Appendix 11.21a Autoimmune Hepatitis: Cumulative Cases with WHO Causality and Confounders-Case listings

Case ID	Country	Report Type	ALL PT'S	Case Seriousness	Patient Age (Years)	Patient Gender	Medical History	EASL	WHO	Confounders	Concomitant Medications	MAH Comment	WW Identifier	Batch/Lot Number	RP	Generic Name
[redacted]		Regulatory Authority	Acute hepatic failure, Acute kidney injury	Serious	74	Female	Food allergy; Hepatic cirrhosis(H); Cardiac failure congestive(H); Diabetes mellitus(C); Autoimmune hepatitis(H)	not AIH	Unlikely	CHF, Cirrhosis	0	Based on the current available information and temporal association between the use of the product and the start date of these events, a causal relationship cannot be excluded.	[redacted]	012L20A	Prior to Review Period	mRNA-1273
		Spontaneous	Acute hepatic failure, Hepatic enzyme increased	Serious	85	Male	No adverse event(H)	not AIH	Unlikely	age	0	Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.		0	Prior to Review Period	mRNA-1273
		Spontaneous	Autoimmune hepatitis, Condition aggravated, Hepatic enzyme increased, Incomplete course of vaccination, Vaccination site erythema, Vaccination site pruritus, Vaccination site urticaria, Vaccination site warmth	Serious	73	Female	Autoimmune disorder(C); Autoimmune hepatitis(C); Hepatitis B(C); Hepetitis C(C); Acute hepatic failure(C); Thyroiditis(C); SHINGRIX; PREDNISONE(H); Surgery	not AIH	Conditional	preexistiog AIH, chronic hep B and C, Shingrix vaccination despite dates unclear in the narrative	ESTRATEST; GABAPENTIN; OMEPRAZOLE; ZINC; B50; COQ10 COMPLEX; COCONUT OIL; MAGNESIUM; [redacted]	0		631L20A	Prior to Review Period	mRNA-1273
	UNITED STATES	Spontaneous	Hepatic failure, Palpitations, Renal failure, Vomiting	Serious	39	Female	No adverse event(H)	not AIH	Unlikely	autoimmune underlying background (Sjogren, Hashimoto)	0	This is a case of death in a 39year-old female subject with unknown medical history of anaphylactic reactions, allergic reactions to pneumovax vaccine, Sjogren's syndrome, Hashimoto's, inflammatory joint disease, osteoporosis, osteoarthritis, who died 4 days after receiving second dose of vaccine. Very limited information has been provided at this time. Further information has been requested.		0	Prior to Review Period	mRNA-1273
	UNITED STATES	Spontaneous	Aphasia, Cardiac failure, Death, General physical health deterioration, Headache, Hepatic failure, Immunisation reaction, Incoherent, Nausea, Palpitations, Renal failure, Vaccination site pain, Vomiting	Serious	39	Female	No adverse event(H)	not AIH	Unlikely	multiorgan failure	0	This is a case of death in a 39-year-old male subject with unknown medical history of, who died 4 days after receiving first dose of vaccine. Very limited information has been provided at this time. Further information has been requested.		0	Prior to Review Period	mRNA-1273
		Regulatory Authority	Abdominal pain, Autoimmune hepatitis, Chromaturia, Jaundice	Serious	54	Female	Rubber sensitivity; Allergy to arthropod sting	not AIH	Conditional	None explaining liver and renal failure	0	Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.		027L20A	Prior to Review Period	mRNA-1273
		Regulatory Authority	Autoimmune hepatitis, Guillain-Barre syndrome	Serious	52	Male	Drug hypersensitivity; Hypertension(C); Alpha-1 anti-trypsin(C)	not AIH	Conditional	none reported	VALTREX; BENICAR; ASPIRIN 81; VITAMIN D NOS	Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.		025J20A; 028L26A	Prior to Review Period	mRNA-1273
		Spontaneous	Hepatitis acute	Serious	63	Female	No adverse event(H)	not AIH	Unlikely	medications	LANTUS; ATORVASTATIN; ANASTROZOLE; ASPIRIN (B.C.)	Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. Very limited information regarding this event has been provided at this time. Further information has been requested.		0	Prior to Review Period	mRNA-1273
		Spontaneous	Autoimmune hepatitis, Fatigue, Pain, Somnolence, Tinnitus	Serious	79	Female	0	not AIH	Unlikely	conco medications	PLAQUENIL [HYDROXYCHLOROQUINE SULFATE]; RESTASIS; SEROQUEL; AZATHIOPRINE	0		026A21A	Prior to Review Period	mRNA-1273
		Regulatory Authority	Disseminated intravascular coagulation, Generalised tonic-clonic seizure, Leukocytosis, Liver injury, Pyrexia, Respiratory failure, Rhabdomyolysis, Shock	Serious	37	Female	Drug hypersensitivity; Tuberous sclerosis complex(C); Angiomyolipoma(C); Hepatic cyst(H); Hypertension(C); Intellectual disability(C); Autism spectrum disorder(C); Depression(H); Anxiety(H); Epilepsy(C); Clonic convulsion(H)	not AIH	Unlikely	yes,DIC and medications	KEPPRA; OXCARBAZEPINE; XCOPRI; ALTACB; ZOLOFT; EVEROLIMUS	Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.		0	Prior to Review Period	mRNA-1273
	UNITED STATES	Regulatory Authority	COVID-19, COVID-19 pneumonia, Death, Dyspnoea, Encephalopathy, Gastrointestinal disorder, Haemodynamic instability, Liver injury, Shock, Supraventricular tachycardia, Tachycardia, Thrombocytopenia	Serious	74	Male	End stage renal disease(H); Hypertension(H); Atrial septal defect(H)	not AIH	Unlikely	yes, end stage renal failure	0	0		031M20A	Prior to Review Period	mRNA-1273
		Spontaneous	Gait inability, Joint swelling, Liver injury, Muscle strain, Vaccination site bruising, Vaccination site pain	Serious	89	Male	No adverse event(H)	not AIH	Unlikely	age	0	0		040A21A	Prior to Review Period	mRNA-1273
		Spontaneous	Fluid intake reduced, Hepatitis acute, Vomiting	Serious	88	Female	0	not AIH	Unassessable	age	0	0		0	Prior to Review Period	mRNA-1273
	UNITED STATES	Regulatory Authority	Hepatic failure, Hypotension, Internal haemorrhage, Pleural effusion, Pulmonary oedema	Serious	75	Female	Cardiac fibrillation(C)	not AIH	Unlikely	yes,fibrillation	WARFARIN	0		042L20A	Prior to Review Period	mRNA-1273
		Regulatory Authority	Acute respiratory failure, Agitation, Anaemia, Asthenia, Atelectasis, Benign prostatic hyperplasia, Cardiac failure congestive, Chronic left ventricular failure, Chronic obstructive pulmonary disease, Condition aggravated, Confusional state, Coronary artery disease, Depression, Discomfort, Enteritis, Fall, Gastrointestinal haemorrhage, Gastrooesophageal reflux disease, General physical health deterioration, Haemoperitoneum, Hepatic cirrhosis, Hepatic failure, Hypercapnia, Hypotension, Mental status changes, Neuropathy peripheral, Pain, Peripheral arterial occlusive disease, Pulmonary mass, Quadriplegia, Sepsis, Subdural haematoma, Syncope, Thyroid disorder, Toxic encephalopathy, Urinary tract infection, Wernicke's encephalopathy	Serious	58	Male	Hypertension(C); Hypothyroidism(C); Chronic obstructive pulmonary disease(C); Hypercholesterolaemia(C); Cardiac failure congestive(H); Pain(C); Cirrhosis alcoholic(C); Renal failure(H); Deep vein thrombosis(H); Neuropathy peripheral(H); Hallucination(C); Drug hypersensitivity; Drug hypersensitivity; Atrial fibrillation(C); Disability(C); General physical health deterioration(C); Mental impairment(C)	not AIH	Unlikely	CHF, Cirrhosis, renal failure	DUONEB; AMIODARONE; LIPITOR; COREG; VITAMIN D3; [redacted] DOXYCYCLINE; FINASTERIDE; FLONASE [MOMETASONE FUROATE]; GABAPENTIN; LACTULOSE; LEVOTHYROXINE; REGLAN [METOCLOPRAMIDE HYDROCHLORIDE]; MORPHINE; STIOLTO RESPIMAT; OMEPRAZOLE; POTASSIUM CHLORIDE; PREDNISONE; SERTRALINE; SPIRONOLACTON; MAGNESIUM;	0	[redacted]	013A21A	Prior to Review Period	mRNA-1273

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[redacted]		Regulatory Authority	Cardio-respiratory arrest, Dyspnoea, Hepatic failure, Renal failure	Serious	71	Male	Obstructive sleep apnoea syndrome(C); Hypertension(C); Myocardial infarction(H); Diabetes mellitus(C); Chronic kidney disease(C); Cerebrovascular accident(H); Atrial fibrillation(C); Endotracheal intubation	not AIH	Unlikely	CVA, MI, renal failure	0	0	[redacted]	0	Prior to Review Period	mRNA-1273
		Regulatory Authority	Autoimmune hepatitis	Serious	41	Female	0	not AIH	Unlikely	no medical info provided	0	0		300042722	Prior to Review Period	mRNA-1273
		Regulatory Authority	Autoimmune hepatitis, Chromaturia, Decreased appetite, Fatigue	Serious	76	Female	Transitional cell carcinoma(H); COVID-19(H); Hypothyroidism(H); Chronic obstructive pulmonary disease(H); Hypercholesterolaemia(H); Ex-tobacco user(H)	not AIH	Possible	COPD, hyperCholesterolemia	GUTRON; MOLAXOLE; ELTROXIN; ZOLPIDEM	0		3000424	Prior to Review Period	mRNA-1273
		Regulatory Authority	Abdominal pain upper, Chromaturia, Fatigue, Immune-mediated hepatitis, Jaundice, Pruritus	Serious	74	Male	Drug hypersensitivity; Allergy to arthropod sting; Type 2 diabetes mellitus(C); Hypothyroidism(C); Coronary artery disease(C); Stress cardiomyopathy(C); Osteoarthritis(C); Erectile dysfunction(C); Urinary retention(C); Obstructive sleep apnoea syndrome(C); Benign prostatic hyperplasia(C); Adrenal mass(C); Breast mass(C); Cholecystectomy	not AIH	Possible	CHF, cardiomyopathy, diabetes	LISINOPRIL/HYDROCHLOROTHIAZIDE; DICLOFENAC; ACETAMINOPHEN; SILDENAFIL; CARVEDILOL; LEVOTHYROXINE; AMLODIPINE; TAMSULOSIN; METFORMIN; GLIMEPIRIDE	0		031L20A	Prior to Review Period	mRNA-1273
	UNITED STATES	Regulatory Authority	Abdominal discomfort, Cardiac failure, Death, Decreased appetite, Fatigue, Hepatic failure, Illness, Lethargy, Neck pain, Pain in extremity, Renal failure, Shock	Serious	86	Female	Renal failure(C); Cardiac disorder(C); Pulseless electrical activity(C)	not AIH	Unlikely	Cardiac and renal failure, age	BLIQUIS; SYNTHROID; LOSARTAN; METOPROLOL	0		0	Prior to Review Period	mRNA-1273
	UNITED STATES	Regulatory Authority	Cerebrovascular accident, Death, Hepatic failure, Pulmonary embolism, Renal failure	Serious	76	Male	Blood cholesterol increased(C); Hypertension(C); Sleep apnoea syndrome(C); Tachycardia(H)	not AIH	Unlikely	CVA, PE, renal failure	SOTALOL; PLAVIX	0		0	Prior to Review Period	mRNA-1273
	UNITED STATES	Spontaneous	Abdominal pain upper, Death, Hepatic failure, Nausea, Renal failure, Unresponsive to stimuli	Serious	62	Female	Primary biliary cholangitis(C)	not AIH	Unlikely	Underlying primary biliary cholangitis	0	0		0	Prior to Review Period	mRNA-1273
		Regulatory Authority	Drug-induced liver injury, Fatigue, Headache	Serious	34	Female	Abortion spontaneous(H); Food allergy; Hepatitis A(H)	not AIH	Unlikely	none	0	0		300042698 e 300042723; 300042698 e 300042723	Prior to Review Period	mRNA-1273
		Regulatory Authority	Abdominal pain upper, Acute hepatic failure, Acute kidney injury, Chills, Fatigue, Fluid retention, Gastric dilatation, Headache, Malaise, Nausea	Serious	69	Male	Drug hypersensitivity; Coronary artery disease(H); Gastrooesophageal reflux disease(H)	not AIH	Unlikely	CAD, medications	PRADAXA; RANEXA; ISOSORBIDE; GLUCOSAMINE CHONDROITIN & MSM; L ARGININE [ARGININE]; PEPCID [FAMOTIDINE];	0		001B21A	Prior to Review Period	mRNA-1273
		Regulatory Authority	Autoimmune hepatitis, Fatigue, Jaundice	Serious	50	Male	Food allergy	not AIH	Possible	none	0	0		007M20A	Prior to Review Period	mRNA-1273
		Regulatory Authority	Chills, Dysgeusia, Dyspnoea, Feeding disorder, Hepatic failure, Muscle fatigue, Pyrexia, Renal failure, Tremor	Serious	74	Male	Leukaemia(C)	not AIH	Unlikely	leukemia, paracetamol use	TYLENOL	0		0	Prior to Review Period	mRNA-1273
		Regulatory Authority	Hepatic failure, Mesenteric vein thrombosis, Renal failure, Small intestinal resection	Serious	73	Female	Drug hypersensitivity	not AIH	Possible	Thrombosis	0	0		0	Prior to Review Period	mRNA-1273
		Regulatory Authority	Abdominal pain, Asthenia, Dehydration, Hepatic failure, Mobility decreased, Muscle injury, Myalgia, Renal failure, Retching, Vomiting	Serious	73	Male	Drug hypersensitivity; Aortic aneurysm(H); Barrett's oesophagus(H); Spinal cord disorder(H)	not AIH	Unlikely	yes	0	0		002A21A	Prior to Review Period	mRNA-1273
		Regulatory Authority	Autoimmune haemolytic anaemia, Hepatocellular injury	Serious	72	Female	Arrhythmia(H); Aortic valve incompetence(H); Mitral valve incompetence(H)	not AIH	Possible	vascular diseases	DILTIAZEM [redacted] LACTOSE MONOHYDRATE; MAGNESIUM STEARATE; MACROGOL; CASTOR OIL, HYDROGENATED; [redacted]	0		0001413	Prior to Review Period	mRNA-1273
		Regulatory Authority	Hepatitis acute, Nausea, Vomiting	Serious	39	Female	Premenstrual dysphoric disorder(H); Attention deficit hyperactivity disorder(H); Generalised anxiety disorder(C); Endometriosis(H); Vitamin D deficiency(C); HEPATITIS A; HEPATITIS B VACCINE	not AIH	Unlikely	multimedicated	AMETHYST; ARIPIPRAZOLE; CYMBALTA; METHYL FOLATE; PRAZOSIN; PROPRANOLOL; TRAZODONE; LISDEXAMFETAMINE DIMESYLATE; CONTRAVE	0		0	Prior to Review Period	mRNA-1273
		Spontaneous	Hepatic failure	Serious	62	Female	0	not AIH	Unassessable	none reported	0	0		0	Prior to Review Period	mRNA-1273
	POLAND	Regulatory Authority	Acute kidney injury, Dyspnoea, Embolism, Escherichia sepsis, Gallbladder enlargement, General physical health deterioration, Hyperuricaemia, Left ventricular hypertrophy, Leukopenia, Liver injury, Pyrexia, Renal cyst, Respiratory failure	Serious	72	Male	Cystitis(C); Tobacco abuse(H); Lung neoplasm(H); Type 2 diabetes mellitus(C); Chronic obstructive pulmonary disease(C); Aortic valve calcification(H); Arteriosclerosis(C); Aortic valve calcification(H); Benign prostatic hyperplasia(H); Left ventricular hypertrophy(H); Mediastinum neoplasm(H)	not AIH	Unlikely	COPD, cardiac & vascular disorders, diabetes	0	0		00004272L	Prior to Review Period	mRNA-1273
	[redacted]	Regulatory Authority	Hepatocellular injury	Serious	73	Female	B-cell lymphoma(H); Internal fixation of fracture; Oophorectomy; Mixed anxiety and depressive disorder(C); Hypercholesterolaemia(C)	not AIH	Unlikely	hypercholesterolemia, lymphoma	0	0		0	Prior to Review Period	mRNA-1273

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[redacted]	UNITED STATES	Regulatory Authority	Death, Hepatic failure, Renal failure	Serious	48	Female	0	not AIH	Possible	renal failure, medications	VENLAFAXINE; VENLAFAXINE; DIVIGEL; PANTOPRAZOLE; ADDERALL	0	[redacted]	016C219	Prior to Review Period	mRNA-1273
[redacted]		Spontaneous	Alopecia, Dehydration, Dysphagia, Impaired work ability, Liver injury, Nausea, Pyrexia, Vomiting	Serious	25	Female	Anxiety(C)	not AIH	Unassessable	conco medications	CLONAZEPAM; ADDERALL	0		008C21A; 030B21A	Prior to Review Period	mRNA-1273
[redacted]		Regulatory Authority	Acute kidney injury, Chills, Disseminated intravascular coagulation, Fatigue, General physical health deterioration, Haemophagocytic lymphohistiocytosis, Hepatic failure, Hyponatraemia, Malaise, Multiple organ dysfunction syndrome, Pyrexia, Respiratory failure, Shock, Thrombocytopenia	Serious	62	Male	Hyperlipidaemia(C); Seasonal allergy(C)	not AIH	Unassessable	multi organ failure	0	0		0	Prior to Review Period	mRNA-1273
[redacted]	UNITED STATES	Regulatory Authority	Acute hepatic failure, Death, Fatigue, Haemophagocytic lymphohistiocytosis, Hyperferritinaemia, Pneumonia legionella, Pruritus, Sleep disorder	Serious	65	Male	Hypersensitivity; Leukaemia(C); Atrial fibrillation(C); Aortic stenosis(C); Hypertension(C); Gastrooesophageal reflux disease(C); Cerebrovascular accident(C)	not AIH	Unlikely	conco medications and diseases	ALLOPURINOL; FLECAINIDE; VITAMIN D3; FOLIC ACID; MAGNESIUM OXIDE; OMEPRAZOLE; PENTAMIDINE; VALACYCLOVIR [VALACICLOVIR]; DILTIAZEM; MELATONIN; DECITABINE	0		0	Prior to Review Period	mRNA-1273
[redacted]	UNITED STATES	Regulatory Authority	Acute respiratory failure, Angina pectoris, Cardiogenic shock, Death, Hepatic failure, Renal failure	Serious	82	Female	Drug hypersensitivity; Drug hypersensitivity; Chronic obstructive pulmonary disease(C); Atrial fibrillation(C)	not AIH	Unassessable	cardiogenic shock, renal failure	0	0		042L20A	Prior to Review Period	mRNA-1273
[redacted]		Regulatory Authority	Acute hepatic failure, Hepatic pain, Loss of consciousness	Serious	38	Female	Von Willebrand's disease(C)	not AIH	Possible	underlying disease	EFFEXOR; VITAMIN D3 1000; OMEGA-3 FATTY ACIDS	0		04642IA	Prior to Review Period	mRNA-1273
[redacted]		Regulatory Authority	Feeling abnormal, Hepatic failure, Pain	Serious	76	Female	Hepatic failure(C); Vascular graft; Pacemaker generated rhythm	not AIH	Possible	qudruple bypass, arrhythmia	OMEPRAZOL [OMEPRAZOLE]; BABY ASFIRIN	0		031A21A	Prior to Review Period	mRNA-1273
[redacted]		Regulatory Authority	Autoimmune hepatitis, Drug-induced liver injury, Jaundice	Serious	68	Female	Diabetes mellitus(C); Gastrooesophageal reflux disease(C)	not AIH	Possible	Diabetes	0	0		0	Prior to Review Period	mRNA-1273
[redacted]		Regulatory Authority	Autoimmune hepatitis, Chromaturia, Fatigue, Myalgia, Nausea	Serious	37	Female	0	not AIH	Unlikely	None reported	0	0		0	Prior to Review Period	mRNA-1273
[redacted]		Regulatory Authority	Cardiac failure, Intensive care, Liver injury, Loss of consciousness, Mechanical ventilation, Nausea, Pneumonia, Renal injury, Sepsis, Thrombosis	Serious	73	Male	Drug hypersensitivity; Drug hypersensitivity; Asthma(H)	not AIH	Unassessable	CHF,sepsis, thrombosis	METOPROLOL; TRAMADOL; TRAZODONE; [redacted] [SALBUTAMOL SULFATE]; ATORVASTATIN; VITAMIN B-12; GABAPENTIN; GLUCOSAMINE; MULTIVITAMINS [VITAMINS NOS]; OLMESARTAN; OMEPRAZOLE; TAMSULOSIN; VITAMIN D3	0		014M20A	Prior to Review Period	mRNA-1273
[redacted]		Regulatory Authority	Acute kidney injury, Dyspnoea, Fatigue, Liv injury, Myocardial injury, Pain	Serious	40	Male	0	not AIH	Unlikely	MI	ANDROGEL; SYNTHROID; MULTIVITAMINS [VITAMINS NOS]	0		011J20A; 028L20A	Prior to Review Period	mRNA-1273
[redacted]		Regulatory Authority	Autoimmune hepatitis, Exposure during pregnancy, Hepatitis C, Hepatomegaly	Serious	40	Female	0	not AIH	Unlikely	Hep C	0	0		025J20-2A	Prior to Review Period	mRNA-1273
[redacted]		Regulatory Authority	Autoimmune hepatitis	Serious	35	Male	0	not AIH	Possible	none reported	0	0		0	Prior to Review Period	mRNA-1273
[redacted]		Regulatory Authority	Asthma, Blood alkaline phosphatase increased, Blood bilirubin increased, Chronic obstructive pulmonary disease, Condition aggravated, Hepatic lymphocytic infiltration, Hepatitis acute, International normalised ratio increased, Leukaemic infiltration hepatic, Liver iron concentration increased, Peritonitis, Portal fibrosis, Prothrombin time prolonged	Serious	65	Male	Chronic lymphocytic leukaemia(C); Renal failure(H); Drug hypersensitivity; Chronic obstructive pulmonary disease(C); Asthma(C)	not AIH	Unlikely	underlying conditions	[redacted] [SALBUTAMOL]; FLUTICASONE; BUDESONIDE; OMEPRAZOLE; LASIX [FUROSEMIDE]; COUMADIN; VITAMIN D NOS; METOPROLOL	0		012L20A; 013M20A	Prior to Review Period	mRNA-1273
GERMANY	Regulatory Authority	Acute hepatic failure, Haemorrhagic ascites, Shock haemorrhagic, Truncus coeliacus thrombosis	Serious	63	Female	0	not AIH	Unlikely	Thrombosis, shock hemorrhagic	0	0		3002620	Prior to Review Period	mRNA-1273
UNITED STATES	Regulatory Authority	Carditis, Confusional state, Dysarthria, Hepatic failure, Mobility decreased	Serious	65	Male	Renal disorder(H)	not AIH	Possible	none reported	0	0		0	Prior to Review Period	mRNA-1273
[redacted]	Literature-Non Study	Autoimmune hepatitis	Serious	41	Female	Premature menopause(C)	AIH	Probable		0	0		0	Prior to Review Period	mRNA-1273
[redacted]	Regulatory Authority	Chromaturia, Drug-induced liver injury, Hepatitis, Hepatitis cholestatic, Pyrexia	Serious	43	Male	0	not AIH	Possible	ibuprofen	IBUPROFEN	0		0	Prior to Review Period	mRNA-1273
[redacted]	Regulatory Authority	Hepatocellular injury	Serious	73	Female	Uterine leiomyoma(H); Macular degeneration(C); Hypothyroidism(C)	not AIH	Possible	none reported	0	0		3001413	Prior to Review Period	mRNA-1273

