacted]) on 29-Apr-2022 and was forwarded to Moderna on 29-Apr-2022. This regulatory authority case was reported by a consumer and describes the occurrence of URTICARIA CHRONIC (chronic Urticaria factitia) in a 32-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 000110A) for COVID-19 vaccination. No Medical History information was reported. On 17-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 24-Dec-2021, the patient experienced URTICARIA CHRONIC (chronic Urticaria factitia). The patient was treated with CETIRIZINE at an unspecified dose and frequency. On 15-Feb-2022, URTICARIA CHRONIC (chronic Urticaria factitia) had resolved with sequelae. No concomitant medication reported. No risk factors and previous illnesses reported. It was reported that itching/skin rash first appeared around 23-Dec-21 or 24-Dec-21 which were still slight. Then firstly severe episode on 28-Dec-21, generalized all over the body. Despite repeated visits to the doctor, the family doctor and dermatologist treated with purely symptomatic with antihistamines (cetirizine). Further reported that symptoms resisting to date. No treatment medication details reported.

CASE NARRATIVES FOR "POTENTIAL" CASES OF CHRONIC URTICARIA (N=64)

Case ID	WW Identifier	Narrative (Complete)
[redacted]		This regulatory authority case was reported by a physician and describes the occurrence of SKIN REACTION (Delayed skin reaction), URTICARIA CHRONIC (Chronic urticaria) and URTICARIA (Urticaria aggravated) in a 37-year-old patient of an unknown gender who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination. Concomitant products included ELASOMERAN (COVID-19 VACCINE MODERNA) for COVID-19 vaccination. In June 2021, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form once a day. In January 2022, received third dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) dosage was changed to 1 dosage form. In June 2021, the patient experienced SKIN REACTION (Delayed skin reaction) and URTICARIA CHRONIC (Chronic urticaria). In January 2022, the patient experienced URTICARIA (Urticaria aggravated). In January 2022, URTICARIA (Urticaria aggravated) had resolved. At the time of the report, SKIN REACTION (Delayed skin reaction) and URTICARIA CHRONIC (Chronic urticaria) had not resolved. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered SKIN REACTION (Delayed skin reaction), URTICARIA CHRONIC (Chronic urticaria) and URTICARIA (Urticaria aggravated) to be possibly related. On Jan-2022, the patient received the booster dose. Urticaria arose one week after the first dose of Spikevax vaccine (late), then chronicized and exacerbated 6 days after the booster dose. Following the second dose of Spikevax, there was no worsening of skin symptomatology was observed. 6 days after Spikevax booster dose, the patient experienced exacerbation of chronic urticaria, with resolution of symptomatology on 26-Jan-2022 with corticotherapy to scale on 12 days. It was reported that continuation of the SC currently, there was an increase in urticaria notifications reported after booster vaccination (booster), particularly with Spikevax, which occur in different parts of the body after a latency period ranging from a few days to 1 to 2 weeks after vaccination, sometimes relapsing. PubMed contained several publications concerning urticaria following anti-Covid-19 vaccination with mRNA vaccines, both new and re-exacerbation in patients already known for chronic urticaria, including type late [1-8]. In particular, Thomas J's article et al (2019) [2] describes the clinical case of a patient who developed a delayed chronic urticaria, approximately one week after administration of the 2nd dose of Comirnaty (Pfizer/Biontech), in the absence of any other systemic symptomatology. The publication of Pitlick MM et al (2022) [5] concerns a limited group of patients (N=12) who experienced delayed skin reactions following COVID-19 vaccination with mRNA vaccines (7) subjects with Comirnaty and 5 with Spikevax) of whom 11 patients experienced the adverse event after administration of the first dose. The adverse reactions reported were limited to skin, in the absence of systemic manifestations. The hypothesized etiopathogenesis involves T cells, stimulated by a previous infection with SARS-CoV-2 or certain components/excipients of the vaccine.
[redacted]		This regulatory authority case was reported by a consumer and describes the occurrence of URTICARIA CHRONIC (Chronic urticaria) and MECHANICAL URTICARIA (Dermographism) in a 35-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination. No Medical History information was reported. On 04-Jan-2022, the patient received dose of mRNA-1273 (COVID-19 Vaccine Moderna) (unknown route) 1 dosage form. On 13-Jan-2022, the patient experienced URTICARIA CHRONIC (Chronic urticaria) and MECHANICAL URTICARIA (Dermographism). At the time of the report, URTICARIA CHRONIC (Chronic urticaria) and MECHANICAL URTICARIA (Dermographism) had not resolved. The action taken with mRNA-1273 (COVID-19 Vaccine Moderna) (Unknown) was unknown. Concomitant medications details were not reported by the reporter. The case was non-serious and unlabelled. Due to temporal relationship and the known safety profile of the drug the causality was assessed as possible. Treatment details were not reported by the reporter.
[redacted]		This regulatory authority case was reported by a physician and describes the occurrence of URTICARIA CHRONIC (urticaria) in a 52-year-old female patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination.

CASE NARRATIVES FOR "POTENTIAL" CASES OF CHRONIC URTICARIA (N=64)

Case ID	WW Identifier	Narrative (Complete)
		The patient's past medical history included Non-smoker, COVID-19 PCR test (Mild progression.) on 18-Oct-2020 and Abstains from alcohol. Concomitant products included ELASOMERAN (COVID-19 VACCINE MODERNA) from 05-May-2021 to 02-Jun-2021 for COVID-19 vaccination. On 10-Dec-2021, the patient received third dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 50 microgram. On 20-Dec-2021, the patient experienced URTICARIA CHRONIC (urticaria) (seriousness criterion medically significant). At the time of the report, URTICARIA CHRONIC (urticaria) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Laboratory test: test : routinelabor 4.1.2022 [redacted] TEST : Routinelabor 4.1.2022 [redacted] The action taken with mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) was unknown. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered URTICARIA CHRONIC (urticaria) to be possibly related. Company comment This regulatory authority case concerns a 52-year-old female patient, with no reported medical history, who experienced the unexpected serious (medically significant) event of URTICARIA CHRONIC, which occurred approximately 10 days after receiving the third dose of mRNA-1273 vaccine. The patient went to emergency due to the exanthema all over the body. Routine laboratory 15 days later was unobtrusive. There was no further allergological clarification. One month later, the treating dermatologist diagnosed chronic recurrent urticaria. Therapy with antihistamines was initiated and a monthly therapy with Xolair (omalizumab), which came in extensive relief of urticaria. At the time of reporting, the patient had not yet fully recovered. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Text for Relevant Medical History and Concurrent Conditions included no kidney ailment, no liver sufferer. On 05/May/2021, the first and second dose of Spikevax was given and 02/Jun/2021. Ten days after the third vaccination, the patient developed urticaria from 20/Dec/2021. On 21/Dec/2021, the patient introduced herself as an emergency due to the exanthema all over the body. The routine laboratory from 04/Jan/2022 was unobtrusive. There was no further allergological clarification. The patient had no previous history of allergies. In February 2022, the treating dermatologist diagnosed chronic recurrent urticaria. Therapy with antihistamines was initiated and a monthly therapy with Xolair (omalizumab) started on 14/Feb/2022, which came in extensive relief of urticaria. At the time of reporting, the patient had not yet fully recovered. The patient was non-smoking and did not consume alcohol. Liver or kidney disease does not exist. Additional information on drug included ROUTE:030. Sender's comments included that According to Spikevax's [redacted] drug information (elasomeran), urticaria and injection site rash can often occur (1-10%). Urticaria all over [redacted] especially after a latency period of several days, was not explicitly listed as a UAW. In the Pharmacovigilance WHO database, 19,371 cases of "PT: Urticaria" have been listed from a total of 712,156 individual case safety reports on "Elasomeran" since 2020. There was a temporal relationship between the use of Spikevax (Elasomeran) and the occurrence of urticaria. The improvement of the symptoms during the course can be evaluated in the sense of a positive decallenge. In summary, we assess the causality between the use of Spikevax (Elasomeran) and the causality between the use of Spikevax (Elasomeran) and the Occurrence of urticaria formally as possible according to WHO/CIOMS criteria.
[redacted]		This regulatory authority case was reported by a physician and describes the occurrence of URTICARIA CHRONIC (chronic urticaria symptoms: wheals all overthe body) in a 21-year-old female patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination. No Medical History information was reported. On 17-Dec-2021, the patient received third dose of mRNA-1273 (COVID-19 Vaccine Moderna) (unknown route) 1 dosage form. On 27-Dec-2021, the patient experienced URTICARIA CHRONIC (chronic urticaria symptoms: wheals all overthe body). At the time of the report, URTICARIA CHRONIC (chronic urticaria symptoms: wheals all overthe body) had not resolved. For mRNA-1273 (COVID-19 Vaccine Moderna) (Unknown), the reporter considered URTICARIA CHRONIC (chronic urticaria symptoms: wheals all overthe body) to be possibly related.