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[redacted]	[redacted]	Regulatory Authority	Acute hepatic failure, Asthenia, Chest pain, Dizziness, Dyspnoea, Epstein-Barr virus infection reactivation, Headache, Immune thrombocytopenia, Influenza like illness, Myalgia, Off label use, Pain in extremity, Pyrexia	Serious	46	Female	Autoimmune disorderFH; Endometriosis(C); Alcohol use(C)	not AIH	Possible	paracetamol and NSAIDs last introduced, EBV serology positive	VISANNE; PARACETAMOL; PONSTAN; SIRDALUD	La survenue d'hépatite aigue et de thrombocytopénie immune n'est pas décrite par le fabricant du vaccin Moderna®. [1] Les autorités sanitaires françaises (ANSM) ont rapporté dans leur dernier rapport (du 13.05.2021) 2 cas de thrombopénie et 1 cas d'atteinte hépatique qualifiés de « graves » dans les suites de l'administration du vaccin Moderna. [2] A noter que 37 cas codés sous différents termes pouvant correspondre au tableau d'atteinte hépatique de la patiente et > 150 cas de thrombocytopénie immune ou non, ont été recensés par l'European Medicine Agency (EMA) après la vaccination par l vaccin à ARNm Moderna®. [3] Nous ne retrouvons pas de cas publiés d'atteinte hépatique suite à l'administration de vaccin à ARNm contre le Covid-19 ; trois rapports de cas de thrombocytopénie immune post-vaccination sont rapportés (dans ces cas la thrombopénie est profonde avec atteinte cutanée). [4-6] Des publications de cas d'exacerbations d'atteintes auto-immunes ou de révélation d'atteintes auto-immunes (poussée de purpura thrombocytopénique immun, maladie de Graves, vascularites) commencent à être décrites dans la littérature. [7-8] La physiopathologie de ce type d'effet indésirable reste à étayer, un syndrome inflammatoire induit pa le vaccin lui-même qui booste globalement l'immunité contre u virus est parfois évoqué. Les autres médicaments pris par la patiente sont peu suspects. En conclusion, l'imputabilité de la vaccination contre le Covid-19 dans la survenue d'un tableau d'hépatite aigue et de thrombocytopénie immune paraît possible dans le cas de cette patiente, avec terrain familial auto-immun. L'imputabilité des divers traitements en cours est jugée improbable. Le diagnostic d'infection aigue à EBV est un autre diagnostic possible.	[redacted]	0	Prior to Review Period	mRNA-1273
		Regulatory Authority	Hepatitis acute, Jaundice	Serious	38	Female	0	not AIH	Possible	Mycobacterium tuberculosis complex test +	0	0		0	Prior to Review Period	mRNA-1273
		Regulatory Authority	Abdominal distension, Abdominal pain upper, Chills, Dizziness, Headache, Liver injury, Musculoskeletal pain, Nausea	Serious	38	Female	Drug hypersensitivity; Drug hypersensitivity; Hypertension(C); Depression(C)	not AIH	Unlikely	medications	METOPROLOL; [redacted]BENADRYL [DIPHENHYDRAMINE HYDROCHLORIDE]	0		0	Prior to Review Period	mRNA-1273
		Regulatory Authority	Hepatitis acute	Serious	39	Male	0	not AIH	Unassessable	None reported	0	0		001C21A	Prior to Review Period	mRNA-1273
		Regulatory Authority	Anxiety, Depression, Drug-induced liver injury, Ear infection, Fatigue, Impaired work ability, Loss of personal independence in daily activities, Malaise, Restlessness, Tonsillitis	Serious	46	Female	Drug hypersensitivity; Blood triglycerides increased(H); Anxiety(H); Depression(H); Gastrooesophageal reflux disease(H); Drug hypersensitivity	not AIH	Unassessable	underlying diseases/infections	FENOFIBRATE; CITALOPRAM; VITAMIN D NOS; IBUPROFEN; ESTRADIOL; OMEPRAZOLE	0		013M20A	Prior to Review Period	mRNA-1273
		Regulatory Authority	Anxiety, Asthenia, Balance disorder, Bradyphrenia, Cognitive disorder, Condition aggravated, Deafness neurosensory, Depression, Discomfort, Fatigue, Feeling abnormal, Glucose tolerance impaired, Headache, Hemiparesis, Hypersomnia, Impaired work ability, Liver injury, Nausea, Nystagmus, Pain, Pyrexia, Rash, Skin exfoliation, Skin lesion, Tinnitus, Vestibular disorder, Vision blurred, Vitamin D deficiency	Serious	54	Female	Drug hypersensitivity; Post-traumatic stress disorder(H); Toxoplasmosis(H); Sporotrichosis(H); Oral herpes(H)	not AIH	Unlikely	no	0	0		002A21A	Prior to Review Period	mRNA-1273
		Regulatory Authority	Autoimmune cholangitis, Biliary tract disorder, Cholangitis acute, Cholangitis infective, Chromaturia, Fatigue, Hepatocellular injury, Idiosyncratic drug reaction, Nausea, Vomiting	Serious	35	Female	Depression(H); Constipation(C); Cholecystectomy; Drug hypersensitivity	not AIH	Unlikely	No	LEXAPRO; COLACR; DULCOLAX [BISACODYL]	0		005C21A	Prior to Review Period	mRNA-1273
		Spontaneous	Diarrhoea, Fatigue, Hepatitis acute	Serious	78	Female	Hypothyroidism(C)	not AIH	Unassessable	Hypothyroidism	SYNTHROID	0		0	Prior to Review Period	mRNA-1273
		Regulatory Authority	Acute respiratory failure, Aggression, Agitation, Arteriosclerosis, Confusional state, Cough, COVID-19, COVID-19 pneumonia, Delirium, Hepatic cirrhosis, Hepatic encephalopathy, Hepatic failure, Lactic acidosis, Lung hyperinflation, Lung opacity, Malaise, Neuropathy peripheral, Non-Hodgkin's lymphoma, Portal hypertension, Portal hypertensive colopathy, Respiratory tract congestion, Thrombocytopenia	Serious	67	Male	Drug hypersensitivity; Drug hypersensitivity; Drug hypersensitivity; Drug hypersensitivity; Drug hypersensitivity; Hepatic cirrhosis(C); Varices oesophageal(C); Gastric varices(C); Alcohol abuse(H); Atrial fibrillation(C); Cardiac failure congestive(C); Coronary artery disease(C); Type 2 diabetes mellitus(C); Gastrooesophageal reflux disease(C); Hyperlipidaemia(C); Hypertension(C); Neuropathy peripheral(C); Hypothyroidism(C); Non-Hodgkin's lymphoma(C); Obstructive sleep apnoea syndrome(C)	not AIH	Unlikely	COVID19, cirrhosis, alcohol	DEXAMETHASONE; REMDESIVIR; RIFAXIMIN; HALOPERIDOL; GABAPENTIN; TRESIBA; INSULIN; METFORMIN	0		0	Prior to Review Period	mRNA-1273
		Regulatory Authority	Hepatic failure	Serious	60	Female	0	not AIH	Unassessable	None reported	0	0		0	Prior to Review Period	mRNA-1273
		Spontaneous	Acute kidney injury, Hepatic failure, Illness, Pancreatic failure	Serious	0.00	Male	0	not AIH	Unlikely	Multiprgan failure	0	0		0	Prior to Review Period	mRNA-1273
		Regulatory Authority	Drug-induced liver injury, Pyrexia	Serious	34	Male	No adverse event(H)	Not AIH	Unassessable	None reported	0	Not reported.		0	Prior to Review Period	mRNA-1273

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[redacted]		Regulatory Authority	Acute hepatic failure, Foetal hypokinesia, Foetal movement disorder, Low birth weight baby	Serious	0	Unknown	Hypercoagulation(C); Drug hypersensitivity; Endometrial ablation; Exposure during pregnancy(H)	not AIH	Unlikely	Mother received the vaccine	0	0	[redacted]	030L20A; 025J20A	Prior to Review Period	mRNA-1273
		Regulatory Authority	Acute hepatic failure, Autoimmune hepatitis, Drug-induced liver injury, Hepatitis viral, Ischaemic hepatitis, Vaccination complication	Serious	57	Female	Non-small cell lung cancer(C); Hypertension(C); Neuropathy peripheral(C)	not AIH	Unlikely	lung cancer recently diagnosed; possible liver metastasis	0	0		0	Prior to Review Period	mRNA-1273
		Regulatory Authority	Bacterial infection, Hepatitis acute, Septic shock	Serious	74	Female	0	not AIH	Unlikely	infection, septic shock	0	0		0	Prior to Review Period	mRNA-1273
		Literature-Non Study	Autoimmune hepatitis	Serious	63	Male	Type 2 diabetes mellitus(C); Myocardial ischaemia(C); Alcohol use(C)	not AIH	Possible	MI, diabetes, alcool and overweight	METFORMIN; ACETYLSALICYLIC ACID; ROSUVASTATIN	0		0	Prior to Review Period	mRNA-1273
		Regulatory Authority	Autoimmune hepatitis, Decreased appetite, Fatigue, Hepatic enzyme increased, Jaundice, Malaise, Scleral discolouration	Serious	57	Male	0	not AIH	Possible	None reported	0	0		3002338; 3004493	Prior to Review Period	mRNA-1273
		Regulatory Authority	Hepatitis acute, Leukopenia, Thrombocytopenia	Serious	24	Male	Alcohol use(C)	not AIH	Possible	ibuprofen and paracetamol prior events	IBUPROFENE; DAFALGAN	0		0	Prior to Review Period	mRNA-1273
		Regulatory Authority	Autoimmune hepatitis	Serious	0.00	Male	0	not AIH	Unassessable	None reported	0	0		0	Prior to Review Period	mRNA-1273
	UNITED STATES	Regulatory Authority	Acute hepatic failure, Acute myocardial infarction, Aortic stenosis, Brain hypoxia, Cardiac arrest, Cardiogenic shock, Cardiomyopathy, Condition aggravated, Dyspnoea, General physical health deterioration, Lactic acidosis, Malaise, Pulmonary embolism, Rash, Rash erythematous, Renal failure, Rheumatoid arthritis	Serious	58	Male	Anxiety(H); Rheumatoid arthritis(H)	not AIH	Unlikely	MI, RA, multiorgan failure	ASPRIN; CITALOPRAM; PREDNISONE; FUROSEMIDE	0		0	Prior to Review Period	mRNA-1273
	[redacted]	Regulatory Authority	Autoimmune hepatitis, Liver disorder, Transaminases increased	Serious	33	Female	Crohn's disease(C)	not AIH	Unlikely	conco medication, Chron	ADALIMUMAB	0		3003183	Prior to Review Period	mRNA-1273
	UNITED STATES	Spontaneous	Hepatic failure, Portal vein thrombosis	Serious	85	Female	Hypertension(C); Diabetes mellitus(C)	not AIH	Unlikely	Portal thrombosis	0	0		002A21A; 041L20A	Prior to Review Period	mRNA-1273
		Regulatory Authority	Arthralgia, Asthenia, Erythema, Hepatocellular injury, Hypertension, Leukopenia	Serious	71	Female	Lung neoplasm malignant(H); Lung lobectomy	not AIH	Possible	history lung neoplasm-meta?	NEXIUM [ESOMEPRAZOLE SODIUM]	0		0	Prior to Review Period	mRNA-1273
		Regulatory Authority	Chest pain, Liver injury, Myopericarditis	Serious	25	Male	Chest pain(H); Magnetic resonance imaging heart(H); Clinical trial participent(H)	not AIH (coding error)	Unassessable	Myocarditis case	0	0		0	Prior to Review Period	mRNA-1273
		Regulatory Authority	Autoimmune hepatitis, Product dose omission issue	Serious	62	Male	Diabetes mellitus(C); Ischaemic cardiomyopathy(C)	AIH	Possible	possible liver impact of the underlying diabetes and cardiomyopathy, although liver ultrasound did not show fatty liver.	CRESTOR [redacted] ASA SANDOZ; ROSUVASTATIN	0		0	Prior to Review Period	mRNA-1273
		Literature-Non Study	Immune thrombocytopenia, Liver injury, Vaccination site pain	Serious	26	Female	Menstruation irregular(H); ACETAMINOPHEN(H)	not AIH	Unlikely	Yes, ITP	0	0		0	Prior to Review Period	mRNA-1273
		Literature-Non Study	Autoimmune hepatitis, Herpes virus infection	Serious	76	Female	COVID-19(H); Hypothyroidism(C); Transitional cell carcinoma(H); Hypotension(H)	AIH	Possible	yes, prior COVID19 and other autoimmune disease (Hashimoto)	MIDODRINE; ZOLPIDEM; LEVOTHYROXINE	0		300042460	Prior to Review Period	mRNA-1273
		Regulatory Authority	Autoimmune hepatitis, Hepatic necrosis	Serious	43	Female	Headache(H); Parietal cell antibody positive(H)	not AIH	Unlikely	cosuspect ibuprofen, diclofenac, paracetamol	[redacted] [DESOGESTREL;ETHINYLESTRADIOL]	0		0	Prior to Review Period	mRNA-1273
		Literature-Non Study	Autoimmune hepatitis, Jaundice	Serious	71	Female	Cholecystectomy; Hip arthroplasty; Ostoarthritis(H)	AIH	Possible	yes, paracetamol	PARACETAMOL	0		0	Prior to Review Period	mRNA-1273
		Regulatory Authority	Autoimmune hepatitis	Serious	69	Female	0	not AIH	Unlikely		WELLBUTRIN	0		029A21A	Prior to Review Period	mRNA-1273
		Regulatory Authority	Acute kidney injury, Anuria, Atrial fibrillation, Cardiac arrest, Cardiac failure congestive, Cardiogenic shock, Cardiomyopathy, Chills, Dyspnoea, Electrocardiogram QT prolonged, Fatigue, Hyperhidrosis, Joint swelling, Left ventricular dysfunction, Lethargy, Liver injury, Myocardial infarction, Nausea, Peripheral swelling, Tachycardia, Thrombocytopenia, Ventricular fibrillation, Vomiting	Serious	48	Male	[redacted]test positive(C)	not AIH	Unassessable	[redacted]	[redacted]	0		3001946; 3001650	Prior to Review Period	mRNA-1273
		Regulatory Authority	Autoimmune hepatitis	Serious	51	Female	Hypertension(C); Hypothyroidism(C); Gastroesophageal reflux disease(H)	not AIH	Possible	Conco medication	ATENOLOL; BENICAR; SYNTHROID; T3; ROSUVASTATIN; PANTOPRAZOLE	0		0	Prior to Review Period	mRNA-1273
		Regulatory Authority	Cervical vertebral fracture, Hepatitis acute, Inappropriate schedule of product administration, Obstructive pancreatitis	Serious	66	Male	0	not AIH	Possible	surgery prior; antalgics?	0	0		0	Prior to Review Period	mRNA-1273
		Regulatory Authority	Abdominal pain upper, Gallbladder enlargement, Hepatic cirrhosis, Hepatic neoplasm, Hepatitis acute, Metastases to lung, Nausea, Pneumothorax, Pyrexia, Splenomegaly, Vomiting	Serious	66	Male	Splenomegaly(C); Hepatitis B DNA increased(C); Hypertension(C); Haemangioma(C)	not AIH	Unlikely	Hepatitis B, cirrhosis	BARACLUDE	0		0	Prior to Review Period	mRNA-1273