CASE NARRATIVES FOR "POTENTIAL" CASES OF CHRONIC URTICARIA (N=64)

Case ID	WW Identifier	Narrative (Complete)
		No concomitant medication was reported by reporter. Suspect dosage text was reported as Dose 3c. No treatment medication was reported by reporter.
[redacted]		This regulatory authority case was reported by a physician and describes the occurrence of SKIN REACTION (Delayed skin reaction), URTICARIA CHRONIC (Chronic urticaria) and MECHANICAL URTICARIA (Dermographism) in a 36-year-old female patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination. The patient had no known allergies. The patient's past medical history included COVID-19 in February 2022. Concomitant products included ELASOMERAN (COVID-19 VACCINE MODERNA) and ELASOMERAN (COVID-19 VACCINE MODERNA) for COVID-19 vaccination. On 06-Jan-2022, the patient received third dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form once a day. On 16-Jan-2022, the patient experienced SKIN REACTION (Delayed skin reaction), URTICARIA CHRONIC (Chronic urticaria) and MECHANICAL URTICARIA (Dermographism). The patient was treated with BILASTINE (BILAXTEN) at a dose of 20 milligram once a day. At the time of the report, SKIN REACTION (Delayed skin reaction), URTICARIA CHRONIC (Chronic urticaria) and MECHANICAL URTICARIA (Dermographism) was resolving. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered SKIN REACTION (Delayed skin reaction), URTICARIA CHRONIC (Chronic urticaria) and MECHANICAL URTICARIA (Dermographism) to be possibly related. Patient had Post vaccine urticaria Patient reported BAT positive for Moderna and Pfizer.
[redacted]		This regulatory authority case was reported by a physician and describes the occurrence of URTICARIA CHRONIC (Chronic urticaria), SKIN REACTION (Delayed skin reaction) and MECHANICAL URTICARIA (Dermographism) in a 49-year-old female patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination. No Medical History information was reported. On 22-Jan-2022, the patient received third dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form once a day. On 01-Feb-2022, the patient experienced URTICARIA CHRONIC (Chronic urticaria), SKIN REACTION (Delayed skin reaction) and MECHANICAL URTICARIA (Dermographism). At the time of the report, URTICARIA CHRONIC (Chronic urticaria), SKIN REACTION (Delayed skin reaction) and MECHANICAL URTICARIA (Dermographism) was resolving. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered URTICARIA CHRONIC (Chronic urticaria), SKIN REACTION (Delayed skin reaction) and MECHANICAL URTICARIA (Dermographism) to be possibly related. No concomitant medication was provided Treatment medication was not provided by the reporter It was reported that Partial benefit from ongoing anti-histamine therapy. Further course not known
[redacted]		This regulatory authority case was reported by a physician and describes the occurrence of URTICARIA CHRONIC (Urticaria chronic), SKIN REACTION (Delayed skin reaction) and MECHANICAL URTICARIA (Dermographism) in a 39-year-old female patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination. No Medical History information was reported. On 28-Jan-2022, the patient received third dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form once a day. On 09-Feb-2022, the patient experienced URTICARIA CHRONIC (Urticaria chronic), SKIN REACTION (Delayed skin reaction) and MECHANICAL URTICARIA (Dermographism). At the time of the report, URTICARIA CHRONIC (Urticaria chronic), SKIN REACTION (Delayed skin reaction) and MECHANICAL URTICARIA (Dermographism) was resolving.

CASE NARRATIVES FOR "POTENTIAL" CASES OF CHRONIC URTICARIA (N=64)

Case ID	WW Identifier	Narrative (Complete)
		For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered URTICARIA CHRONIC (Urticaria chronic), SKIN REACTION (Delayed skin reaction) and MECHANICAL URTICARIA (Dermographism) to be possibly related. No concomitant medications was reported. The case is non-serious and unlabelled. Due to temporal relationship and the known safety profile of the drug the causality is assessed as possible. No treatment drug details was reported.
[redacted]		This regulatory authority case was reported by a physician and describes the occurrence of URTICARIA CHRONIC (Chronic urticaria), SKIN REACTION (Delayed skin reaction) and ANGIOEDEMA (Angioedema) in a 39-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination. Concurrent medical conditions included Drug allergy ([redacted](cefaclor) allergy in childhood). On 12-Jan-2022, the patient received third dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) dosage was changed to 1 dosage form once a day. 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. On 23-Jan-2022, the patient experienced URTICARIA CHRONIC (Chronic urticaria), SKIN REACTION (Delayed skin reaction) and ANGIOEDEMA (Angioedema). At the time of the report, URTICARIA CHRONIC (Chronic urticaria), SKIN REACTION (Delayed skin reaction) and ANGIOEDEMA (Angioedema) was resolving. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered URTICARIA CHRONIC (Chronic urticaria), SKIN REACTION (Delayed skin reaction) and ANGIOEDEMA (Angioedema) to be possibly related. Concomitant medications were not reported. On 23-JAN-2022, Patient experienced emergence of urticaria with angioedema of the feet. Ineffective antihistamine treatment. Physician gave corticosteroids plus antihistamines with beneficial. After stopping the treatment, she relapsed. In March, patient had check-up by an allergist doctor, the symptoms were less intense, controlled with antihistamines as needed. The patient did not do the COVID. Further course not known. Company comment: This is a regulatory case concerning a 39 year-old, male patient with a history of drug hypersensitivity in childhood, who experienced the non serious unexpected, events of Angioedema, Urticaria chronic and Skin reaction (reported as delayed skin reaction), approximately 11 days after the booster dose of mRNA-1273 vaccine. The patient reported urticaria with angioedema of the feet, antihistamine treatment was ineffective. Attending physician prescribed corticosteroids plus antihistamines with improvement. After stopping the treatment, patient relapsed. Two months after vaccination, at a check-up by an allergist, the symptoms were less intense, controlled with antihistamines as needed. The outcome of all the events was reported as recovering. The mentioned medical history remains as a confounder. No further clinical information was available for medical review. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Event´s seriousness assessed as reported.
[redacted]		This regulatory authority case was reported by a physician and describes the occurrence of URTICARIA CHRONIC (Chronic urticaria), PRURITUS (Pruritus), MECHANICAL URTICARIA (Dermographism) and SKIN REACTION (Delayed skin reaction) in a 62-year-old female patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination. No Medical History information was reported. On 22-Jan-2022, the patient received dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form once a day. On 05-Feb-2022, the patient experienced URTICARIA CHRONIC (Chronic urticaria), PRURITUS (Pruritus), MECHANICAL URTICARIA (Dermographism) and SKIN REACTION (Delayed skin reaction). At the time of the report, URTICARIA CHRONIC (Chronic urticaria), PRURITUS (Pruritus), MECHANICAL URTICARIA (Dermographism) and SKIN REACTION (Delayed skin reaction) had not resolved. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered URTICARIA CHRONIC (Chronic urticaria), PRURITUS (Pruritus), MECHANICAL URTICARIA (Dermographism) and SKIN REACTION (Delayed skin reaction) to be possibly related.