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[redacted]		Regulatory Authority	Hepatic failure, Transaminases increased	Serious	51	Female	Schizophrenia(C); Hypothyroidism(C)	not AIH	Unlikely	valproate, hypothymidism	LITHIUM; VALPROATE SODIUM	0	[redacted]	3003184	Prior to Review Period	mRNA-1273
		Regulatory Authority	Hepatocellular injury, Pyrexia	Serious	55	Female	0	not AIH	Unassessable	none reported	0	0		3003187	Prior to Review Period	mRNA-1273
		Regulatory Authority	Autoimmune hepatitis, Deep vein thrombosis	Serious	38	Male	Drug hypersensitivity	not AIH	Possible	Thrombosis	0	0		0	Prior to Review Period	mRNA-1273
		Regulatory Authority	Abdominal pain upper, Irritability, Liver injury, Menstrual disorder, Musculoskeletal chest pain, Vomiting	Serious	31	Female	Drug hypersensitivity; Drug hypersensitivity; Drug hypersensitivity; Drug hypersensitivity; Iodine allergy; Fibromyalgia(H); Anxiety(H); Depression(H); Gastrocesophageal reflux disease(H)	not AIH	Unlikely		EFFEXOR	0		0	Prior to Review Period	mRNA-1273
		Regulatory Authority	Abdominal pain upper, Autoimmune hepatitis, Chromaturia, Fatigue, Haemangioma of liver, Hepatocellular injury, Incorrect route of product administration, Jaundice, Periportal oedema	Serious	43	Female	Food allergy; Seasonal allergy; Depression(C); Arthralgia(H); Autoimmune hepatitis(C)	not AIH	Unlikely	ibuprofen	WELLBUTRIN; CLARITIN ALLERGIC; IBUPROFEN	0		041C21A	Prior to Review Period	mRNA-1273
		Regulatory Authority	Acute hepatic failure, Acute hepatitis B, Chromaturia, Hyperaesthesia, Hypoglycaemia, Hypotension, Jaundice, Lactic acidosis, Maternal exposure during pregnancy, Ocular icterus, Premature labour, Septic shock, Tachypnoea, Vaccination site pain, Vaginal haemorrhage	Serious	38	Female	Autoimmune thyroiditis(C); Chronic hepatitis B(H)	not AIH	Unlikely	septic shock, chronic Hep B, lactic acidosis in pregnant woman	PREDNISOLONE	0		0	Prior to Review Period	mRNA-1273
		Spontaneous	Asthenia, Chills, Peeling of body temperature change, Heavy menstrual bleeding, Liver injury, Menstrual disorder, Pain, Pain in extremity	Serious	46	Female	Obesity(C); Hypertension(C); Asthma(C); Immunodeficiency(C); Sciatica(C)	not AIH	Unassessable	Underlying diseases	LOSARTAN; [redacted] HYDROCHLOROTHIAZIDE	0		031L20A; 042L20A	Prior to Review Period	mRNA-1273
	UNITED STATES	Regulatory Authority	Acute hepatic failure, Cerebral venous thrombosis, Mesenteric venous occlusion, Superior mesenteric artery syndrome	Serious	64	Female	Breast cancer(H); Mastectomy	not AIH	Unassessable	Breast cancer, CVA, thrombosis	0	0		0	Prior to Review Period	mRNA-1273
		Spontaneous	Acute kidney injury, Acute myocardial infarction, Coronary artery thrombosis, Dehydration, Diarrhoea, Eosinophilia, Hepatocellular injury, Influenza like illness, Multiple organ dysfunction syndrome, Off label use, Rash, Sepsis, Urticaria, Vaccination site pain	Serious	41	Male	Coronary artery disease(C); Stent placement; Hypertension(C); Pericarditis(H); Chest pain(H); Acute myocardial infarction(C); Hyperlipidaemia(C); Tobacco user(H); Catheterisation cardiac; Back pain(C); Drug hypersensitivity; Non-tobacco user(C); Drug hypersensitivity; Cardiac ventricular thrombosis(C); COVID-19(H); Pyrexia(C); Leukocytosis(C); Hypotension(C); Blood lactic acid increased(C); Hyponatraemia(C); Liver function test increased(C); Cardiac failure chronic(C); Gastrooesophageal reflux disease(C)	not AIH	Unassessable	multi organ diseases	LIDODERM; [redacted] XL; NITROSTAT; PRILOSEC [OMEPRAZOLE]; EFFIENT; SPIRONOLACTONE	0		005C21A	Prior to Review Period	mRNA-1273
		Regulatory Authority	Acute kidney injury, Cerebral haemorrhage, Coagulopathy, Coronary artery occlusion, Liver injury	Serious	38	Female	Tobacco abuse(H)	not AIH	Unlikely	Cerebral hemorrhage, CAD, coagulopathy confounding	0	0		0	Prior to Review Period	mRNA-1273
		Spontaneous	Hepatotoxicity, Pruritus	Serious	30	Female	0	not AIH	Unassessable	None reported	0	0		004m204; 025l20a	Prior to Review Period	mRNA-1273
		Regulatory Authority	Adverse reaction, Autoimmune hepatitis, Contusion, Fatigue, Feeling abnormal, Headache, Immune thrombocytopenia, Lymphadenopathy, Pain	Serious	37	Female	Psoriasis(C); Drug hypersensitivity	not AIH	Unlikely	ITP	0	0		018B21A	Prior to Review Period	mRNA-1273
	TAIWAN, PROVINCE OF CHINA	Regulatory Authority	Acute hepatitis B, Altered state of consciousness, Asthenia, Bandaemia, Biliary tract disorder, Biliary tract infection, Cellulitis, Chills, Decubitus ulcer, Delirium, Hepatic failure, Hypokalaemia, Pyrexia, Sepsis	Serious	71	Female	Hepatitis B(C); Hepatic encephalopathy(C)	not AIH	Unlikely	Hep B, sepsis	0	0		0	Prior to Review Period	mRNA-1273
		Regulatory Authority	Decreased appetite, Hepatitis acute	Serious	46	Female	0	not AIH	Unassessable	None reported	0	0		0	Prior to Review Period	mRNA-1273
		Literature-Non Study	Autoimmune hepatitis, Myalgia	Serious	36	Female	Colitis ulcerative(C); Cholangitis sclerosing(C); Pruritus(C)	AIH (definite)	Possible	Ulcerative colitis; primary sclerosing cholangitis	URSODEOXYCHOLIC ACID	0		0	Prior to Review Period	mRNA-1273
		Regulatory Authority	Hepatitis acute	Serious	13	Female	0	not AIH	Unassessable	None reported	0	0		3004234	Prior to Review Period	mRNA-1273
		Regulatory Authority	Cholestatic liver injury, Hepatotoxicity, Oropharyngeal pain, Pyrexia	Serious	25	Male	0	not AIH	Unassessable	None reported	0	.		0	Prior to Review Period	mRNA-1273
		Spontaneous	Drug-induced liver injury, Inappropriate schedule of product administration	Serious	70	Female	Helicobacter test positive(C); Drug-induced liver injury(H); Food allergy; Alcohol use(C); Abdominal discomfort(C); Chronic gastritis(C); Coronavirus infection(H)	not AIH	Possible	alcohol and underlying diseases	0	<[redacted] 400> The event onset after the start of [redacted] 400 shows a temporal relationship. However, causal influence of co-administered medication is also conceivable. <mRNA-1273 (Moderna COVID-19 Vaccine)> Although the event developed after the start of mRNA-1273 (Moderna COVID-19 Vaccine), it is difficult to assess a causal relationship to mRNA-1273 (Moderna COVID-19 Vaccine) because of lack of detailed information.		0	Prior to Review Period	mRNA-1273
		Regulatory Authority	Autoimmune hepatitis	Serious	78	Female	Osteoporosis(C); Neutropenia(H); Ovarian epithelial cancer(C); Vitiligo(C); Hypertriglyceridaemia(C); Hysterectomy	not AIH	Unassessable	cancer - metastases?	0	0		3000493	Prior to Review Period	mRNA-1273
		Regulatory Authority	Hepatitis acute	Serious	23	Male	Ingrowing nail(H); Adenoidectomy; Suicide attempt(H); Mixed anxiety and depressive disorder(H); Road traffic accident(H); Mental disorder(H); [redacted] Tonsillectomy	not AIH	Unlikely	No	0	0		0	Prior to Review Period	mRNA-1273

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[redacted]	UNITED STATES	Regulatory Authority	Ascites, Cardiac arrest, Cardiac failure, Cardiogenic shock, Cardiomegaly, Congestive hepatopathy, COVID-19, Hepatic failure, Hepatomegaly, Hyperventilation, Inflammation, Metabolic acidosis, Myocarditis, Pericardial effusion, Pneumonia, Renal disorder, Renal failure	Serious	26	Male	Suspected COVID-19(C)	not AIH	Unlikely	Multiorgan failure	0	0	[redacted]	0	Prior to Review Period	mRNA-1273
		Regulatory Authority	Coeliac artery stenosis, Hepatic artery thrombosis, Hepatic perfusion disorder, Liver injury	Serious	44	Female	Drug hypersensitivity; Chronic sinusitis(C); Hepatic steatosis(H); Vascular malformation(C); Haemangioma(H)	not AIH	Unlikely	underlying liver steatosis	CETIRIZINE; MUCINEX	0		043b21a	Prior to Review Period	mRNA-1273
		Spontaneous	Hepatic function abnormal, Hepatitis acute, Jaundice	Serious	40	Male	0	not AIH	Unassessable	none reported	0	Not reported.		0	Prior to Review Period	mRNA-1273
		Regulatory Authority	Hepatic failure, Myocarditis, Pyrexia, Renal failure, Respiratory failure	Serious	52	Male	0	not AIH	Unassessable	Myocarditis, multiorgan failure	0	0		0	Prior to Review Period	mRNA-1273
		Regulatory Authority	Hepatitis fulminant	Serious	30	Female	0	not AIH	Unassessable	No	0	0		214013	Prior to Review Period	mRNA-1273
		Regulatory Authority	Ascites, Autoimmune hepatitis, Portal vein thrombosis, Thrombosis, Varices oesophageal	Serious	64	Male	Autoimmune hepatitis(C); Liver transplant(H); Hypertension(H)	not AIH	Possible	Portal thrombosis	IMURAN [AZATHIOPRINE SODIUM]; ATORVASTATIN; AZATHIOPRINE [AZATHIOPRINE SODIUM]; ONDANSETRON; METOPROLOL; MAGNESIUM OXIDE	0		0	Prior to Review Period	mRNA-1273
		Regulatory Authority	Immunisation reaction, Liver injury	Serious	74	Female	0	not AIH	Unassessable	none reported	0	0		214011	Prior to Review Period	mRNA-1273
		Regulatory Authority	Hepatitis acute	Serious	70	Male	0	not AIH	Unassessable	No	0	0		214029; 3002330; 3001532	Prior to Review Period	mRNA-1273
		Regulatory Authority	Hepatic failure	Serious	80	Female	Drug hypersensitivity; Drug hypersensitivity; Cardiac arrest(H); Diverticulum(H); Hypertension(C); Hypercholesterolaemia(C); Transient ischaemic attack(H); Cardiac ablation; Implantable defibrillator insertion	not AIH	Unlikely	age, TIA, cardiac ablation? !	0	0		037A21B	Prior to Review Period	mRNA-1273
		Regulatory Authority	Chromaturia, Decreased appetite, Disturbance in attention, Drug-induced liver injury, Fatigue, Ocular icterus, Skin discolouration	Serious	77	Male	Type 2 diabetes mellitus(C); Hypertension(C)	not AIH	Unlikely	Augmention co-suspect, thus infection?	AUGMENTIN [AMOXICILLIN;CLAVULANIC ACID]	0		300153c	Prior to Review Period	mRNA-1273
		Regulatory Authority	Acute hepatic failure	Serious	39	Male	0	not AIH	Unlikely	no	0	Initials [redacted] Acute liver failure, suspected autoinflammatory syndrome, DDx macrophage activation syndrome with status post COVID vaccination. The symptoms began on 26-Jun with malaise. On this day, the 2nd COVID vaccination occurred. On the following day, fever up to 39.5° C, taking paracetamol 2-3 units (500 mg). The next day, fever subsided. Blood test revealed elevated liver values. Bilirubin max 33.8 mg/dL, Quick minimal 28.7%, GOT up to 2,658 U/L, CPT up to 2,848 U/L. Plasmapheresis with 12 FFP each, therapy with tofacitinib and prednisolone. Liver values only slightly increased on 01-Sep. No history of alcohol abuse. No evidence of thesaurismosis (hemochromatosis, Wilson's disease) or Alpha-1 antitrypsin deficiency. No evidence of infectious origin. Concomitant disease: nicotine abuse until 2019, bronchial asthma since 6 years old. Allergies: penicillin, house dust mites, blood counts are enclosed		0	Prior to Review Period	mRNA-1273
		Regulatory Authority	Autoimmune hepatitis	Serious	61	Female	Post procedural hypothyroidism(C); Squamous cell carcinoma(C)	not AIH	Unassessable	None reported	0	0		0	Prior to Review Period	mRNA-1273
		Spontaneous	Acute hepatic failure, Disorientation, Hepatic function abnormal, Nausea	Serious	20	Female	0	not AIH	Unassessable	No	0	The patient was admitted to the hospital for acute hepatic failure, the medical examination was conducted, but the cause is unknown at present. The symptoms developed after vaccination with this vaccine, and a causal relationship to the vaccine cannot be ruled out. The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.		3004496	Prior to Review Period	mRNA-1273
		Regulatory Authority	Ageusia, Anosmia, Autoimmune hepatitis, Malaise	Serious	46	Female	Hypertension(C); Glucose tolerance impaired(C); Depression(C); Hyperlipidaemia(C)	not AIH	Possible	Hyperlipidemia, conco medications	LISINOPRIL; HCTZ; ESCITALOPRAM; ATORVASTATIN	0		047C21A	Prior to Review Period	mRNA-1273
		Regulatory Authority	Arthralgia, Autoimmune hepatitis, Fatigue, Sjogren's syndrome	Serious	42	Female	Type 1 diabetes mellitus(C); Colitis microscopic(C); Drug hypersensitivity; Drug hypersensitivity; Drug hypersensitivity; Drug hypersensitivity	not AIH	Possible	underlying autoimmune diseases	ZYRTEC [CETIRIZINE HYDROCHLORIDE]; PEPTO-BISMOL; INSULIN	0		0	Prior to Review Period	mRNA-1273
[redacted]	UNITED STATES	Regulatory Authority	Acute myocardial infarction, COVID-19 pneumonia, Hepatic failure, Hypoxia, Pneumothorax, Respiratory failure, Seizure like phenomena, Shock, Ventricular tachycardia, Vomiting	Serious	68	Male	Chronic obstructive pulmonary disease(H); Hypertension(H); Leukaemia(H)	not AIH	Unlikely	COVID19, MI, shock	0	0	[redacted]	0	Prior to Review Period	mRNA-1273

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[redacted]		Regulatory Authority	Liver injury	Serious	49	Male	0	not AIH	Possible	no	0	Liver damage of unknown origin in temporal correlation with t Spikevax vaccine. Differential diagnosis remains open. Liver damage in relation to the use of Spikevax is not reported in the Swiss monograph, nor in the international monographs. There are two articles in literature presenting a liver injury in a patient with a liver transplant who received an mRNA vaccine (1) and another case of liver injury and thrombocytopenia (2) associated with the COVID-19 vaccine. Lit 3 reports one case of autoimmune hepatitis after the Moderna COVID-19 vaccine. Lit 4-6 report other cases of liver damage in relation to mRNA vaccines and a possible autoimmune mechanism due to the Spike protein is discussed: "Rather, vaccine-induced immunemediated hepatitis is a known phenomenon, and other autoimmune events (e.g., AIH, ITP) have been reported following COVID vaccination. It is plausible that a similar mechanism is occurring here, whereby the host immune response directed against the COVID spike protein triggers an aberrant, autoimmune-like hepatitic condition in predisposed individuals (4)." Lit 7: "As the spike protein believed to be responsible for autoimmunity is the same used in vaccines, ther is physiological feasibility for an association between COVID-19 vaccines and autoimmune conditions." As knowledge currently stands, in the absence of a clear cause of the patient's hepatitis and given the above data, we cannot rule out the fact that the vaccine may have contributed to the hepatitis in the patient in question. Accordingly we considered the causal link as likely.	[redacted]	3003188	Prior to Review Period	mRNA-1273
		Regulatory Authority	Hepatitis acute	Serious	66	Male	0	not AIH (coding error)	Unlikely	Alcolic Hepatitis	0	0		3001939 Moderna/Lonza	Prior to Review Period	mRNA-1273
	UNITED STATES	Regulatory Authority	Acute hepatic failure	Serious	31	Female	Drug hypersensitivity; Drug hypersensitivity; Type 1 diabetes mellitus(C); Endometriosis(C); Hypothyroidism(C)	not AIH	Unassessable	diabetes type 1?	LEVEMIR	0		048F21A	Prior to Review Period	mRNA-1273
		Regulatory Authority	Hepatitis fulminant	Serious	53	Female	COVID-19(H)	not AIH	Unassessable	COVID 19	0	0		0	Prior to Review Period	mRNA-1273
	ITALY	Regulatory Authority	Acute kidney injury, Cough, Disseminated intravascular coagulation, Hepatitis acute, Pyrexia, Systemic inflammatory response syndrome	Serious	69	Male	0	not AIH	Unlikely	DIC, renal failure	CLARITHROMYCIN	0		214019	Prior to Review Period	mRNA-1273
		Regulatory Authority	Autoimmune hepatitis	Serious	73	Female	Hypertension(C); Sleep apnoea syndrome(C); Dyslipidaemia(C)	not AIH	Possible	dyslipidemia, HCTZ	INNOVAIR; CANDESARTAN HYDROCHLOROTHIAZIDE ACTAVIS	Description of adverse reaction progress, diseases and other relevant information: The patient		3001653	Prior to Review Period	mRNA-1273
		Literature-Non Study	Drug-induced liver injury	Serious	60	Male	0	not AIH	Unlikely	none reported	0	The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. Suspected drug-induced liver disorder due to vaccination.		0	Prior to Review Period	mRNA-1273
		Literature-Non Study	Autoimmune hepatitis, Influenza like illness, Intentional dose omission, Malaise	Serious	56	Female	0	AIH	Possible	yes, statins	ROSUVASTATIN	0		0	Prior to Review Period	mRNA-1273
		Regulatory Authority	Autoimmune hepatitis	Non Serious	36	Male	Gastrooesophageal reflux disease(C); Anxiety(H); Stress(C); Arthralgia(C); Orthopaedic procedure; Refraction disorder(H); Body mass index increased(H); Seborrhoeic dermatitis(H); Dermatitis atopic(H); Seizure(H); Major depression(H); Sinusitis(H); Paranasal cyst(H); Dyslipidaemia(C); Glucose tolerance impaired(C); Sleep apnoea syndrome(C); Hepatic steatosis(H)	not AIH	Possible	diclofenac	CLONAZEPAM; DICLOFENAC SODIUM	0		0	Prior to Review Period	mRNA-1273
	UNITED STATES	Regulatory Authority	Asthenia, Atelectasis, Back pain, Chest pain, Condition aggravated, COVID-19, Cyanosis, Disseminated intravascular coagulation, Dyspnoea, Dysstasia, Enterococcal bacteraemia, Fluid intake reduced, Hepatic failure, Hyperventilation, Illness, Immunisation reaction, Impaired self-care, Influenza, Lung infiltration, Oropharyngeal pain, Pain, Painful respiration, Pneumonia, Pseudomonal bacteraemia, Pyrexia, Renal failure, Respiratory arrest, Respiratory failur Respiratory tract congestion, Thrombotic thrombocytopenic purpura	Serious	55	Female	Depression(C); Rheumatoid arthritis(C); Overweight(H)	not AIH	Unlikely	COVID19, DIC, multi organ failure	BUPROPION; HYDROXYCHLOROQUINE	0		003C21A	Prior to Review Period	mRNA-1273
	UNITED STATES	Spontaneous	Chills, Headache, Illness, Immunisation reaction, Liver injury, Lymphopenia, Nausea, Pyrexia	Serious	66	Female	0	not AIH	Unassessable	None reported	0	0		939904	Prior to Review Period	mRNA-1273
		Regulatory Authority	Autoimmune hepatitis	Serious	52	Male	0	not AIH	Possible	none reported	0	0		0	Prior to Review Period	mRNA-1273
		Regulatory Authority	Abdominal symptom, Blood pressure increased, Diarrhoea, Hepatic enzyme abnormal, Influenza like illness, Liver injury, Musculoskeletal discomfort, Parosmia, Taste disorder	Serious	40	Female	Drug hypersensitivity; Rubber sensitivity; Drug hypersensitivity; Food allergy; Fibromyalgia(C); Endometriosis(C); Hemiplegic migraine(C); Hyperhomocysteinaemia(H)	not AIH	Unassessable	ILI, other symptoms	TOPAMAX; CYMBALTA; FLEXERIL [CEFIXIME]; ASPIRIN [ACETYLSALICYLIC ACID]; PEPCID [FAMOTIDINE]	0		0	Prior to Review Period	mRNA-1273

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[redacted]		Literature-Non Study	Autoimmune hepatitis	Serious	52	Female	0	AIH	Conditional	none reported except no background of autoimmunity	0	0	[redacted]	0	Prior to Review Period	mRNA-1273
		Regulatory Authority	Autoimmune hepatitis	Serious	64	Male	Thyroidectomy	not AIH	Possible	No	LEVOTHYROX	0		214011	Prior to Review Period	mRNA-1273
		Literature-Non Study	Autoimmune hepatitis	Serious	65	Female	Polycythaemia vera(H)	AIH	Possible	yes, polycythemia is involved in thrombosis Budd Chiari leading to liver failure which was not the clinical presentation here	ACETYLSALICYLIC ACID; SERTRALINE; ESOMEPRAZOLE	0		0	Prior to Review Period	mRNA-1273
	GERMANY	Regulatory Authority	Autoimmune hepatitis	Serious	77	Male	0	not AIH	Unlikely	None reported	0	Do you or the person affected have any known allergies? If yes which? No. Information on risk factors or pre-existingconditions: depression, dementia, arterial hypertension, hyperlipoproteinemia/ on 30-Jul-2021 1st Spikevax vaccination On 04-Aug-2021, start of the performance status reduction with general weakness. On 09-Aug onset of jaundice and on 14-Aug hospitalization with initial diagnosis of hepatitis, which was subsequently classified as autoimmune hepatitis. Initially very high transaminases and very high bilirubin. Start of therapy with prednisolone and then azathioprine. Then development of transient cytopenia with improvement again except for persistent leukopenia (2.5) upon reduction of the azathioprine dose. Liver values incl. bilirubin showed a trend to improvement. Ultimately, however, progressive deterioration of the performance status, ultimately with lethal outcome on 10/11/2021. The doctor who performed the 2nd post-mortem examination also considered the Spikevax vaccination to be causative and subsequently reported it as an unnatural death.		3004217	Prior to Review Period	mRNA-1273
		Literature-Non Study	Immune-mediated hepatitis, Inappropriate schedule of product administration	Serious	47	Male	Alcohol use(C)	AIH or DILI	Possible	No medical history reported - According to authors patient completely well	0	0		0	Prior to Review Period	mRNA-1273
		Regulatory Authority	Autoimmune hepatitis, Blood test, Liver function test	Serious	64	Male	Drug hypersensitivity; Drug hypersensitivity; Drug hypersensitivity; Asthma(C)	not AIH	Possible	No	0	0		0	Prior to Review Period	mRNA-1273
	UNITED STATES	Regulatory Authority	Arthropathy, Cardiac failure, Death, Fall, Gait disturbance, Head injury, Hepatic failure, Loss of consciousness, Renal failure, Syncope, Walking aid user, Wheelchair user	Serious	63	Male	0	not AIH	Unlikely	Multiorgan failure	0	0		012M20A; 029A21A	Prior to Review Period	mRNA-1273
		Regulatory Authority	Ammonia increased, Anti-thyroid antibody increased, Autoimmune thyroiditis, Axillary pain, Blood glucose increased, Blood iron, Blood lactic acid, Blood thyroid stimulating hormone increased, Chest X-ray, Colonoscopy normal, Confusional state, Diabetes mellitus, Fatigue, Full blood count, Glycosylated haemoglobin increased, Hepatitis acute, Hyperammonaemia, Hypersomnia, Lethargy, Liver function test increased, Metabolic function test, Oesophagogastroduodenoscopy normal, Positron emission tomogram normal, Procalcitonin, SARS-CoV-2 test, Serum ferritin, Viral test negative, Vitamin B12	Serious	67	Female	Drug hypersensitivity; Hypertension(C); Squamous cell carcinoma of lung(C); Chronic obstructive pulmonary disease(C); Intervertebral disc disorder(C); Gastrooesophageal reflux disease(H)	not AIH	Possible	Underlying conditions	0	0		050E21A; 039901	Prior to Review Period	mRNA-1273
	UNITED STATES	Regulatory Authority	Deafness, Death, Dizziness, Hepatic failure, Laboratory test, Renal failure, Vertigo	Serious	73	Male	Diabetes mellitus(H)	not AIH	Unassessable	renal failure	0	0		0	Prior to Review Period	mRNA-1273
		Spontaneous	Immune-mediated hepatic disorder	Serious	66	Male	Hepatic cirrhosis(C)	not AIH	Unassessable	Cirrhosis	0	0		042L20A	Prior to Review Period	mRNA-1273
		Regulatory Authority	Cholecystitis acute, Cholelithiasis, Hepatocellular injury	Serious	85	Female	JANSSEN COVID-19 VACCINE	not AIH	Unassessable	Cosuspect Jansen vaccine	COVID-19 VACCINE JANSSEN	0		305789	Prior to Review Period	mRNA-1273
		Regulatory Authority	Hepatocellular injury	Serious	56	Male	0	Not AIH	Unassessable	RA, dermatitis	0	0		3002919	Prior to Review Period	mRNA-1273
	GERMANY	Regulatory Authority	Autoimmune hepatitis	Serious	77	Male	Dementia(H); Lipid metabolism disorder(H); Hypertonia(H)	not AIH	Unlikely	None reported	0	Start of complaints with jaundice and AZ reduction on 04.08.2021, hospitalization and diagnosis (autoimmune) hepatitis, therapy with prednisolone and azathioprine. In the course of slow liver value improvement but clinical deterioration with exitus letalis on 11.10.2021.		3004217	Prior to Review Period	mRNA-1273
		Regulatory Authority	Autoimmune hepatitis, Hepatitis	Serious	60	Female	Autoimmune thyroiditis(C)	not AIH	Possible	Hashimoto thus autoimmune susceptibility	LEVOTHYROXINE SODIUM; LEVOTHYROXINE SODIUM	0		3002543	Prior to Review Period	mRNA-1273
		Regulatory Authority	Cholestasis, Fatigue, Hepatotoxicity, Pruritus	Serious	96	Female	Nephrectomy(H)	not AIH	Unassessable	Age, 1 kidney	0	0		0	Prior to Review Period	mRNA-1273
		Spontaneous	Back pain, Chest pain, Diplopia, Dizziness, Liver injury, Myopericarditis, Nausea, Vomiting	Serious	0.00	Female	0	not AIH	Unassessable	Myocarditis event	0	0		3002187	Prior to Review Period	mRNA-1273
	TAIWAN, PROVINCE OF CHINA	Regulatory Authority	Abdominal pain, Hepatic failure	Serious	65	Male	0	not AIH	Unlikely	sepsis, MI, chronic liver disease	0	0		0	Prior to Review Period	mRNA-1273

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[redacted]		Regulatory Authority	Biopsy liver abnormal, Erythema, Hepatic enzyme increased, Inflammation, Liver injury, Skin lesion	Serious	49	Female	Anxiety(C); Gastrooesophageal reflux disease(C); Depression(C); Osteoarthritis(C); Rheumatoid arthritis(C); Intervertebral disc degeneration(H); Drug hypersensitivity; Drug hypersensitivity; Drug hypersensitivity; Sensitive skin; Dermatitis contact	not AIH	Unlikely	RA, dermatitis	0	0	[redacted]	032B21A; 026A211A	Prior to Review Period	mRNA-1273
		Regulatory Authority	Abdominal pain, Acute kidney injury, Acute myocardial infarction, Alanine aminotransferase increased, Aspartate aminotransferase increased, Autoimmune hepatitis, Blood bilirubin, Blood lactic acid normal, Diarrhoea, Hypophagia, Liver function test increased, Troponin increased	Serious	80	Female	Atrial fibrillation(H); Anxiety(H); Arthritis(H); Back pain(H); Coronary artery disease(H); Neoplasm malignant(C); Cardiomyopathy(H); Carotid artery stenosis(H); Cardiac failure congestive(C); Chronic obstructive pulmonary disease(C); Depression(H); Dyslipidaemia(H); Myocardial infarction(C); Hypertension(C); Thyroiditis(H); Tobacco abuse(H); Drug hypersensitivity; Drug hypersensitivity; Drug hypersensitivity	not AIH	Unlikely	Multi organ diseases	0	0		065F21A	Prior to Review Period	mRNA-1273
		Regulatory Authority	Arthralgia, Blood test normal, Computerised tomogram abnormal, Headache, Hepatic failure, Hepatic steatosis, Impaired work ability, Musculoskeletal chest pain, Pyrexia, Sleep disorder, Ultrasound scan normal	Serious	44	Female	Asthma(C)	not AIH	Unlikely	No	0	0		038K20A	Prior to Review Period	mRNA-1273
	JAPAN	Regulatory Authority	Acute hepatic failure, Cardio-respiratory arrest, Circulatory collapse, Hepatic function abnormal, Pyrexia, Upper gastrointestinal haemorrhage	Serious	41	Male	Hepatic function abnormal(C); Diabetes mellitus(C); Lymphoma(C)	not AIH	Possible	digestive hemorrhagia	METFORMIN HYDROCHLORIDE	It was not possible to identify the cause of acute progression o hepatic function disorder by examinations including viral testi and it is also uncertain whether the event had a causal relationship with the vaccine. The association with adverse events cannot be assessed. Hepatic function disorder may have worsened after the administration, and the onset of adverse events is temporally related to the timing of administration of this vaccine. See "narrative" section		3005685; 3005236	Prior to Review Period	mRNA-1273
	[redacted]	Regulatory Authority	Acute left ventricular failure, Asthenia, Atrial fibrillation, Chest X-ray normal, Chronic left ventricular failure, Condition aggravated, COVID-19, Dyspnoea, Echocardiogram normal, Ejection fraction normal, Faeces discoloured, Haemoglobin normal, Hepatocellular injury, Impaired self-care, Liver function test decreased, Melaena, Oedema, Pulmonary hypertension, Respiratory failure, SARS-CoV-2 test positive, Transaminases increased, Ultrasound abdomen abnormal	Serious	75	Female	Allergy to chemicals; Obstructive sleep apnoea syndrome(H); Dyspnoea exertional(C); Pulmonary mass(H); Obstructive airways disorder(C); Rhinitis(H); Acute respiratory failure(C); Essential hypertension(C); Peripheral venous disease(H); Supraventricular extrasystoles(H); Atrial fibrillation(C); Left ventricular failure(C); Atrial fibrillation(C); Obesity(H); Gastrooesophageal reflux disease(H); Hepatomegaly(H); Irritable bowel syndrome(H); Diarrhoea(H); Arthritis(C); Diverticulitis(C); COVID-19(C); Myelodysplastic syndrome(C); Glaucoma(H); Kidney duplex(C); Urinary incontinence(H); Goitre(C); Glucose tolerance impaired(C); Periodic limb movement disorder(H); Generalised anxiety disorder(C); Large intestine polyp(H); Dysphonia(H); Visual field defect(H); Oedema peripheral(H); Insomnia(H); Pelvic mass(H); Vertigo(H); Anaemia macrocytic(C); Balance disorder(H)	not AIH	Unlikely	COVID and multi organ impairment	0	0		038K20A	Prior to Review Period	mRNA-1273
	UNITED STATES	Spontaneous	Extra dose administered, Hepatic failure	Serious	0.00	Female	Liver disorder(C)	not AIH	Unassessable	No	0	0		0	Prior to Review Period	mRNA-1273
		Regulatory Authority	Autoimmune hepatitis, Chest pain, Cholangitis sclerosing, Dyspnoea, Liver function test abnormal, Palpitations, Pericarditis, Systemic lupus erythematosus	Serious	58	Female	Systemic lupus erythematosus(C); Osteoporosis(C); Crohn's disease(C); Upper limb fracture(H)	not AIH (unassessable)	Possible	Ulcerative colitis, SLE	ACLASTA	0		3001650-031021; 3001942	Prior to Review Period	mRNA-1273
		Regulatory Authority	Autoimmune hepatitis	Serious	61	Female	Autoimmune hepatitis(C); SPIKEVAX(H)	not AIH	Possible	AIH	0	0		0	Prior to Review Period	mRNA-1273
		Regulatory Authority	Abdominal pain, Asthenia, Chromaturia, Decreased appetite, Hepatitis acute	Serious	30	Female	Autoimmune thyroiditis(C); COVID-19(H); SPIKEVAX	not AIH	Possible	COVID, autoimmune thyroiditis	0	Hepatitis of an autoimmune nature in a predisposed patient, in need of hospitalization and monitoring, presented frankly abou a month after the second dose of the anticovid 19 Moderna vaccine. The parameters are currently improving. The biopsy identified aggressive chronic hepatitis but monitoring over tim is required to establisb its chronic character.		0	Prior to Review Period	mRNA-1273
		Regulatory Authority	Liver injury, Pyrexia	Serious	56	Male	Suspected COVID-19(C)	not AIH	Unlikely	COVID19, Vaxzevria	COVID-19 VACCINE ASTRAZENECA	0		3004732	Prior to Review Period	mRNA-1273
		Regulatory Authority	Antinuclear antibody increased, Autoimmune disorder, Autoimmune hepatitis, Cryoglobulins present, Cytomegalovirus test positive, Epstein-Barr virus test positive, Hepatic enzyme increased, Metabolic function test, Palpitations	Non Serious	49	Female	Mixed connective tissue disease(C); Sjogren's syndrome(C); Thyroid disorder(C)	not AIH	Possible	Infections	0	0		025A21A	Prior to Review Period	mRNA-1273
		Regulatory Authority	Acute hepatic failure, Fatigue, Pyrexia, Thrombocytopenia	Serious	55	Male	Immunodeficiency(H); Tobacco user(H); NEBIVOLOL(H); ATORVASTATIN(H); (H); Angina pectoris(C); Suspected COVID-19(C)	not AIH	Unlikely	Alcohol, COVID19	0	0		0	Prior to Review Period	mRNA-1273

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[redacted]		Regulatory Authority	Alanine aminotransferase increased, Aspartat aminotransferase increased, Autoimmune hepatitis, Blood alkaline phosphatase increased, Blood bilirubin increased, Jaundice, Liver function test increased	Serious	72	Female	Drug hypersensitivity; Dementia(C); Urina tract infection(C)	not AIH	Unassessable	No	0	0	[redacted]	0	Prior to Review Period	mRNA-1273
		Regulatory Authority	Autoimmune hepatitis	Serious	57	Male	Gluten sensitivity(C); Seasonal allergy	not AIH	Unassessable	No	0	Trigger of autoimmune hepatitis The case is serious and unlabelled. Due to temporal relationshi and the known safety profile of the vaccine the causality is assessed as possible.		3002912	Prior to Review Period	mRNA-1273
		Regulatory Authority	Autoimmune hepatitis	Serious	36	Female	0	not AIH	Conditional	Ulcerative colitis; PSC	0	0		0	Review Period	mRNA-1273
		Regulatory Authority	Aggression, Arthritis, Chills, Diarrhoea, Dizziness, Dyspnoea, Fatigue, Headache, Hyperhidrosis, Liver injury, Lymphadenopathy, Malaise, Mood swings, Myalgia, Nausea, Pyrexia, Rash, Vaccination site erythema, Vaccination site pain, Vomiting	Serious	32	Male	Hyperhidrosis(C); Depression(C); Panic attack(C)	not AIH	Unassessable		DIAZEPAM; DITROPAN; SL B12	0		3005697	Review Period	mRNA-1273
		Spontaneous	Hepatitis, Liver injury	Serious	0.00	Male	0	not AIH	Unassessable		0	0		0	Review Period	mRNA-1273
		Regulatory Authority	Autoimmune hepatitis, Transaminases increased	Serious	81	Female	0	not AIH	Unlikely	s/p thyroidectomy; breast cancer receiving trastuzumab, pertuzumab, anastrozole	[redacted] TIROSINT	EX-SMOKER, EX-METAL MECHANICS, TOTAL THYROIDECTOMY FOR TOXIC MULTINODULAR GOITER (IN 2015) .IN 1996 K INFILTRATING DUCTAL BREAST. IN 2020 BRAIN, HEPATIC AND BONE SECONDARY ILLNESSES. suspected adverse reactions during triple oncology therapy started after administration of the second dose of comirnaty. hepatologist report is attached		3001941	Review Period	mRNA-1273
		Regulatory Authority	Autoimmune hepatitis	Serious	79	Female	Oophorectomy; Iron deficiency anaemia(H); Hypertension(C); Acute myocardial infarction(H); Mitral valve incompetence(H); Depression(H); Hypothyroidism(C); Cholecystitis acute(H) Type 2 diabetes mellitus(C)	not AIH	Possible	Cholecystitis	EMPAGLIFLOZIN	0		0	Review Period	mRNA-1273
		Spontaneous	Autoimmune hepatitis, Fatigue, Inappropriate schedule of product administration, Pyrexia	Serious	32	Male	BBIBP-CORV; BBIBP-CORV	not AIH	Possible	Sinopharm x2	0	0		0	Review Period	mRNA-1273
		Regulatory Authority	Autoimmune hepatitis, Hypertransaminasaemia	Serious	26	Male	0	Not AIH	Probable		0	The patient was only taking multivitamin supplements, maltoestrins and branched amino acids taken from time to time for years, this intake was discontinued in luglio 2021. Occurrence of acute autoimmune hepatitis arising after II administration of Moderna vaccine.		3004498	Review Period	mRNA-1273
		Regulatory Authority	Hepatitis acute, Jaundice	Serious	30	Female	0	not AIH	Probable		0	Updated on 12/01/2022: contacted the reporting physician who provides the attached brief clinical report.		3005687	Review Period	mRNA-1273
	GERMANY	Regulatory Authority	Coagulopathy, COVID-19, Hepatic failure, Multiple organ dysfunction syndrome, Shock haemorrhagic, Thrombocytopenia	Serious	69	Female	COVID-19(C); VAXZEVRIA; COMIRNATY	not AIH	Unlikely	Multiple types of prior covid vaccines; SARS-COV-2 infection	0	0		000105A	Review Period	mRNA-1273
		Regulatory Authority	Liver injury	Serious	64	Female	Psoriatic arthropathy(C); Rheumatoid arthritis(C)	not AIH	Possible	Prior covid vaccine with another product; psoriatic arthritis; rheumatoid arthritis; sekinumab	OMEPRAZOLE; SECUKINUMAB	0		000022A	Review Period	mRNA-1273
		Regulatory Authority	Hepatocellular injury, Influenza like illness, Jaundice	Serious	48	Male	Gastrooesophageal reflux disease(C)	not AIH	Unassessable		0	0		0	Review Period	mRNA-1273
		Regulatory Authority	Acute hepatic failure, Asthenia, Decreased appetite, Hepatic encephalopathy, Hepatitis fulminant, Pyrexia, Rectal haemorrhage, Vomiting	Serious	46	Female	Breast cancer(H)	not AIH	Possible	on liver transplant list; breast cancer	0	0		3005698	Review Period	mRNA-1273
		Regulatory Authority	Fatigue, Jaundice, Liver injury, Somnolence	Serious	48	Female	Obesity(C); Hypertension(C); VAXZEVRIA; VAXZEVRIA	not AIH	Possible	Prior vaccination x2 with Vaxzevria	0	0		3005697	Review Period	mRNA-1273
		Regulatory Authority	Abdominal pain, Liver injury	Serious	44	Female	Drug hypersensitivity; Behcet's syndrome(H)	not AIH	Possible	Behcet's syndrome	0	0		214011	Review Period	mRNA-1273
		Regulatory Authority	Hepatitis acute	Serious	24	Male	0	not AIH	Unassessable		0	Statistic hospital stay required hepatitis of unclear etiology infection: stat.locked out none exclude liver biopsy, as improvement		0	Review Period	mRNA-1273
		Regulatory Authority	Autoimmune hepatitis	Non Serious	20	Female	VAXZEVRIA	not AIH	Unassessable	Vaxzevria x1	0	0		0	Review Period	mRNA-1273
		Regulatory Authority	Ascites, COVID-19, Hepatitis acute	Serious	49	Male	Alcoholic(H)	not AIH	Unlikely	Alcoholism	0	Do not present vaccination data (as soon as they are available they will be entered in RNF)		0	Review Period	mRNA-1273
		Regulatory Authority	Acute hepatic failure, Autoinflammatory disease, Haemophagocytic lymphohistiocytosis	Serious	0.00	Male	0	not AIH	Conditional	Bronchial asthma	0	0		0	Review Period	mRNA-1273
		Regulatory Authority	Application site erythema, Application site swelling, Liver injury, Sepsis	Serious	50	Female	Overweight(C)	not AIH	Conditional		0	[redacted]omment: Follow-up information has been requested		0	Review Period	mRNA-1273
	THAILAND	Spontaneous	Aplastic anaemia, Circulatory collapse, Decreased immune responsiveness, Febrile neutropenia, Haemoptysis, Hepatic failure, Klebsiella sepsis, Renal failure, Wound haemorrhage	Serious	50	Female	CORONAVAC; CORONAVAC; PFIZER BIONTECH COVID-19 VACCINE	not AIH	Conditional	Prior immunization with Sinovac x2 and Pfizer	0	0		049F21A	Review Period	mRNA-1273