CASE NARRATIVES FOR "POTENTIAL" CASES OF CHRONIC URTICARIA (N=64)

Case ID	WW Identifier	Narrative (Complete)
		No concomitant medication was provided. Habitually healthy, non-atopic patient who does not take medications regularly. Two first vaccines with Spikevax (date unknown) without major problems. Spikevax Booster on 22-Jan-2022. From 05-Feb-2022 appearance of severe itching with marked dermographism requiring the intake of antihistamines and application of Dexeril cream. At the end of March 2022 the patient had controlled skin reactions with the intake of Bilaxten as needed. Negative allergic balance, C3 and C4 normal. Normal tryptase. Further course not known.
[redacted]		This regulatory authority case was reported by a physician and describes the occurrence of URTICARIA CHRONIC (Chronic urticaria), MECHANICAL URTICARIA (Dermographism) and SKIN REACTION (Delayed skin reaction) in a 48-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination. Previously administered products included for COVID-19 vaccination: Spikevax (Vaccinated with two doses of Spikevax in summer 2021 without any problems-Dose 2) in 2021 and Spikevax (Vaccinated with two doses of Spikevax in summer 2021 without any problems-Dose 1) in 2021. Past adverse reactions to the above products included No adverse event with Spikevax and Spikevax. Concurrent medical conditions included Pollinosis. On 04-Jan-2022, the patient received third dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form once a day. On 25-Jan-2022, the patient experienced URTICARIA CHRONIC (Chronic urticaria), MECHANICAL URTICARIA (Dermographism) and SKIN REACTION (Delayed skin reaction). The patient was treated with CETIRIZINE HYDROCHLORIDE (ZYRTEC [CETIRIZINE HYDROCHLORIDE]) at a dose of UNK, prn; BILASTINE (BILAXTEN) at a dose of UNK, qd (1-0-0) and BILASTINE (BILAXTEN) at a dose of prescribed 0-0-01 for 4-5 days then try every other day. At the time of the report, URTICARIA CHRONIC (Chronic urticaria), MECHANICAL URTICARIA (Dermographism) and SKIN REACTION (Delayed skin reaction) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Allergy test: not known result not known result. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered URTICARIA CHRONIC (Chronic urticaria), MECHANICAL URTICARIA (Dermographism) and SKIN REACTION (Delayed skin reaction) to be possibly related. No concomitant medications were reported. It was reported that, the patient usually in good health with no regular therapy. Patient had a large local reaction to the arm with swollen lymph node. After about 3 weeks the appearance of a severe urticaria with marked dermographism. Initial therapy of Zyrtec as needed was prescribed, but it proved ineffective. Later, the attending physician prescribed Bilaxten 1-0-0 with which there was a good attenuation of the skin symptomatology that relapsed as soon as the patient discontinued treatment. In Mar-2022, at the allergic visit, a severe dermographism persisted despite taking an antihistamine two days first. The clinical picture was suggestive for a hives induced by the booster in an atopic subject for which they underwent an ALEX test that searches for the presence of specific immunoglobulin E (IgE) for a large number of tophus and pneumonia allergens (not known result). Later, patient was prescribed therapy with Bilaxten 0-0-01 for 4-5 days then try every other day and if symptomatology attenuation reduces the administration of the antihistamine to one day out of three in order to try to suspend it. Further course not known. Late and chronic urticaria (present for> 6 weeks) with dermographism arising in temporal correlation with the Booster dose of Spikevax vaccine. Spikevax's [redacted] monograph mentions rash (common) as one of the possible adverse drug reactions (ADRs) without further specification, as also reported in the EMA / FDA monographs. UpToDate instead specifically reports "Delayed urticarial reactions" among the adverse events reported post-marketing for mRNA vaccines. In PubMed there were several publications concerning urticaria following vaccination against COVID-19 with mRNA vaccines, both de novo and exacerbation in patients already known for urticaria, even of the late type [1-8]. In particular, Lit2 describes the clinical case of a patient who developed chronic delayed urticaria approximately one week after administration patients (N = 12) who experienced delayed skin reactions following vaccination against COVID-19 with vaccines a mRNA (7 subjects with Comirnaty and 5 with Spikevax) of which 11 patients experienced the adverse event after the first dose. The adverse reactions reported were limited to the skin, in the absence of systemic manifestations. Hives and / or angioedema that develop hours or days later are extremely unlikely to represent an allergic reaction to the vaccine. Rather, this time course corresponds to the onset of the normal immune / inflammatory response to an immunization, which might include the generation of cytokines or other factors leading

CASE NARRATIVES FOR "POTENTIAL" CASES OF CHRONIC URTICARIA (N=64)