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[redacted]	[redacted]	Spontaneous	Arthralgia, Hepatitis acute	Serious	37	Male	Gastrooesophageal reflux disease(H)	not AIH	Probable	prior infection with EB virus	0	The patient had liver disorder, which was triggered by jaundice 18 days after receiving this vaccine and 6 days after receiving vonoprazan fumarate. Since other factors were negative on examination, the diagnosis of exclusion was made, and the adverse events and the vaccine administration were considered temporally related. See "narrative" section The events developed after the administration of ELASOMERAN and there is temporal relationship.	[redacted]	[redacted]004734	Review Period	mRNA-1273
		Regulatory Authority	Chest pain, Dizziness, Dyspnoea, Fatigue, Liver injury, Migraine, Palpitations, Pyrexia, Tachycardia	Serious	26	Male	Illness(H)	not AIH	Unassessable		0	0		[redacted]	Review Period	mRNA-1273
		Regulatory Authority	Autoimmune hepatitis, Hepatitis A	Serious	43	Male	Suspected COVID-19(H)	not AIH	Unassessable		0	0		[redacted]	Review Period	mRNA-1273
		Literature-Non Study	Autoimmune hepatitis	Serious	73	Female	0	AIH	Probable		0	0		[redacted]	Review Period	mRNA-1273
		Regulatory Authority	Autoimmune hepatitis, Hepatic enzyme increased	Serious	59	Female	0	not AIH	Probable		0	Information on risk factors or pre-existing conditions reported as none of the liver autoimmune disease caused by vaccination After the second dose, the values increased even more. 6 months after vaccination, they drop slightly.		[redacted]002183	Review Period	mRNA-1273
		Regulatory Authority	Autoimmune hepatitis	Serious	0.00	Unknown	0	not AIH	Possible		Moderna CoviD-19 Vaccine	0		[redacted]002332	Review Period	mRNA-1273
	JAPAN	Spontaneous	Acute hepatic failure, Cardio-respiratory arrest, Circulatory collapse, Coagulopathy, Hepatitis fulminant, Livedo reticularis, Metabolic acidosis, Myocarditis, Renal disorder	Serious	63	Male	0	not AIH	Probable		0	The patient who had no appreciable medical history experienced worsening of the general condition from the following day of vaccination, leading to metabolic acidosis, renal disorder, and coagulation disorder in several days, eventually resulted in cardiopulmonary arrest. The events developed after the administration of ELASOMERAN and there is temporal relationship.		[redacted]	Review Period	mRNA-1273
		Regulatory Authority	COVID-19 immunisation, Hepatitis acute	Serious	42	Female	COVID-19 immunisation; COVID-19 immunisation	not AIH	Possible	Vaxzevria x2	0	0		[redacted]214029	Review Period	mRNA-1273
		Regulatory Authority	Autoimmune hepatitis	Non Serious	65	Female	0	not AIH	Possibe	Breast cancer; rheumatism	0	0		[redacted]LOT [redacted]004951	Review Period	mRNA-1273
		Regulatory Authority	Hepatitis acute	Serious	24	Male	0	not AIH	Possible		0	0		[redacted]214020	Review Period	mRNA-1273
		Spontaneous	Hepatic failure, Hepatic steatosis	Serious	39	Male	Food allergy; Glucose tolerance impaired(C)	not AIH	Conditional	Unspecified problem with glucose	PLONASB [FLUTICASONE PROPIONATE]; HYOSCYAMINE; TUMS [CALCIUM CARBONATE;MAGNESIUM CARBONATE;MAGNESIUM CARBONATE;MAGNESIUM TRISILICATE]; PEPCID [ALUMINIUM HYDROXIDE GEL, DRIED;MAGNESIUM CARBONATE]; [redacted] [OMEPRAZOLE]	0		[redacted]	Review Period	mRNA-1273
		Regulatory Authority	Autoimmune hepatitis	Serious	52	Male	Seasonal allergy(C)	not AIH	Possible		0	0		[redacted]000110A	Review Period	mRNA-1273
		Regulatory Authority	Ascites, Autoimmune hepatitis, Computerised tomogram abnormal, Laboratory test, Ultrasound scan abnormal	Serious	82	Female	Gammopathy(C); Cardiac failure(H); Cardiac resynchronisation therapy(C); Lymphoma(C); Chemotherapy; Plasma cell myeloma(C)	not AIH	Possible	Gammopathy heart failure; chemotherapy s/p lymphoma with myeloma ongoing	0	0		[redacted]216044	Review Period	mRNA-1273
		Regulatory Authority	Ascites, Autoimmune hepatitis, Computerised tomogram abnormal, Laboratory test, Ultrasound scan abnormal	Serious	82	Female	Gammopathy(C); Cardiac failure(C); Cardiac resynchronisation therapy; Lymphoma(C); Chemotherapy; Plasma cell myeloma(C)	not AIH	#N/A		0	0		[redacted]216044	Review Period	mRNA-1273
		Regulatory Authority	Autoimmune hepatitis, Influenza	Non Serious	45	Male	Hypertension(H)	not AIH	Conditional	Comirnaty as 3rd vaccine	0	0		[redacted]	Review Period	mRNA-1273
		Regulatory Authority	Asthenia, Hepatocellular injury, Pyrexia	Serious	75	Female	Diabetes mellitus(C); Bipolar disorder(C); Hypercholesterolaemia(C); METFORMIN(H)	not AIH	Conditional	Type 2 diabetes mellitus	0	0		[redacted]	Review Period	mRNA-1273
		Regulatory Authority	Autoimmune hepatitis, COVID-19 immunisation, Rash	Serious	81	Female	COVID-19 immunisation(H); COVID-19 immunisation(H); Atrial fibrillation(C); Cerebrovascular accident(H); Hypertension(C); COVID-19 immunisation(H)	not AIH	Possible	Comirnaty doses 1, 2, 3; atorvastatin	LIPITOR; KALCIPOS-D; BETOLVEX [CYANOCOBALAMIN ZINC TANNATE]; ZOLEDRONIC ACID Z; [redacted]	0		[redacted]006270	Review Period	mRNA-1273
		Regulatory Authority	Asthenia, Cellulitis, COVID-19, Diarrhoea, Fatigue, Hepatic function abnormal, Liver injury, Malaise, Nausea, Pain, Rash, Renal impairment, Renal injury, Tremor, Vomiting	Serious	49	Female	Suspected COVID-19(H); Chronic kidney disease(H); Hepatic steatosis(H)	not AIH	Unlikely	chronic renal injury; fatty liver; prior covid infection; mixed vaccines	COVID-19 VACCINE ASTRAZENECA; COVID-19 VACCINE ASTRAZENECA; FENTANYL	0		[redacted]005237	Review Period	mRNA-1273
		Regulatory Authority	Autoimmune hepatitis, Condition aggravated	Serious	37	Female	Autoimmune hepatitis(C); Systemic lupus erythematosus(C)	not AIH	Possible	autoimmune hepatitis; disseminated lupus erythramatosus; mixed vaccine	COMIRNATY	0		[redacted]	Review Period	mRNA-1273

Case ID	Country	Report Type	ALL PT'S	Case Seriousness	Patient Age (Years)	Patient Gender	Medical History	EASL	WHO	Confounders	Concomitant Medications	MAH Comment	WW Identifier	Batch/Lot Number	RP	Generic Name
[redacted]	[redacted]	Spontaneous	Autoimmune hepatitis, Inappropriate schedul of product administration	Serious	57	Female	Hypertension(C); Seizure(C); Drug hypersensitivity; Dermatitis atopic; SHINGRIX	not AIH	Probable	atopic dermatitis	0	0	[redacted]	002F21A; 047621A	Review Period	mRNA-1273
		Spontaneous	Drug-induced liver injury	Serious	60	Female	0	not AIH	Conditional		0	The event developed after the administration of ELASOMERAN and there is temporal relationship. The vaccine recipient did not have any disease or take any medication, so this case is considered to have been caused by this vaccine.		0	Review Period	mRNA-1273
		Regulatory Authority	Hepatitis acute, Nausea	Serious	24	Female	0	not AIH	Conditional		0	0		0	Review Period	mRNA-1273
		Regulatory Authority	Autoimmune hepatitis	Serious	42	Female	Hypothyroidism(C); Subarachnoid haemorrhage(H); Adjustment disorder(H); COMIRNATY; COMIRNATY	not AIH	Possible	Comirnaty x2; hypothyroidism	0	0		000125A	Review Period	mRNA-1273
		Spontaneous	Hepatotoxicity, Pain in extremity	Serious	69	Male	Glioblastoma(C); Tumour excision; Chemotherapy	not AIH	Possible	glioblastoma; chemotherapy	0	0		056M21A; 033F21A; 032B21A; 048A21A	Review Period	mRNA-1273
		Literature-Non Study	Asthenia, Drug interaction, Drug-induced liv injury, Dysuria, Fall, Pyrexia	Serious	77	Male	Dementia(C); Osteoarthritis(C); Neuropath peripheral(H); Fall(C); ENOXAPARIN(H)	not AIH	Possible	enoxaparin; acetaminophen	0	0		0	Review Period	mRNA-1273

Appendix 11.21b Autoimmune Hepatitis: Cumulative Cases with WHO Causality and Confounders-Case narratives

Case ID	Narrative (Complete)
[redacted]	A Regulatory authority report [redacted] was received from other health professional, concerning a 74-year-old, female patient , who received Moderna's COVID-19 vaccine(mRNA-1273) and experienced acute hepatic failure and acute kidney failure . The patient's medical history included allergy to sesame , cirrhosis , congestive heart failure , diabetes, and autoimmune hepatitis. Concomitant medication history was not provided. On 06 Feb 2021, prior to the onset of events the patient received their first of two planned doses of mRNA-1273(Lot/batch: 012L20A) intramuscularly in the right arm for prophylaxis of COVID-19 infection. On 08 Feb 2021, the patient experienced acute liver failure and acute kidney failure and patient was hospitalized .Abnormal liver function test and renal function test labs eported. No treatment information was provided . Action taken with mRNA-1273 in response to the events was not applicable . At the time of the report , the patient was continuing hospitalization and outcome of the events were not recovered .
[redacted]	A spontaneous report [redacted] was received from a health care professional concerning a 85-year-old, male patient who received Moderna's COVID-19 Vaccine (mRNA-1273) and developed Acute liver failure and hepatic enzymes increased The patient's medical history was not provided. Products known to have been used by the patient, within two weeks prior to the event, was not reported. On unknown date in Feb 2021, the patient received their second of two planned doses of mRNA-1273 (Lot unknown) intramuscularly for prophylaxis of COVID-19 infection. On 27 Feb 2021, the patient was hospitalized for 2-3 days (approximate date of admission on 27 February 2021 and date of discharge on 1 March 2021) . Reason for hospitalization is secondary to acute liver dysfunction with laboratory evidence of elevated liver enzymes. Treatment for the event was not reported. Action taken with mRNA-1273 in response to the event was not applicable The outcome of the event's, reported were considered unknown. .

Case ID	Narrative (Complete)
[redacted]	This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of AUTOIMMUNE HEPATITIS (autoimmune hepatitis is triggered) and CONDITION AGGRAVATED (autoimmune hepatitis is triggered/might have triggered the reactivation of the autoimmune hepatitis) in a 73-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 631L20A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Surgery (unspecified.). Previously administered products included for Autoimmune hepatitis: prednisone from 2016 to 2017; for an unreported indication: SHINGRIX. Concurrent medical conditions included Autoimmune disorder NOS (Patient reported autoimmune diseases and had autoimmune hepatitis in the past, 2017 last one.), Autoimmune hepatitis (underwent prednisone treatment for about a year to get it back into remission.) since 05-May-2016, Hepatitis B (contracted Hep B and C in 1979 from FFP for surgery) since 05-Apr-1979, Hepatitis C since 05-Apr-1979, Acute liver failure (In remission 3.5 years. Within 2 weeks of 1st vaccine dose, liver enzymes went from normal to very high,) since 05-May-2016 and Thyroiditis (added [redacted] medication in March, 2021) since June 2020. Concomitant products included OMEPRAZOLE for Gastroesophageal reflux disease, GABAPENTIN for Nerve pain, THYROID ([redacted] for Thyroiditis, ESTROGENS ESTERIFIED, METHYLTESTOSTERONE (ESTRATEST) for Unevaluable therapy, ZINC, CHLOROPHYLLIN COPPER COMPLEX SODIUM (B50), UBIDECARENONE, VITAMIN E NOS (COQ10 COMPLEX), COCONUT OIL and MAGNESIUM for an unknown indication. On 12-Feb-2021 at 10:00 AM, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 14-Feb-2021, the patient experienced VACCINATION SITE WARMTH (palm size red hot on my arm but way below the shot/Kind of hot and itchy), VACCINATION SITE PRURITUS (palm size red hot on my arm but way below the shot/Kind of hot and itchy) and VACCINATION SITE ERYTHEMA (palm size red hot on my arm but way below the shot/Kind of hot and itchy). 14-Feb-2021, the patient experienced VACCINATION SITE URTICARIA (welt/ large red welt). On 22-Feb-2021, the patient experienced VACCINATION SITE URTICARIA (a second large red welt lasting several days). On 02-Mar-2021, the patient experienced HEPATIC ENZYME INCREASED (liver enzyme are way out of site, very high). On 12-Mar-2021, the patient experienced INCOMPLETE COURSE OF VACCINATION (supposed to get the second dose on March 12 but my PCP warned me not to get it). On an unknown date, the patient experienced AUTOIMMUNE HEPATITIS (autoimmune hepatitis is triggered) (seriousness criterion medically significant) and CONDITION AGGRAVATED (autoimmune hepatitis is triggered/might have triggered the reactivation of the autoimmune hepatitis) (seriousness criterion medically significant). In February 2021, VACCINATION SITE ERYTHEMA (palm size red hot on my arm but way below the shot/Kind of hot and itchy) had resolved. On 16-Feb-2021, VACCINATION SITE URTICARIA (welt/ large red welt) had resolved. On 12-Mar-2021, INCOMPLETE COURSE OF VACCINATION (supposed to get the second dose on March 12 but my PCP warned me not to get it) had resolved. At the time of the report, AUTOIMMUNE HEPATITIS (autoimmune hepatitis is triggered), CONDITION AGGRAVATED (autoimmune hepatitis is triggered/might have triggered the reactivation of the autoimmune hepatitis), HEPATIC ENZYME INCREASED (liver enzyme are way out of site, very high), VACCINATION SITE WARMTH (palm size red hot on my arm but way below the shot/Kind of hot and itchy) and VACCINATION SITE PRURITUS (palm size red hot on my arm but way below the shot/Kind of hot and itchy) had not resolved and VACCINATION SITE URTICARIA (a second large red welt lasting several days) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In 2017, Hepatic enzyme: normal (normal) Summer. On 09-Dec-2020, Blood test: normal (normal) normal. In February 2021, Hepatic enzyme: normal (normal) blood work done before vaccine. On 02-Mar-2021, Blood bilirubin: normal (normal) normal. On 02-Mar-2021, Hepatic enzyme: 700 points over the highest allowed (High) and the other was 400 points over the highest allowed.. On 31-Mar-2021, Hepatic enzyme: one enzyme had increased and one had decreased (abnormal) abnormal. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter considered AUTOIMMUNE HEPATITIS (autoimmune hepatitis is triggered), CONDITION AGGRAVATED (autoimmune hepatitis is triggered/might have triggered the reactivation of the autoimmune hepatitis), HEPATIC ENZYME INCREASED (liver enzyme are way out of site, very high), VACCINATION SITE URTICARIA (a second large red welt lasting several days) and VACCINATION SITE URTICARIA (welt/ large red welt) to be possibly related. No further causality assessments were provided for VACCINATION SITE WARMTH (palm size red hot on my arm but way below the shot/Kind of hot and itchy), INCOMPLETE COURSE OF VACCINATION (supposed to get the second dose on March 12 but my PCP warned me not to get it), VACCINATION SITE PRURITUS (palm size red hot on my arm but way below the shot/Kind of hot and itchy) and VACCINATION SITE ERYTHEMA (palm size red hot on my arm but way below the shot/Kind of hot and itchy). No treatment information was provided. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Most recent FOLLOW-UP information incorporated above includes: On 01-Apr-2021: Updated patient medical history, suspect product details, concomitant medications, event details, outcome and reporter causality were added.

Case ID	Narrative (Complete)
[redacted]	A spontaneous report (United States) was received from a consumer concerning a 39-year-old, female patient, who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced heart racing, kidney failure, liver failure,vomiting and death. The patient's medical history included Sjogren's syndrome, Hashimoto's, inflammatory joint disease, osteoporosis, osteoarthritis. She has history of fractured tail bone and leg in three places. Concomitant medications included D3 2 pills a day, folic acid, B12, and calcium citrate. She was allergic to 15 different antibiotics two of which she had anaphylaxis; had huge autoimmune issues; had had reaction to Pneumovax vaccine. On an unown date ,prior to the onset of the events, the patient received their second of two planned doses of mRNA-1273 intramuscularly for prophylaxis of COVID-19 infection. Approximately after three days of receiving second dose vaccine patient experienced heart racing and went to the emergency room .The patient started vomiting and developed a kidney and liver failure. And on the next day she died.Autopsy is doing and the results are not available at the time of report. Action taken with mRNA-1273 in response to the events was reported as not applicable. The events heart racing, kidney failure, liver failure and death were considered serious and medically significant. The outcome of the events renal failure,hepatic failure,palpitations and vomiting was considered as Fatal.
[redacted]	This spontaneous report was received from a consumer (United States) via social media, who was the father of a 39-year-old female patient who experienced heart shut down (cardiac failure), kidney shut down (renal failure), liver was not functioning/liver shut down (hepatic failure), condition deteriorated (general physical heath deterioration), became less coherent (incoherent), couldn't talk (aphasia), heart was racing (palpitations), nausea, headache, vomiting, started feeling not so great (vaccine complication), and soreness at shot location (injection site pain). The patient had no known medical history. Concomitant product use was not provided. On 01-Feb-2001, one day before the onset of the events, this patient was administered their second planned dose of mRNA-1273 (Lot/Batch number: Not provided) for prophylaxis of COVID-19 infection. On 01 Feb 2021, the patient experienced soreness at shot location. That evening she started feeling "not so great." On 02-Feb-2020, the day after vaccination, She complained she was drinking lots of fluids, but was not urinating, and she had a headache and nausea. She spent 02 and 03 Feb 2021 in bed. She felt a little better on 03 Feb 2021. On 04 Feb 2021, the patient's heart began racing and she felt like she needed to get to the emergency room, for which her father took her. As soon as they arrived, she began throwing up. A blood test showed she was "very, very sick" and her liver was not functioning. She then became less coherent. On 04 Feb 2021 in the evening, she was transported to a trauma center for a liver transplant. Attempts to stabilize her for the liver transplant failed and her condition deteriorated. On the morning of 05 Feb 2021, the patient couldn't talk and her condition worsened throughout the day. Her father reported, her liver, kidney and heart shut down. At 9:00 that night, 30 hours after first arriving to the hospital, the patient passed away. Action taken with the drug in response to the events is not applicable. The patient died on 05 Feb 2021. The autopsy was performed and the results were pending at the time of this report. The outcome for the events renal failure, hepatic failure and heart failure was considered as unknown.
[redacted]	A regulatory authority report [redacted] was received from a health care professional concerning a 54 year-old, female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced abdominal pain, autoimmune hepatitis, orange urine (chromaturia) and jaundice. The patient was allergic to latex and bees. Concomitant product use included trazodone and vilazodone. On 11-JAN-2021, the patient received their first of two planned doses of mRNA-1273 (Lot number: 027L20A) intramuscularly in left arm for prophylaxis of COVID-19 infection. On 26-JAN-2021, 15 days after receiving the vaccine, the patient experienced abdominal pain, orange urine, jaundice and autoimmune hepatitis. The patient was hospitalized for approximately one week. Treatment information was not provided. Action taken with mRNA-1273 in response to the events was not applicable. The outcomes of the events, abdominal pain, autoimmune hepatitis, chromaturia and jaundice, were not resolved.

Case ID	Narrative (Complete)
[redacted]	A Regulatory Authority report [redacted] was received from other healthcare professional for a 52-year-old male patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced autoimmune hepatitis and Guillain-Barre syndrome. The patient's current conditions included alpha one antitrypsin carrier (MS prototype) and hypertension. The patient was allergic to penicillin. Concomitant product use included valaciclovir hydrochloride, olmesartan medoxomil, acetylsalicylic acid and vitamin d nos. On an unspecified date, the patient received the first of two planned doses of mRNA-1273 (Lot number 025J20A) intramuscularly for prophylaxis of COVID-19 infection. On 25-JAN-2021, the patient received the second of two planned doses of mRNA-1273 (Lot number 028L26A) intramuscularly for prophylaxis of COVID-19 infection. On 10-FEB-2021, 16 days after receiving the vaccine, the patient experienced Guillain-Barre syndrome and autoimmune hepatitis and was hospitalized. The laboratory data included lipoprotein-associated phospholipase A2 (LPx2), contrasted and un-contrasted magnetic resonance imaging (MRI) holo spine X2 and multiple blood tests. The patient was treated on day 3 with intravenous immunoglobulin (IVIG) with peripherally inserted central catheter (PICC) line and then treated for 3 days with high dose of Solumedrol(methylprednisolone) then plasmapheresis. The patient was hospitalized for 7 days. The seriousness criteria for the event's autoimmune hepatitis and Guillain-Barre syndrome was hospitalization, life-threatening and disability. Action taken with mRNA-1273 was not applicable. The outcome of the events, autoimmune hepatitis and Guillain-Barre syndrome was not recovered/ not resolved.
[redacted]	This spontaneous case was reported by a physician and describes the occurrence of HEPATITIS ACUTE (acute hepatitis) in a 63-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine). No Medical History information was reported. Concomitant medications included insulin glargine, acetylsalicylic acid, atorvastatin, and anastrozole. On 11 Mar 2021, the patient received their first dose of dose of mRNA-1273 (Moderna COVID-19 Vaccine) intramuscular (Batch number unknown). On 15-Mar-2021, the patient came in for a follow-up visit with her physician and she presented with acute hepatitis. Relevant laboratory results included aspartate aminotransferase (AST) -1900, alanine aminotransferase (ALT)- 2562, bilirubin of 3, alkaline phosphatase – 550, and mild elevation for amylase. She was admitted in the Emergency Room (ER)for 6 hours, to be accessed. For mRNA-1273 (Moderna COVID-19 Vaccine), the reporter did not provide any causality assessments. The outcome for the event of HEPATITIS ACUTE (acute hepatitis) was unknown.

Case ID	Narrative (Complete)
[redacted]	This spontaneous case was reported by a consumer and describes the occurrence of AUTOIMMUNE HEPATITIS (autoimmune hepatitis) in a 79-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 026A21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No medical history was reported. Concomitant products included HYDROXYCHLOROQUINE SULFATE (PLAQUENIL [HYDROXYCHLOROQUINE SULFATE]), CICLOSPORIN (RESTASIS), QUETIAPINE FUMARATE (SEROQUEL) and AZATHIOPRINE for an unknown indication. On 05-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 06-Mar-2021, the patient experienced PAIN (Pain in various parts of the body), SOMNOLENCE (Slept for 15 hrs a day), TINNITUS (Constant ring in the ears) and FATIGUE (Extreme fatigue). On an unknown date, the patient experienced AUTOIMMUNE HEPATITIS (autoimmune hepatitis) (seriousness criterion medically significant). On 15-Mar-2021, PAIN (Pain in various parts of the body), SOMNOLENCE (Slept for 15 hrs a day), TINNITUS (Constant ring in the ears) and FATIGUE (Extreme fatigue) had resolved. At the time of the report, AUTOIMMUNE HEPATITIS (autoimmune hepatitis) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In March 2021, SARS-CoV-2 antibody test: negative (Negative) Negative. 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. Patient 's Concomitant medications reported were PII(36):AaS6l0Skg/HfTSAD212iZdgVLaJ0VFhupdqo 10mg daily No treatment information was provided. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Most recent FOLLOW-UP information incorporated above includes: On 24-Jun-2021: Follow up received on 25-jun-2021 On 07-Jul-2021: Follow-up information received provides no new information.
[redacted]	A regulatory authority report [redacted] was received from other healthcare professional concerning a 37-year-old female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced disseminated intravascular coagulation, generalised tonic-clonic seizure, leukocytosis, liver injury, pyrexia, respiratory failure, rhabdomyolysis and shock. The patient's medical history, as provided by the reporter, included depakote phenobarbital allergy, tuberous sclerosis complex, renal angiomyolipoma, hepatic cyst, hypertension, mild intellectual disability, autism, mild depression and anxiety, epilepsy with complex partial seizures, remote history of generalized tonic clonic seizures. Products known to have been used by the patient, within two weeks prior to the event, included levetiracetam, oxcarbazepine, cenobamate, ramipril, sertraline hydrochloride and everolimus. On an unspecified date, the patient received their first of two planned doses of mRNA-1273 (Batch/Lot number: unknown) for prophylaxis of COVID-19 infection. On 24 Feb 2021, prior to the onset of the events, the patient received their second of two planned doses of mRNA-1273 (Batch/Lot number: unknown) intramuscularly in the arm for prophylaxis of COVID-19 infection. On 24 Feb 2021, the patient experienced fever (105 F), disseminated intravascular coagulation, liver injury, respiratory failure, shock, generalized tonic clonic seizure lasting greater than 60 minutes resulting in rhabdomyolysis, leukocytosis. On 25 Feb 2021, patient was transferred to the hospital. Treatment information for the events included endotracheal intubation. Laboratory information included alanine aminotransferase increased, aspartate aminotransferase increased, blood creatine phosphokinase increased, blood creatinine increased, blood gases abnormal, blood lactic acid increased, haemoglobin decreased, influenza A virus test negative, influenza B virus test, international normalised ratio increased, platelet count decreased, respiratory syncytial virus test negative, SARS-CoV-2 test negative, Serum ferritin increased, troponin increased and white blood cell count increased. Action taken with mRNA-1273 in response to the events was not applicable. The outcome of the events, disseminated intravascular coagulation, generalised tonic-clonic seizure, leukocytosis, liver injury, pyrexia, respiratory failure, rhabdomyolysis and shock, was not resolved at the time of this report.

Case ID	Narrative (Complete)
[redacted]	This case was initially received via United States FDA VAERS (Reference number: [redacted]on 23-Mar-2021. The most recent information was received on 23-Mar-2021 and was forwarded to Moderna on an unknown date. This regulatory authority case was reported by an other health care professional and describes the occurrence of DEATH (Death), COVID-19 (COVID-19), COVID-19 PNEUMONIA (COVID-19 pneumonia), DYSPNOEA (Dyspnoea), ENCEPHALOPATHY (Encephalopathy), GASTROINTESTINAL DISORDER (Gastrointestinal disorder), HAEMODYNAMIC INSTABILITY (Haemodynamic instability), LIVER INJURY (Liver injury), SHOCK (Shock), SUPRAVENTRICULAR TACHYCARDIA (Supraventricular tachycardia), TACHYCARDIA (Tachycardia) and THROMBOCYTOPENIA (Thrombocytopenia) in a 74-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 031M20A) for COVID-19 vaccination. The patient's past medical history included End stage renal disease (On Hemodialysis) since an unknown date, Hypertension and Atrial septal defect. On 11-Feb-2021, the patient received dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 20-Feb-2021, the patient experienced COVID-19 (COVID-19) (seriousness criterion death), COVID-19 PNEUMONIA (COVID-19 pneumonia) (seriousness criterion death), DYSPNOEA (Dyspnoea) (seriousness criterion death), ENCEPHALOPATHY (Encephalopathy) (seriousness criterion death), GASTROINTESTINAL DISORDER (Gastrointestinal disorder) (seriousness criterion death), LIVER INJURY (Liver injury) (seriousness criterion death), SUPRAVENTRICULAR TACHYCARDIA (Supraventricular tachycardia) (seriousness criterion death), TACHYCARDIA (Tachycardia) (seriousness criterion death) and THROMBOCYTOPENIA (Thrombocytopenia) (seriousness criterion death). On 02-Mar-2021, the patient experienced HAEMODYNAMIC INSTABILITY (Haemodynamic instability) (seriousness criterion death) and SHOCK (Shock) (seriousness criterion death). The patient died on 02-Mar-2021. The cause of death was not reported. It is unknown if an autopsy was performed. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Treatment of these events included dexamethasone and convalescent plasma. This is a case of sudden death in a 74-year-old male patient with a history of End stage renal disease (On Hemodialysis) and Hypertension, who died 20 days after receiving first dose of vaccine. Very limited information has been provided at this time. Very limited information regarding these events has been provided at this time. No further follow-up information is expected. Patient's advances age along with prior medical history of End Stage Renal Disease, hypertension and an atrial septum defect may be contributory to the occurrence of the death. Most recent FOLLOW-UP information incorporated above includes: On 23-Mar-2021: Upon internal review on 04AUG2021, the event of Atrial septal defect was removed as an event and moved to medical history.
[redacted]	This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of LIVER INJURY (liver level was up 1000 times what it normally is) in an 89-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 040A21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event. On 12-Mar-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 12-Mar-2021, the patient experienced VACCINATION SITE PAIN (pain in arm) and VACCINATION SITE BRUISING (a little bruising on that arm). On an unknown date, the patient experienced LIVER INJURY (liver level was up 1000 times what it normally is) (seriousness criterion medically significant), MUSCLE STRAIN (pulled a muscle in the back of my thigh), JOINT SWELLING (calves and ankles are all swollen) and GAIT INABILITY (hardly walk). At the time of the report, LIVER INJURY (liver level was up 1000 times what it normally is), VACCINATION SITE PAIN (pain in arm), VACCINATION SITE BRUISING (a little bruising on that arm), MUSCLE STRAIN (pulled a muscle in the back of my thigh), JOINT SWELLING (calves and ankles are all swollen) and GAIT INABILITY (hardly walk) outcome was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Treatment information included one dose of acetaminophen 500mg and heating pad. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded

Case ID	Narrative (Complete)
[redacted]	This spontaneous case was reported by a consumer and describes the occurrence of HEPATITIS ACUTE (Acute hepatitis), VOMITING (Intense and constant vomiting) and FLUID INTAKE REDUCED ("she could not even drink water") in an 88-year-old female patient who received mRNA-1273 (COVID 19 Vaccine Moderna) for COVID-19 vaccination. No Medical History information was reported. On 19-Mar-2021, the patient received first dose of mRNA-1273 (COVID 19 Vaccine Moderna) (unknown route) 1 dosage form. In March 2021, the patient experienced HEPATITIS ACUTE (Acute hepatitis) (seriousness criteria hospitalization and medically significant). On 19-Mar-2021, the patient experienced VOMITING (Intense and constant vomiting) (seriousness criteria hospitalization and medically significant). On 29-Mar-2021, the patient experienced FLUID INTAKE REDUCED ("she could not even drink water") (seriousness criteria hospitalization and medically significant). At the time of the report, HEPATITIS ACUTE (Acute hepatitis), VOMITING (Intense and constant vomiting) and FLUID INTAKE REDUCED ("she could not even drink water") outcome was unknown. The action taken with mRNA-1273 (COVID 19 Vaccine Moderna) (Unknown) was unknown. Concomitant product use was not provided by the reporter. No treatment information was provided. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Most recent FOLLOW-UP information incorporated above includes: On 18-May-2021: Follow-up received and appended on 18MAY2021 includes a new event and updates to the reporter contact information.
[redacted]	This case was received via United States FDA VAERS (Reference number: [redacted] on 06-Apr-2021 and was forwarded to Moderna on 06-Apr-2021. This regulatory authority case was reported by an other health care professional (subsequently medically confirmed) and describes the occurrence of INTERNAL HAEMORRHAGE (Severe internal bleeding), HEPATIC FAILURE (Liver failure), PLEURAL EFFUSION (Fluid build up around lungs), PULMONARY OEDEMA (Fluid build up around heart) and HYPOTENSION (Low blood pressure) in a 75-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 042L20A) for COVID-19 vaccination. Concurrent medical conditions included Fibrillation (Reported as A-VIB). Concomitant products included WARFARIN for an unknown indication. On 02-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 10-Feb-2021, the patient experienced INTERNAL HAEMORRHAGE (Severe internal bleeding) (seriousness criteria death and hospitalization), HEPATIC FAILURE (Liver failure) (seriousness criterion hospitalization), PLEURAL EFFUSION (Fluid build up around lungs) (seriousness criterion hospitalization), PULMONARY OEDEMA (Fluid build up around heart) (seriousness criterion hospitalization) and HYPOTENSION (Low blood pressure) (seriousness criterion hospitalization). The patient died on 07-Mar-2021. The cause of death was not reported. It is unknown if an autopsy was performed. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Reporter did not allow further contact

Case ID	Narrative (Complete)
[redacted]	This case was received via [redacted] (Reference number: [redacted]) on 06-Apr-2021 and was forwarded to Moderna on 06-Apr-2021. A regulatory authority report ([redacted]) was received from a health professional concerning a 58- year old-male patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced Acute respiratory failure, cardiac failure congestive, Wernicke's encephalopathy, Hemoperitoneum , Gastrointestinal hemorrhage , Hepatic cirrhosis , Hepatic failure , Toxic encephalopathy , Subdural hematoma , Neuropathy peripheral, syncope, Quadriplegia, Atelectasis, Agitation, Anemia , Anticoagulation drug level above therapeutic , asthenia, Benign prostatic hyperplasia , Chronic left ventricular failure, Chronic obstructive pulmonary disease , Condition aggravated , confusional state, Coronary artery disease , depression, discomfort, Gastroesophageal reflux disease , enteritis, fall, hypercapnia, hypotension, Mental status changes , pain, Peripheral arterial occlusive disease , pulmonary mass, sepsis, thyroid disorder, urinary tract infection, General physical health deterioration and the patient was hospitalized. The patient's medical history as provided by the reporter, included, Atrial Fibrillation on warfarin therapy, hypertension, hypothyroidism, Chronic obstructive pulmonary disease, hypercholesterolemia, Congestive heart failure, chronic pain, cirrhosis, renal failure, DVT. Patient has a history of peripheral neuropathy, hallucinations, drug allergy to Wellbutrin and Cymbalta, handicap for past 10 years was provided. Concomitant medications included, Duoneb(Ipratropium bromide, Salbutamol sulfate), Amiodarone, Lipitor, Magnesium, Coreg(Carvedilol), Vitamin D3 [redacted](Clonazepam), Doxycycline, Finasteride, Flonase NS(mometasone furoate), Gabapentin, Lactulose, Levothyroxine, Reglan(Metoclopramide hydrochloride), Morphine ER tabs, Stiolto(olodaterol hydrochloride), Omeprazole, Potassium Cl, Prednisone, Sertraline, Spironolactone and Precedex(Dexmedetomidine hydrochloride) were reported. On an unknown date, Prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 intramuscularly for prophylaxis of COVID-19 infection. On 04-Mar-2021, prior to the onset of the events, the patient received their second of two planned doses of mRNA-1273 (lot/batch 013A21A) intramuscularly on left arm for prophylaxis of COVID-19 infection. On 12-Mar-2021,the patient experienced Acute respiratory failure, cardiac failure congestive, Wernicke's encephalopathy, Hemoperitoneum , Gastrointestinal hemorrhage , Hepatic cirrhosis , Hepatic failure , Toxic encephalopathy , Subdural hematoma , Neuropathy peripheral, syncope, Quadriplegia, Atelectasis, Agitation, Anemia , Anticoagulation drug level above therapeutic , asthenia, Benign prostatic hyperplasia , Chronic left ventricular failure, Chronic obstructive pulmonary disease , Condition aggravated , confusional state, Coronary artery disease , depression, discomfort, Gastroesophageal reflux disease , enteritis, fall, hypercapnia, hypotension, Mental status changes , pain, Peripheral arterial occlusive disease , pulmonary mass, sepsis, thyroid disorder, urinary tract infection, General physical health deterioration and the patient was hospitalized. The events Acute respiratory failure, cardiac failure congestive, Wernicke's encephalopathy, Hemoperitoneum, Gastrointestinal hemorrhage, Hepatic cirrhosis, Hepatic failure , Toxic encephalopathy , Subdural hematoma , Neuropathy peripheral, syncope, Quadriplegia are medically significant. The case is considered as serious. Laboratory data included, Bilevel positive airway pressure, Blood culture, Blood lactic acid, cardiac monitoring, chest x-ray, Catheter placement, Differential white blood cell count, echocardiogram, electrocardiogram, full blood count, gram stain, International normalized ratio(Coumadin level INR greater than 9.), lipids, liver function test increased, metabolic function test, Packed red blood cell transfusion, platelet culture, sputum culture, troponin 1, Ultrasound Doppler and prothrombin time was provided. The results and the outcome of the laboratory details was unknown. Treatment information included, BiPAP was reinstituted to avoid CO2 retention, benzodiazepine and morphine supported initially for the 1st 36 hours with BiPAP, broad-spectrum antibiotics and hemoglobin's was provided. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) was not applicable. Treatment for the events included Tylenol and Morphine. BiPAP was reinstituted to avoid CO2 retention. Continuation of empiric antibiotics. Required units of packed RBCs on 12-Mar-2021. The outcome of the events Acute respiratory failure, cardiac failure congestive, Wernicke's encephalopathy, Hemoperitoneum , Gastrointestinal hemorrhage , Hepatic cirrhosis , Hepatic failure , Toxic encephalopathy , Subdural hematoma , Neuropathy peripheral, syncope, Quadriplegia, Atelectasis, Agitation, Anemia , Anticoagulation drug level above therapeutic , asthenia, Benign prostatic hyperplasia , Chronic left ventricular failure, Chronic obstructive pulmonary disease , Condition aggravated , confusional state, Coronary artery disease , depression, discomfort, Gastroesophageal reflux disease , enteritis, fall, hypercapnia, hypotension, Mental status changes , pain, Peripheral arterial occlusive disease , pulmonary mass, sepsis, thyroid disorder, urinary tract infection, General physical health deterioration was considered as unknown at the time of the report.

Case ID	Narrative (Complete)
[redacted]	This case was received via [redacted] (Reference number: [redacted] on 06-Apr-2021 and was forwarded to Moderna on 06-Apr-2021. This regulatory authority case was reported by an other health care professional (subsequently medically confirmed) and describes the occurrence of CARDIO-RESPIRATORY ARREST (Cardio-respiratory arrest), DYSPNOEA (Shortness of breath), HEPATIC FAILURE (Liver failure) and RENAL FAILURE (Kidney failure) in a 71-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The patient's past medical history included Heart attack, Stroke and Endotracheal intubation on 11-Mar-2021. Concurrent medical conditions included Obstructive sleep apnea syndrome, Hypertension, Diabetes, Chronic kidney disease and Atrial fibrillation. On 11-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 11-Mar-2021, the patient experienced CARDIO-RESPIRATORY ARREST (Cardio-respiratory arrest) (seriousness criteria hospitalization, medically significant and life threatening), DYSPNOEA (Shortness of breath) (seriousness criteria hospitalization and life threatening), HEPATIC FAILURE (Liver failure) (seriousness criteria hospitalization, medically significant and life threatening) and RENAL FAILURE (Kidney failure) (seriousness criteria hospitalization, medically significant and life threatening). At the time of the report, CARDIO-RESPIRATORY ARREST (Cardio-respiratory arrest), DYSPNOEA (Shortness of breath), HEPATIC FAILURE (Liver failure) and RENAL FAILURE (Kidney failure) outcome was unknown. 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 relevant concomitant medications were reported. Treatment information included endotracheal intubation and intensive care. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Reporter did not allow further contact
[redacted]	This regulatory authority case was reported by a physician and describes the occurrence of AUTOIMMUNE HEPATITIS (Autoimmune hepatitis) in a 41-year-old female patient who received mRNA-1273 (COVID 19 Vaccine Moderna) (batch no. 300042722) for COVID-19 vaccination. No Medical History information was reported. On 07-Feb-2021, the patient received first dose of mRNA-1273 (COVID 19 Vaccine Moderna) (Intramuscular) .5 milliliter. On 08-Mar-2021, received second dose of mRNA-1273 (COVID 19 Vaccine Moderna) (Intramuscular) dosage was changed to .5 milliliter. On 15-Mar-2021, after starting mRNA-1273 (COVID 19 Vaccine Moderna), the patient experienced AUTOIMMUNE HEPATITIS (Autoimmune hepatitis) (seriousness criterion medically significant). At the time of the report, AUTOIMMUNE HEPATITIS (Autoimmune hepatitis) had not resolved. For mRNA-1273 (COVID 19 Vaccine Moderna) (Intramuscular), the reporter did not provide any causality assessments. Action taken with mRNA-1273 was not applicable as the patient received both doses. No concomitant medications reported. No treatment information provided. Very limited information regarding this event has been provided at this time. No follow up is possible. Most recent FOLLOW-UP information incorporated above includes: On 08-Apr-2021: Translation received On 26-Apr-2021: no new information

Case ID	Narrative (Complete)
[redacted]	This case was received via an unknown source (no reference has been entered for a health authority or license partner) on 13-Apr-2021 and was forwarded to Moderna on 15-Apr-2021. This regulatory authority case was reported by a physician (subsequently medically confirmed) and describes the occurrence of AUTOIMMUNE HEPATITIS (autoimmune hepatitis) in a 76-year-old female patient who received mRNA-1273 (COVID-19 Vaccine Moderna) (batch no. 3000424) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Urothelial carcinoma, COVID-19 in October 2020, Hypothyroidism, Chronic obstructive bronchopneumopathy, Hypercholesteraemia and Ex-smoker. Concomitant products included MIDODRINE HYDROCHLORIDE (GUTRON) for Hypotension, MACROGOL 3350, POTASSIUM CHLORIDE, SODIUM BICARBONATE, SODIUM CHLORIDE (MOLAXOLE), LEVOTHYROXINE SODIUM (ELTROXIN) and ZOLPIDEM for an unknown indication. On 02-Feb-2021, the patient received dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form. In February 2021, the patient experienced DECREASED APPETITE (appetite decreased), CHROMATURIA (urine coloring black) and FATIGUE (fatigue). On 01-Mar-2021, the patient experienced AUTOIMMUNE HEPATITIS (autoimmune hepatitis) (seriousness criterion medically significant). In February 2021, DECREASED APPETITE (appetite decreased), CHROMATURIA (urine coloring black) and FATIGUE (fatigue) outcome was unknown. In March 2021, AUTOIMMUNE HEPATITIS (autoimmune hepatitis) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 01-Mar-2021, Alanine aminotransferase increased: 680 u/l. On 01-Mar-2021, Aspartate aminotransferase: 895 u/l. On 01-Mar-2021, Gamma-glutamyltransferase: 425 u/l. On 12-Mar-2021, Alanine aminotransferase increased: 579 u/l. On 12-Mar-2021, Aspartate aminotransferase: 811 u/l. On 12-Mar-2021, Blood immunoglobulin G: 39.4 g/dl. On 12-Mar-2021, Gamma-glutamyltransferase: 361 u/l. On 16-Mar-2021, Alanine aminotransferase increased: 564 u/l. On 16-Mar-2021, Aspartate aminotransferase: 731 u/l. On 16-Mar-2021, Gamma-glutamyltransferase: 307 u/l. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered FATIGUE (fatigue) to be possibly related and AUTOIMMUNE HEPATITIS (autoimmune hepatitis), DECREASED APPETITE (appetite decreased) and CHROMATURIA (urine coloring black) to be unlikely related. Although the patient's has a past history of urothelial cancer, based on the information provided which includes a temporal association between the use of mRNA-1273 vaccine and onset of the reported events, causal relationship cannot be excluded. Fatigue s is consistent with the product known safety profile Reporter did not allow further contact