Case ID	WW Identifier	Narrative (Complete)
		to non-IgE-mediated mast cell degranulation. The causal link between urticaria and the booster dose of Spikevax was therefore considered to be possible.
[redacted]		This case was received via European Medicines Agency (Reference number: [redacted] on 09-May-2022 and was forwarded to Moderna on 09-May-2022. This regulatory authority case was reported by a consumer and describes the occurrence of CHRONIC SPONTANEOUS URTICARIA (Chronic spontaneous urticaria throughout the body after 3rd vaccination with Moderna vaccine.) and RASH (Chronic spontaneous urticaria throughout the body after 3rd vaccination with Moderna vaccine.) in a 30-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 000087A) for COVID-19 vaccination. Concurrent medical conditions included Drug allergy (Drug Plenvu. Testing on which ingredient was for may planned as an inpatient in the skin clinic) and Celiac disease. On 18-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 31-Dec-2021, the patient experienced CHRONIC SPONTANEOUS URTICARIA (Chronic spontaneous urticaria throughout the body after 3rd vaccination with Moderna vaccine.) (seriousness criterion hospitalization) and RASH (Chronic spontaneous urticaria throughout the body after 3rd vaccination with Moderna vaccine.) (seriousness criterion hospitalization). On 23-Mar-2022, CHRONIC SPONTANEOUS URTICARIA (Chronic spontaneous urticaria throughout the body after 3rd vaccination with Moderna vaccine.) and RASH (Chronic spontaneous urticaria throughout the body after 3rd vaccination with Moderna vaccine.) had resolved with sequelae. No concomitant medication reported. It was reported that 13 days after the 3rd vaccination with the Moderna vaccine was for the first time Urticaria symptoms appeared. Since then she had to do at least 1-2 every day Taking tablets of antihistamines. she was at the family doctor, who postponed a 10-day treatment with cortisone has (without success), then to the dermatologist and allergist, who says that the Side effect most likely comes from the Corona vaccination. Around Diagnostically excluding other factors would be one in the dermatology clinic in May allergen test done. She never had urticaria or anything else before 31-Dec-2021 had skin diseases. No treatment medication details reported. CC: This is a regulatory case concerning a 30-year-old female patient, with a relevant history of drug allergy and Celiac disease, who experienced the unexpected, serious (hospitalization) events of CHRONIC SPONTANEOUS URTICARIA and RASH, which occurred 13 days after receiving the third dose of mRNA-1273 vaccine. Thirteen days after the 3rd vaccination with the Moderna vaccine, urticaria symptoms appeared for the first time. Since then patient took antihistamines at least 1-2 every day. Patient consulted with many doctors, and was told that the side effects might be due to the COVID-19 vaccine. Allergen test done was done at the dermatology clinic. Patient never had any of the events reported before. Underlying history of drug allergy and Celiac disease could be a confounder for the events. The outcome of the events was reported as resolved with sequelae. The benefit-risk relationship of mRNA-1273 is not affected by this report. Event retained as serious as per Regulatory Authority.
[redacted]		This case was received via European Medicines Agency (Reference number: [redacted] on 10-May-2022 and was forwarded to Moderna on 10-May-2022. This regulatory authority case was reported by a physician and describes the occurrence of ANGIOEDEMA (Developing angioedema on entire body) and URTICARIA CHRONIC (Developing urticaria chronic on entire body) in a 42-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 000036A) for COVID-19 vaccination. Previously administered products included for COVID-19 immunisation: SPIKEVAX on 29-Jun-2021 and SPIKEVAX on 03-Aug-2021. Past adverse reactions to the above products included No adverse event with SPIKEVAX and SPIKEVAX. On 22-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 01-Jan-2022, the patient experienced ANGIOEDEMA (Developing angioedema on entire body) (seriousness criterion medically significant) and URTICARIA CHRONIC (Developing urticaria chronic on entire body) (seriousness criterion medically significant). At the time of the report, ANGIOEDEMA (Developing angioedema on entire body) and URTICARIA CHRONIC (Developing urticaria chronic on entire body) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In 2022, Blood test: normal (normal) Normal. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.