Case ID	Narrative (Complete)
[redacted]	This regulatory authority case was reported by an other health professional (subsequently medically confirmed) and describes the occurrence of IMMUNE-MEDIATED HEPATITIS (Immune-mediated hepatitis) in a 74-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 031L20A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Cholecystectomy. Concurrent medical conditions included Drug allergy (Ampicillin (rash); statins (myalgias)), Allergic reaction to bee sting (Bee stings (anaphylaxis)), Type II diabetes mellitus ((well controlled)), Hypothyroidism, Coronary artery disease, Takotsubo syndrome, Osteoarthritis, Erectile dysfunction, Urinary retention, Obstructive sleep apnea syndrome, Benign prostatic hypertrophy (with lower urinary tract symptoms), Adrenal mass ((declined workup)) and Breast mass ((declined workup)). Concomitant products included HYDROCHLOROTHIAZIDE, LISINOPRIL (LISINOPRIL/HYDROCHLOROTHIAZIDE), DICLOFENAC, ACETAMINOPHEN, SILDENAFIL, CARVEDILOL, LEVOTHYROXINE, AMLODIPINE, TAMSULOSIN, METFORMIN and GLIMEPIRIDE for an unknown indication. On 27-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 01-Mar-2021, the patient experienced IMMUNE-MEDIATED HEPATITIS (Immune-mediated hepatitis) (seriousness criterion medically significant), ABDOMINAL PAIN UPPER (Upper abdominal pain (RUQ greater than LUQ)), JAUNDICE (Jaundice), PRURITUS (Diffuse itching without rash), CHROMATURIA (Dark colored urine) and FATIGUE (Fatigue). At the time of the report, IMMUNE-MEDIATED HEPATITIS (Immune-mediated hepatitis), ABDOMINAL PAIN UPPER (Upper abdominal pain (RUQ greater than LUQ)), JAUNDICE (Jaundice), PRURITUS (Diffuse itching without rash), CHROMATURIA (Dark colored urine) and FATIGUE (Fatigue) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 12-Mar-2021, Alanine aminotransferase: 318 (High) elevated. On 12-Mar-2021, Aspartate aminotransferase: 176 (High) elevated. On 12-Mar-2021, Bilirubin conjugated: 4.6 (High) elevated. On 12-Mar-2021, Blood alkaline phosphatase: 659 High. On 12-Mar-2021, Blood bilirubin: 7.6 (High) elevated. On 12-Mar-2021, Blood creatinine: 0.96 High. On 12-Mar-2021, Blood glucose: 283 (High) High. On 12-Mar-2021, Blood urea: 13 (normal) Normal. On 12-Mar-2021, Haemoglobin: 13.3 Low. On 12-Mar-2021, Hepatitis A antibody: (Negative) nonreactive. On 12-Mar-2021, Hepatitis B core antibody: (Negative) nonreactive. On 12-Mar-2021, Hepatitis B surface antigen: (Negative) nonreactive. On 12-Mar-2021, Hepatitis C antibody: (Negative) nonreactive. On 12-Mar-2021, Platelet count: 17.6 Inconclusive. On 12-Mar-2021, Ultrasound abdomen: (abnormal) mild intrahepatic biliary ductal dilatation and surgically absent gallbladder. On 12-Mar-2021, White blood cell count: 5.3 Inconclusive. 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. Patient was initiated on cholestyramine for pruritus. 12-MAR-2021 Acute hepatitis panel negative/acute hepatitis panel nonreactive (Hep A IgM, Hep B SAg, Hep B core Ab, Hep C Ab) 18-MAR-2021: ferritin, ANA, alpha 1 antitrypsin, ceruloplasmin, AMA, anti-smooth muscle Ab negative/normal. Liver function tests improved (report not available for review at time of VAERS report). Company comment: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. No follow up is possible. Reporter did not allow further contact This case was received via [redacted] (Reference number: [redacted] on 20-Apr-2021 and was forwarded to Moderna on 20-Apr-2021. This regulatory authority case was reported by an other health professional (subsequently medically confirmed) and describes the occurrence of IMMUNE-MEDIATED HEPATITIS (Immune-mediated hepatitis) in a 74-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 031L20A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Cholecystectomy. Concurrent medical conditions included Drug allergy (Ampicillin (rash); statins (myalgias)), Allergic reaction to bee sting (Bee stings (anaphylaxis)), Type II diabetes mellitus ((well controlled)), Hypothyroidism, Coronary artery disease, Takotsubo syndrome, Osteoarthritis, Erectile dysfunction, Urinary retention, Obstructive sleep apnea syndrome, Benign prostatic hypertrophy (with lower urinary tract symptoms), Adrenal mass ((declined workup)) and Breast mass ((declined workup)). Concomitant products included HYDROCHLOROTHIAZIDE, LISINOPRIL (LISINOPRIL/HYDROCHLOROTHIAZIDE), DICLOFENAC, ACETAMINOPHEN, SILDENAFIL, CARVEDILOL, LEVOTHYROXINE, AMLODIPINE, TAMSULOSIN, METFORMIN and GLIMEPIRIDE for an unknown indication. On 27-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 01-Mar-2021, the patient experienced IMMUNE-MEDIATED HEPATITIS (Immune-mediated hepatitis) (seriousness criterion medically significant), ABDOMINAL PAIN UPPER (Upper abdominal pain (RUQ greater than LUQ)), JAUNDICE (Jaundice), PRURITUS (Diffuse itching without rash), CHROMATURIA (Dark colored urine) and FATIGUE (Fatigue). At the time of the report, IMMUNE-MEDIATED HEPATITIS (Immune-

Case ID	Narrative (Complete)
	mediated hepatitis), ABDOMINAL PAIN UPPER (Upper abdominal pain (RUQ greater than LUQ)), JAUNDICE (Jaundice), PRURITUS (Diffuse itching without rash), CHROMATURIA (Dark colored urine) and FATIGUE (Fatigue) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 12-Mar-2021, Alanine aminotransferase: 318 (High) elevated. On 12-Mar-2021, Aspartate aminotransferase: 176 (High) elevated. On 12-Mar-2021, Bilirubin conjugated: 4.6 (High) elevated. On 12-Mar-2021, Blood alkaline phosphatase: 659 High. On 12-Mar-2021, Blood bilirubin: 7.6 (High) elevated. On 12-Mar-2021, Blood creatinine: 0.96 High. On 12-Mar-2021, Blood glucose: 283 (High) High. On 12-Mar-2021, Blood urea: 13 (normal) Normal. On 12-Mar-2021, Haemoglobin: 13.3 Low. On 12-Mar-2021, Hepatitis A antibody: (Negative) nonreactive. On 12-Mar-2021, Hepatitis B core antibody: (Negative) nonreactive. On 12-Mar-2021, Hepatitis B surface antigen: (Negative) nonreactive. On 12-Mar-2021, Hepatitis C antibody: (Negative) nonreactive. On 12-Mar-2021, Platelet count: 17.6 Inconclusive. On 12-Mar-2021, Ultrasound abdomen: (abnormal) mild intrahepatic biliary ductal dilatation and surgically absent gallbladder. On 12-Mar-2021, White blood cell count: 5.3 Inconclusive. 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. Patient was initiated on cholestyramine for pruritus. 12-MAR-2021 Acute hepatitis panel negative/acute hepatitis panel nonreactive (Hep A IgM, Hep B SAg, Hep B core Ab, Hep C Ab) 18-MAR-2021: ferritin, ANA, alpha 1 antitrypsin, ceruloplasmin, AMA, anti-smooth muscle Ab negative/normal. Liver function tests improved (report not available for review at time of VAERS report). Company comment: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. No follow up is possible. Reporter did not allow further contact

Case ID	Narrative (Complete)
[redacted]	This case was received via United States FDA VAERS (Reference number: [redacted] on 27-Apr-2021 and was forwarded to Moderna on 27-Apr-2021. This regulatory authority case was reported by an other health care professional (subsequently medically confirmed) and describes the occurrence of DEATH (Death), HEPATIC FAILURE (Hepatic failure), CARDIAC FAILURE (Cardiac failure), RENAL FAILURE (Renal failure), SHOCK (Shock), ILLNESS (Illness), LETHARGY (Lethargy), NECK PAIN (Neck pain), PAIN IN EXTREMITY (Pain in extremity), ABDOMINAL DISCOMFORT (Abdominal discomfort), DECREASED APPETITE (Decreased appetite) and FATIGUE (Fatigue) in an 86-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. Concurrent medical conditions included Kidney failure (under control with medication.), Heart disorder (under control with medication) and Pulseless electrical activity. Concomitant products included APIXABAN (ELIQUIS), LEVOTHYROXINE SODIUM (SYNTHROID), LOSARTAN and METOPROLOL for an unknown indication. On 18-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 19-Feb-2021, the patient experienced ILLNESS (Illness) (seriousness criterion hospitalization), LETHARGY (Lethargy) (seriousness criterion hospitalization), NECK PAIN (Neck pain) (seriousness criterion hospitalization), PAIN IN EXTREMITY (Pain in extremity) (seriousness criterion hospitalization), ABDOMINAL DISCOMFORT (Abdominal discomfort) (seriousness criterion hospitalization), DECREASED APPETITE (Decreased appetite) (seriousness criterion hospitalization) and FATIGUE (Fatigue) (seriousness criterion hospitalization). On 26-Feb-2021, the patient experienced SHOCK (Shock) (seriousness criteria hospitalization and medically significant). On an unknown date, the patient experienced HEPATIC FAILURE (Hepatic failure) (seriousness criteria hospitalization and medically significant), CARDIAC FAILURE (Cardiac failure) (seriousness criteria hospitalization and medically significant) and RENAL FAILURE (Renal failure) (seriousness criteria hospitalization and medically significant). On 05-Mar-2021, HEPATIC FAILURE (Hepatic failure), CARDIAC FAILURE (Cardiac failure), RENAL FAILURE (Renal failure) and SHOCK (Shock) outcome was unknown. The patient died on 05-Mar-2021. The cause of death was not reported. It is unknown if an autopsy was performed. At the time of death, ILLNESS (Illness), LETHARGY (Lethargy), NECK PAIN (Neck pain), PAIN IN EXTREMITY (Pain in extremity), ABDOMINAL DISCOMFORT (Abdominal discomfort), DECREASED APPETITE (Decreased appetite) and FATIGUE (Fatigue) outcome was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. On 24 Feb 2021, the patient's doctor told her to rest and give her electrolytes and vitamin B6. On 26 Feb 2021, the doctor told to take the patient to the emergency (ER). On 18 Feb 2021, she was still driving and doing all of her cooking, banking, shopping, showering, walking every day. Treatment information was not reported.
[redacted]	This case was received via United States FDA VAERS (Reference number: [redacted] on 27-Apr-2021 and was forwarded to Moderna on 27-Apr-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of DEATH (death), CEREBROVASCULAR ACCIDENT (Stroke), HEPATIC FAILURE (Liver failure), PULMONARY EMBOLISM (Pulmonary embolism) and RENAL FAILURE (Kidney failure) in a 76-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The patient's past medical history included Tachycardia. Concurrent medical conditions included High cholesterol, Blood pressure high and Sleep apnea. Concomitant products included SOTALOL and CLOPIDOGREL BISULFATE (PLAVIX) for an unknown indication. On 04-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 16-Feb-2021, the patient experienced CEREBROVASCULAR ACCIDENT (Stroke) (seriousness criterion medically significant), HEPATIC FAILURE (Liver failure) (seriousness criterion medically significant), PULMONARY EMBOLISM (Pulmonary embolism) (seriousness criterion medically significant) and RENAL FAILURE (Kidney failure) (seriousness criterion medically significant). On 16-Feb-2021, CEREBROVASCULAR ACCIDENT (Stroke), HEPATIC FAILURE (Liver failure), PULMONARY EMBOLISM (Pulmonary embolism) and RENAL FAILURE (Kidney failure) outcome was unknown. The patient died on 04-Mar-2021. It is unknown if an autopsy was performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 16-Feb-2021, Computerised tomogram: unknown (Inconclusive) unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. .Treatment information was not provided. Limited information regarding the events has been provided at this time and a causal relationship cannot be excluded. Cause of death not reported.

Case ID	Narrative (Complete)
[redacted]	This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of UNRESPONSIVE TO STIMULI (Unresponsive), DEATH (Died), RENAL FAILURE (Renal failure) and HEPATIC FAILURE (Liver failure) in a 62-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Primary biliary cirrhosis. On 07-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 07-Apr-2021, the patient experienced ABDOMINAL PAIN UPPER (Stomach pain) and NAUSEA (Nausea). On 08-Apr-2021, the patient experienced UNRESPONSIVE TO STIMULI (Unresponsive) (seriousness criterion hospitalization). On 23-Apr-2021, the patient experienced DEATH (Died) (seriousness criterion death), RENAL FAILURE (Renal failure) (seriousness criterion hospitalization) and HEPATIC FAILURE (Liver failure) (seriousness criterion hospitalization). On 23-Apr-2021, RENAL FAILURE (Renal failure) and HEPATIC FAILURE (Liver failure) had resolved and NAUSEA (Nausea) outcome was unknown. The patient died on 23-Apr-2021. The cause of death was not reported. It is unknown if an autopsy was performed. At the time of death, UNRESPONSIVE TO STIMULI (Unresponsive) and ABDOMINAL PAIN UPPER (Stomach pain) outcome was unknown. The concomitant medication included liver medications, as reported by the reporter. On 07Apr2021 around 1230pm, the patient experienced stomach pain and nausea which the family attributed to her liver medications. The patient went to sleep later that evening. The next day, 08Apr2021, the patient was found to be sleeping around 8am but was unresponsive around 1:30pm. She was taken by ambulance to the local hospital. The patient was eventually placed on life support and passed on 23Apr2021. No other treatment medication were reported. Company comment: Very limited information regarding this events has been provided at this time. However, based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. Further information has been requested.

Case ID	Narrative (Complete)
[redacted]	This regulatory authority case was reported by an other health care professional and describes the occurrence of DRUG-INDUCED LIVER INJURY (Hepatitis drug-induced), HEADACHE ([redacted] and FATIGUE [redacted]astenia) in a 34-year-old female patient who received mRNA-1273 (COVID 19 Vaccine Moderna) (batch nos. 300042698 e 300042723 and 300042698 e 300042723) for COVID-19 vaccination. The patient's past medical history included Abortion spontaneous in November 2020 and Hepatitis A (during infancy). Concurrent medical conditions included Allergy to nuts (Allergic to almonds. Caused itching). On 04-Feb-2021, the patient received first dose of mRNA-1273 (COVID 19 Vaccine Moderna) (Intramuscular) 1 dosage form. On 05-Mar-2021, received second dose of mRNA-1273 (COVID 19 Vaccine Moderna) (Intramuscular) dosage was changed to 1 dosage form. On 05-Feb-2021, the patient experienced HEADACHE [redacted] (seriousness criterion disability). On 06-Feb-2021, the patient experienced FATIGUE [redacted]astenia) (seriousness criterion disability). On 08-Mar-2021, the patient experienced DRUG-INDUCED LIVER INJURY (Hepatitis drug-induced) (seriousness criteria disability and medically significant). At the time of the report, DRUG-INDUCED LIVER INJURY (Hepatitis drug-induced) was resolving and HEADACHE ([redacted] and FATIGUE [redacted]astenia) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 18-Mar-2021, Alanine aminotransferase: 274 274 mg/dL IU international unit(s). On 18-Mar-2021, Aspartate aminotransferase: 127 127 mg/dL IU international unit(s).. On 18-Mar-2021, Bilirubin conjugated: 3.12 3.12 mg/dL IU international unit(s). On 18-Mar-2021, Blood bilirubin: 5.1 5.1 mg/dL IU International unit(s). On 07-Apr-2021, Alanine aminotransferase: 96 96 IU international units. On 07-Apr-2021, Aspartate aminotransferase: 96 47 IU international unit(s). On 07-Apr-2021, Bilirubin conjugated: 0.98 0.98 mg/dL IU international unit(s). On 07-Apr-2021, Blood bilirubin: 1.6 1.6 mg/dL Iu international unit(s). In 2021, Cytomegalovirus test: negative (Negative) negative. In 2021, HIV test: negative (Negative) negative. In 2021, Hepatitis A: negative (Negative) negative. In 2021, Hepatitis B: negative (Negative) negative. In 2021, Hepatitis C: negative (Negative) negative. In 2021, Serology test: negative (Negative) EBV: negative IU international units. In 2021, Toxoplasmosis: negative (Negative) negative. In 2021, Ultrasound liver: normal (normal) international unit(s) Without changes.. For mRNA-1273 (COVID 19 Vaccine Moderna) (Intramuscular), the reporter considered DRUG-INDUCED LIVER INJURY (Hepatitis drug-induced), HEADACHE[redacted] and FATIGUE [redacted]/astenia) to be probably related. Concomitant medications were not reported. Treatment information was not provided. Follow-up received on 07-May-2021 included translated document. Most recent FOLLOW-UP information incorporated above includes: On 03-May-2021: Translated document appended on 07-May-2021.

Case ID	Narrative (Complete)
[redacted]	This case was received via [redacted] (Reference number: [redacted] on 04-May-2021 and was forwarded to Moderna on 04-May-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of ACUTE HEPATIC FAILURE (Acute liver failure) and ACUTE KIDNEY INJURY (Acute renal failure) in a 69-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 001B21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Coronary artery disease and Gastroesophageal reflux. Concurrent medical conditions included Drug allergy (Compazine). Concomitant products included DABIGATRAN ETEXILATE MESILATE (PRADAXA), RANOLAZINE (RANEXA), ISOSORBIDE, CHONDROITIN SULFATE, GLUCOSAMINE SULFATE, METHYLSULFONYLMETHANE (GLUCOSAMINE CHONDROITIN & MSM), ARGININE (L ARGININE [ARGININE]), FAMOTIDINE (PEPCID [FAMOTIDINE]) and LISINOPRIL for an unknown indication. On 10-Mar-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 13-Mar-2021, the patient experienced ACUTE HEPATIC FAILURE (Acute liver failure) (seriousness criteria hospitalization and medically significant), ACUTE KIDNEY INJURY (Acute renal failure) (seriousness criteria hospitalization and medically significant), ABDOMINAL PAIN UPPER (Pain in upper abdomen) (seriousness criterion hospitalization), CHILLS (Chills) (seriousness criterion hospitalization), FATIGUE (Fatigued) (seriousness criterion hospitalization), FLUID RETENTION (Fluid retention in legs and feet) (seriousness criterion hospitalization), GASTRIC DILATATION (Layer developed dissented stomach) (seriousness criterion hospitalization), HEADACHE (Headache) (seriousness criterion hospitalization), MALAISE (Feeling unwell) (seriousness criterion hospitalization) and NAUSEA (Nausea) (seriousness criterion hospitalization). The patient was hospitalized on 24-Mar-2021 due to ABDOMINAL PAIN UPPER, ACUTE HEPATIC FAILURE, ACUTE KIDNEY INJURY, CHILLS, FATIGUE, FLUID RETENTION, GASTRIC DILATATION, HEADACHE, MALAISE and NAUSEA. At the time of the report, ACUTE HEPATIC FAILURE (Acute liver failure), ACUTE KIDNEY INJURY (Acute renal failure), ABDOMINAL PAIN UPPER (Pain in upper abdomen), CHILLS (Chills), FATIGUE (Fatigued), FLUID RETENTION (Fluid retention in legs and feet), GASTRIC DILATATION (Layer developed dissented stomach), HEADACHE (Headache), MALAISE (Feeling unwell) and NAUSEA (Nausea) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 13-Mar-2021, Blood test: unknown (Inconclusive) unknown. On 13-Mar-2021, Ultrasound scan: abnormal (abnormal) abnormal. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. No treatment medication was reported by reporter. Patient reported that possibly it can Rhabdomyolysis. Company Comment: Very limited information regarding this event/s has been provided at this time. No further information is expected.