CASE NARRATIVES FOR "POTENTIAL" CASES OF CHRONIC URTICARIA (N=64)

Case ID	WW Identifier	Narrative (Complete)
		No concomitant medication reported. No treatment medication details reported. Company Comment: This is a regulatory case concerning a 42-year-old male patient with previous COVID-19 vaccination history using 2 doses of mRNA-1273 COVID-19 vaccine with no associated adverse events, who experienced the unexpected serious events of Angioedema and Urticaria Chronic. The events were medically significant as reported by the regulatory authority and occurred 10 days after receiving the third dose of mRNA-1273 Vaccine. No clinical or treatment details were given. It was reported that the outcome of the events has not resolved. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report.
[redacted]		This regulatory authority case was reported by a consumer and describes the occurrence of URTICARIA CHRONIC (Chronic urticaria) and PRURITUS (Pruritus) in a 35-year-old female patient who received mRNA-1273 (COVID-19 Vaccine Moderna) (batch no. 3006324) for COVID-19 vaccination. Concurrent medical conditions included Pollen allergy. Concomitant products included mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination. On 09-Jan-2022, the patient received third dose of mRNA-1273 (COVID-19 Vaccine Moderna) (unknown route) 1 dosage form. On 09-Jan-2022, the patient experienced PRURITUS (Pruritus) (seriousness criterion medically significant). On 19-Jan-2022, the patient experienced URTICARIA CHRONIC (Chronic urticaria) (seriousness criterion medically significant). At the time of the report, URTICARIA CHRONIC (Chronic urticaria) and PRURITUS (Pruritus) had not resolved. No concomitant medication information was provided. No treatment medication was provided. Company comment This regulatory authority case concerns a 35-year-old female patient, with medical history of Pollen allergy, who experienced the unexpected serious (medically significant) events of URTICARIA CHRONIC and PRURITUS. Event pruritus occurred on the same day after receiving the third dose of mRNA-1273 vaccine, event urticaria chronic developed approximately 10 days after third dose. The mentioned medical history could be a contributing factor for the events. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.

Appendix 11.20c Chronic Urticaria: Literature Search Methodology

((((urticaria chronic) OR (chronic spontaneous urticaria)) OR (urticaria)) OR (hives)) AND (("2019-nCoV Vaccine mRNA-1273"[21] OR "COVID-19 Vaccines/adverse effects"[21] OR "COVID-19 Vaccines"[21] OR "SARS-CoV-2"[21] OR "COVID-19"[21] OR "COVID-19 Vaccines"[21] OR "mRNA Vaccines"[21] OR mRNA COVID vaccination [tw] OR mRNA-1273 [tw] OR "mRNA 1273" [tw] OR mRNA1273 [tw] OR "modernatx 1273" [tw] OR "Moderna Covid19 Vaccine" [tw] OR "Moderna Covid-19 Vaccine" [tw] OR Spikevax [tw] OR "2019 nCoV Vaccine mRNA 1273" [tw] OR "mRNA-1273, 2019-nCoV Vaccine" [tw] OR "Moderna COVID-19 Vaccine" [tw] OR "COVID-19 Vaccine, Moderna" [tw] OR "Moderna COVID 19 Vaccine" [tw] OR "Moderna COVID 19 Vaccine" [tw] OR "Vaccine, Moderna COVID-19" [tw] OR Elasomeran [tw] OR "Moderna COVID-19 Vaccine RNA" [tw] OR "Moderna COVID 19 Vaccine RNA" [tw] OR "COVID-19 Vaccine Moderna" [tw] OR "COVID 19 Vaccine Moderna" [tw] OR "Moderna, COVID-19 Vaccine" [tw] OR "mRNA-1273" [tw] OR "mRNA 1273" [tw] OR TAK-919 [tw] OR "TAK 919" [tw] OR TAK919 [tw] OR M-1273 [tw] OR "M 1273" [tw] OR M1273 [tw] OR mRNA-1273.211 [tw] OR "mRNA 1273.211" [tw] OR COVID-19[tw] OR SARS-CoV-2[tw] OR "COVID-19 vaccines"[tw] OR "mRNA Vaccines"[tw])) AND (("2022/01/01"[Date - Publication] : "2022/06/18"[Date - Publication])))