Case ID	Narrative (Complete)
[redacted]	This case was received via [redacted] (Reference number: [redacted] on 11-May-2021 and was forwarded to Moderna on 11-May-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of AUTOIMMUNE HEPATITIS (Autoimmune hepatitis), JAUNDICE (Jaundice) and FATIGUE (Fatigue) in a 50-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 007M20A) for COVID-19 vaccination. Concurrent medical conditions included Shellfish allergy. On 06-Feb-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 08-Mar-2021, the patient experienced AUTOIMMUNE HEPATITIS (Autoimmune hepatitis) (seriousness criteria hospitalization and medically significant), JAUNDICE (Jaundice) (seriousness criterion hospitalization) and FATIGUE (Fatigue) (seriousness criterion hospitalization). At the time of the report, AUTOIMMUNE HEPATITIS (Autoimmune hepatitis), JAUNDICE (Jaundice) and FATIGUE (Fatigue) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 08-Mar-2021, Alanine aminotransferase: 2500 (High) Reported as 2500. On 08-Mar-2021, Aspartate aminotransferase: 2500 (High) Reported 2500. On 08-Mar-2021, Biopsy liver: results were not reported (Inconclusive) Results were not reported. On 08-Mar-2021, Blood bilirubin: 30 (High) Bilirubin level reported to be extremely elevated. On 08-Mar-2021, Hepatic enzyme: abnormal (abnormal) Abnormal results were reported. On 08-Mar-2021, Magnetic resonance imaging: results were not reported (Inconclusive) Results were not reported. On 08-Mar-2021, Ultrasound scan: results were not reported (Inconclusive) Results were not reported. On 07-Apr-2021, Alanine aminotransferase: 478 (High) Reported as 478 post the treatment medication. On 07-Apr-2021, Aspartate aminotransferase: 341 (High) Reported as 341 post the treatment medication. On 07-Apr-2021, Blood bilirubin: 20.3 (High) Reported as 20.3 post the treatment medication. On an unknown date, Alanine aminotransferase: 2100 (High) Reported as 2100. On an unknown date, Aspartate aminotransferase: 2100 (High) Reported as 2100. On an unknown date, Blood bilirubin: 16 (High) Extremely elevated level of bilirubin was reported. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medications were reported. The patient was admitted in the ER followed by the physician's suggestion on 23 March 2021. The lab tests were done under hepatology care at a medical center. Treatment details included use of oral prednisone 30 mg oid on 02 Apr 2021. Later, on 09 Apr 2021 the dose was reduced to 20 mg, given for a week with a follow up blood test scheduled on 16 Apr 2021. The patient received both scheduled doses of mRNA-1273 prior to the event(s); therefore, action taken with the drug in response to the event(s) were not applicable. This case was received via [redacted] (Reference number: [redacted] on 11-May-2021 and was forwarded to Moderna on 11-May-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of AUTOIMMUNE HEPATITIS (Autoimmune hepatitis) in a 50-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 007M20A) for COVID-19 vaccination. Company Comment - Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.

Case ID	Narrative (Complete)
[redacted]	This case was received via [redacted] (Reference number: [redacted] on 11-May-2021 and was forwarded to Moderna on 11-May-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of HEPATIC FAILURE (Hepatic failure), RENAL FAILURE (Renal failure), FEEDING DISORDER (Feeding disorder), DYSGEUSIA (Dysgeusia), DYSPNOEA (Dyspnoea), MUSCLE FATIGUE (Muscle fatigue), TREMOR (Tremor), CHILLS (Chills) and PYREXIA (Pyrexia) in a 74-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. Concurrent medical conditions included Leukemia. Concomitant products included PARACETAMOL (TYLENOL). On 10-Mar-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 11-Mar-2021, the patient experienced HEPATIC FAILURE (Hepatic failure) (seriousness criteria hospitalization and medically significant), RENAL FAILURE (Renal failure) (seriousness criteria hospitalization and medically significant), FEEDING DISORDER (Feeding disorder) (seriousness criterion hospitalization), DYSGEUSIA (Dysgeusia) (seriousness criterion hospitalization), DYSPNOEA (Dyspnoea) (seriousness criterion hospitalization), MUSCLE FATIGUE (Muscle fatigue) (seriousness criterion hospitalization), TREMOR (Tremor) (seriousness criterion hospitalization), CHILLS (Chills) (seriousness criterion hospitalization) and PYREXIA (Pyrexia) (seriousness criterion hospitalization). The patient was hospitalized on 28-Mar-2021 due to DYSGEUSIA, DYSPNOEA, FEEDING DISORDER and HEPATIC FAILURE. At the time of the report, HEPATIC FAILURE (Hepatic failure), RENAL FAILURE (Renal failure), FEEDING DISORDER (Feeding disorder), DYSGEUSIA (Dysgeusia), DYSPNOEA (Dyspnoea), MUSCLE FATIGUE (Muscle fatigue), TREMOR (Tremor), CHILLS (Chills) and PYREXIA (Pyrexia) had not resolved. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Patient was taking Tylenol after the second shot for leukemia. Action taken was not applicable as the patient completed two doses. Company comment:Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.
[redacted]	This case was received via [redacted] (Reference number: [redacted] on 11-May-2021 and was forwarded to Moderna on 11-May-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of HEPATIC FAILURE (Hepatic failure), MESENTERIC VEIN THROMBOSIS (Mesenteric vein thrombosis), RENAL FAILURE (Renal failure) and SMALL INTESTINAL RESECTION (Small intestinal resection) in a 73-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. Concurrent medical conditions included Drug allergy (Sulphur). On 01-Mar-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 01-Mar-2021, the patient experienced HEPATIC FAILURE (Hepatic failure) (seriousness criteria hospitalization, disability, medically significant and life threatening), MESENTERIC VEIN THROMBOSIS (Mesenteric vein thrombosis) (seriousness criteria hospitalization, disability, medically significant and life threatening), RENAL FAILURE (Renal failure) (seriousness criteria hospitalization, disability, medically significant and life threatening) and SMALL INTESTINAL RESECTION (Small intestinal resection) (seriousness criteria hospitalization, disability and life threatening). At the time of the report, HEPATIC FAILURE (Hepatic failure), MESENTERIC VEIN THROMBOSIS (Mesenteric vein thrombosis), RENAL FAILURE (Renal failure) and SMALL INTESTINAL RESECTION (Small intestinal resection) had not resolved. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Action taken with mRNA-1273 (Moderna COVID-19 Vaccine) in response to events was not applicable. The lab data included magnetic resonance imaging (MRI), ultrasound and unspecified blood test for which the result was unknown. Company Comment: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded

Case ID	Narrative (Complete)
[redacted]	This case was received via [redacted] (Reference number: [redacted] on 11-May-2021 and was forwarded to Moderna on 11-May-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of HEPATIC FAILURE (liver failure), RENAL FAILURE (kidney failure), DEHYDRATION (Dehydrated), MUSCLE INJURY (Muscle damage), ABDOMINAL PAIN (Abdominal pain), ASTHENIA (weakness), MOBILITY DECREASED (unable to get up by himself), MYALGIA (Muscle aches), RETCHING (dry heaving) and VOMITING (Vomiting) in a 73-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 002A21A) for COVID-19 vaccination. The patient's past medical history included Aortic aneurysm, Barrett's esophagus and Spinal cord disorder NOS. Concurrent medical conditions included Sulfonamide allergy. On 24-Feb-2021, the patient received dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 26-Feb-2021, the patient experienced HEPATIC FAILURE (liver failure) (seriousness criteria hospitalization and medically significant), RENAL FAILURE (kidney failure) (seriousness criteria hospitalization and medically significant), DEHYDRATION (Dehydrated) (seriousness criterion hospitalization), MUSCLE INJURY (Muscle damage) (seriousness criterion hospitalization), ABDOMINAL PAIN (Abdominal pain) (seriousness criterion hospitalization), ASTHENIA (weakness) (seriousness criterion hospitalization), MOBILITY DECREASED (unable to get up by himself) (seriousness criterion hospitalization), MYALGIA (Muscle aches) (seriousness criterion hospitalization), RETCHING (dry heaving) (seriousness criterion hospitalization) and VOMITING (Vomiting) (seriousness criterion hospitalization). At the time of the report, HEPATIC FAILURE (liver failure) and RENAL FAILURE (kidney failure) had resolved and DEHYDRATION (Dehydrated), MUSCLE INJURY (Muscle damage), ABDOMINAL PAIN (Abdominal pain), ASTHENIA (weakness), MOBILITY DECREASED (unable to get up by himself), MYALGIA (Muscle aches), RETCHING (dry heaving) and VOMITING (Vomiting) 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. Concomitant product use was not reported. The patient received IVF and spent 7 days at the hospital and is still in Rehab recovering. Very limited information regarding this events has been provided at this time. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. However, patient's underlying medical conditions remains a confounder. Further information can't be requested.
[redacted]	This case was initially received via European Medicines Agency (Reference number: [redacted] on 12-May-2021. The most recent information was received on 06-Aug-2021 and was forwarded to Moderna on 06-Aug-2021. This regulatory authority case was reported by a physician and describes the occurrence of AUTOIMMUNE HAEMOLYTIC ANAEMIA (Anaemia haemolytic autoimmune) and HEPATOCELLULAR INJURY (Hepatocellular damage) in a 72-year-old female patient who received mRNA-1273 (COVID 19 Vaccine Moderna) (batch no. 3001413) for COVID-19 vaccination. The patient's past medical history included Arrhythmia NOS [redacted] 2), Aortic incompetence ([redacted] 2) and Mitral incompetence. Concomitant products included DILTIAZEM HYDROCHLORIDE (DILTIAZEM [redacted], LACTOSE MONOHYDRATE, MAGNESIUM STEARATE, MACROGOL, CASTOR OIL, HYDROGENATED and RICINUS COMMUNIS OIL [redacted] for an unknown indication. On 31-Mar-2021, the patient received first dose of mRNA-1273 (COVID 19 Vaccine Moderna) (Intramuscular) 1 dosage form. On 20-Apr-2021, the patient experienced AUTOIMMUNE HAEMOLYTIC ANAEMIA (Anaemia haemolytic autoimmune) (seriousness criteria hospitalization and medically significant) and HEPATOCELLULAR INJURY (Hepatocellular damage) (seriousness criterion medically significant). The patient was hospitalized on sometime in April 2021 due to AUTOIMMUNE HAEMOLYTIC ANAEMIA. At the time of the report, AUTOIMMUNE HAEMOLYTIC ANAEMIA (Anaemia haemolytic autoimmune) had resolved and HEPATOCELLULAR INJURY (Hepatocellular damage) had not resolved. For mRNA-1273 (COVID 19 Vaccine Moderna) (Intramuscular), the reporter did not provide any causality assessments. Treatment information was not provided. Company Comment Very limited information regarding this events has been provided at this time. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Most recent FOLLOW-UP information incorporated above includes: On 12-May-2021: Translation document was received on 18-May-2021 and No New Information. On 06-Aug-2021: Updated concomitant medication and event outcome.

Case ID	Narrative (Complete)
[redacted]	This case was received via [redacted] (Reference number: [redacted] on 11-May-2021 and was forwarded to Moderna on 11-May-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of HEPATITIS ACUTE (Hepatitis acute) in a 39-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 Premenstrual dysphoric disorder, ADHD and Endometriosis. Previously administered products included for an unreported indication: HEPATITIS B VACCINE and HEPATITIS A. Concurrent medical conditions included Generalized anxiety disorder and Vitamin D deficiency. Concomitant products included ETHINYLESTRADIOL, LEVONORGESTREL (AMETHYST), ARIPIPRAZOLE, DULOXETINE HYDROCHLORIDE (CYMBALTA), CALCIUM LEVOMEFOLATE (METHYL FOLATE), PRAZOSIN, PROPRANOLOL, TRAZODONE, LISDEXAMFETAMINE DIMESYLATE and BUPROPION HYDROCHLORIDE, NALTREXONE HYDROCHLORIDE (CONTRAVE) for an unknown indication. On 19-Jan-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 23-Jan-2021, the patient experienced NAUSEA (Nausea) and VOMITING (Vomiting). On 04-Feb-2021, the patient experienced HEPATITIS ACUTE (Hepatitis acute) (seriousness criterion medically significant). At the time of the report, HEPATITIS ACUTE (Hepatitis acute), NAUSEA (Nausea) and VOMITING (Vomiting) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 23-Jan-2021, Alanine aminotransferase: 282 (High) Increased. On 23-Jan-2021, Aspartate aminotransferase: 300 (High) Increased. On 23-Jan-2021, Blood alkaline phosphatase: 183 (High) Increased. On 23-Jan-2021, Blood creatinine: 0.62 (normal) Normal. On 23-Jan-2021, Blood glucose: 99 (normal) Normal. On 23-Jan-2021, Glomerular filtration rate: 114 (normal) Normal. On 23-Jan-2021, Human chorionic gonadotropin: negative (Negative) negative. On 23-Jan-2021, Urine analysis: abnormal (abnormal) abnormal. On 23-Jan-2021, Urobilinogen urine: >8.0 (High) Increased. 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. Patient started a new medication 1 day prior to her symptoms (22 Jan 2021) so assumed it was due to that. She stopped the medication after 2 doses. Her vomiting continued with only minimal improvement. On 04 Feb 2021, she was seen in the office and diagnosed with acute hepatitis. Treatment information was not provided. Company comment Very limited information regarding this events has been provided at this time. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Further information can't be requested.
[redacted]	This spontaneous case was reported by a nurse and describes the occurrence of HEPATIC FAILURE (Liver failure) in a 62-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. 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 HEPATIC FAILURE (Liver failure) (seriousness criteria hospitalization and medically significant). The patient was hospitalized for 7 days due to HEPATIC FAILURE. At the time of the report, HEPATIC FAILURE (Liver failure) outcome was unknown. 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. On an unknown date, a week post vaccination, the patient had liver failure and she ended up to stay in the hospital for a week. No treatment information was provided. Very limited information regarding this event has been provided at this time. Further information has been requested. Based on the current available information and the temporal association between product use and the start date of the event a causal relationship cannot be excluded. This case was linked t[redacted] (E2B Linked Report).

Case ID	Narrative (Complete)
[redacted]	This regulatory authority case was reported by a physician and describes the occurrence of ESCHERICHIA SEPSIS (Escherishia coli sepsis), EMBOLISM (Suspicion of embolism), RENAL CYST (Small kidney cysts), LIVER INJURY (Liver damage), RESPIRATORY FAILURE (Respiratory failure), GALLBLADDER ENLARGEMENT (Gallbladder enlargement), LEFT VENTRICULAR HYPERTROPHY (Left ventricular of heart hypertrophy), HYPERURICAEMIA (Hyperuricemia), LEUKOPENIA (Leukopenia), GENERAL PHYSICAL HEALTH DETERIORATION (Deterioration of general condition), DYSPNOEA (Dyspnoea), ACUTE KIDNEY INJURY (Acute renal failure) and PYREXIA (Fever) in a 72-year-old male patient who received mRNA-1273 (COVID 19 Vaccine Moderna) (batch no. 30004272L) for COVID-19 vaccination. The patient's past medical history included Tobacco abuse, Lung neoplasm, Aortic valve calcification, Aortic valve calcification, Prostatic hyperplasia, Left ventricular hypertrophy and Mediastinum neoplasm. Concurrent medical conditions included Chronic cystitis, Type 2 diabetes mellitus, Chronic obstructive pulmonary disease and Atherosclerosis generalised (High-grade). On 18-Feb-2021, the patient received first dose of mRNA-1273 (COVID 19 Vaccine Moderna) (Intramuscular) 1 dosage form. On 19-Feb-2021, the patient experienced ESCHERICHIA SEPSIS (Escherishia coli sepsis) (seriousness criterion death), EMBOLISM (Suspicion of embolism) (seriousness criterion death), RENAL CYST (Small kidney cysts) (seriousness criterion death), LIVER INJURY (Liver damage) (seriousness criterion death), RESPIRATORY FAILURE (Respiratory failure) (seriousness criterion death), GALLBLADDER ENLARGEMENT (Gallbladder enlargement) (seriousness criterion death), LEFT VENTRICULAR HYPERTROPHY (Left ventricular of heart hypertrophy) (seriousness criterion death), HYPERURICAEMIA (Hyperuricemia) (seriousness criterion death), LEUKOPENIA (Leukopenia) (seriousness criterion death), GENERAL PHYSICAL HEALTH DETERIORATION (Deterioration of general condition) (seriousness criterion death), DYSPNOEA (Dyspnoea) (seriousness criterion death), ACUTE KIDNEY INJURY (Acute renal failure) (seriousness criteria death and medically significant) and PYREXIA (Fever) (seriousness criterion death). The patient died on 22-Feb-2021. The cause of death was not reported. An autopsy was performed, but no results were provided. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 19-Feb-2021, Body temperature: upto 39 (Inconclusive) up to 39 Celsius degrees. On 20-Feb-2021, Activated partial thromboplastin time: 40 (Inconclusive) 40. On 20-Feb-2021, Alanine aminotransferase: 62.9 (Inconclusive) 62.9. On 20-Feb-2021, Aspartate aminotransferase: 62.6 (Inconclusive) 62.6. On 20-Feb-2021, Base excess: -7.9 (Inconclusive) -7.9 mmol/l. On 20-Feb-2021, Basophil percentage: 0 (Inconclusive) 0. On 20-Feb-2021, Blood bicarbonate: 16 (Inconclusive) 16. On 20-Feb-2021, Blood bilirubin: 0.6 (Inconclusive) 0.6. On 20-Feb-2021, Blood creatinine: 2.4 (Inconclusive) 2.4. On 20-Feb-2021, Blood glucose: 120 (Inconclusive) 120. On 20-Feb-2021, Blood osmolarity: 269 (Inconclusive) 269. On 20-Feb-2021, Blood potassium: 4.2 (Inconclusive) 4.2. On 20-Feb-2021, Blood sodium: 137 (Inconclusive) 137. On 20-Feb-2021, Blood thyroid stimulating hormone: 1.57 (Inconclusive) 1.57. On 20-Feb-2021, Blood urea: 91.6 (Inconclusive) 91.6. On 20-Feb-2021, Blood uric acid: 8.88 (Inconclusive) 8.88. On 20-Feb-2021, C-reactive protein: 439 (Inconclusive) 439. On 20-Feb-2021, Electrocardiogram: unknown (Inconclusive) sinus rhythm accompanied by tachycardia, single ventricular beats. On 20-Feb-2021, Eosinophil percentage: 0 (Inconclusive) 0. On 20-Feb-2021, Fibrin D dimer: 1731 (Inconclusive) 1731. On 20-Feb-2021, Haematocrit: 35.9 (Inconclusive) 35.9. On 20-Feb-2021, Haemoglobin: 12.1 (Inconclusive) 12.1. On 20-Feb-2021, International normalised ratio: 1.4 (Inconclusive) 1.4. On 20-Feb-2021, Lymphocyte percentage: 19.2 (Inconclusive) 19.2. On 20-Feb-2021, Mean cell haemoglobin: 31.7 (Inconclusive) 31.7. On 20-Feb-2021, Mean cell haemoglobin concentration: 33.7 (Inconclusive) 33.7. On 20-Feb-2021, Mean cell volume: 94 (Inconclusive) 94,m5. On 20-Feb-2021, Mean platelet volume: 10.8 (Inconclusive) 10.8. On 20-Feb-2021, Monocyte percentage: 12 (Inconclusive) 12. On 20-Feb-2021, Neutrophil percentage: 68.8 (Inconclusive) 68.8. On 20-Feb-2021, Oxygen saturation: 88 (Inconclusive) 88. On 20-Feb-2021, PCO2: 28.4 (Inconclusive) 28.4. On 20-Feb-2021, PO2: 58.3 (Inconclusive) 58.3. On 20-Feb-2021, Physical examination: abnormal (Inconclusive) Acute alveolar respiratory murmur over the lung fields, rales in the interscapular region on both sides, more to the right.. On 20-Feb-2021, Platelet count: 225 (Inconclusive) 225. On 20-Feb-2021, Platelet distribution width: 12.7 (Inconclusive) 12.7. On 20-Feb-2021, Platelet-large cell ratio: 32.1 (Inconclusive) 32.1 %. On 20-Feb-2021, Procalcitonin: 0.2% (Inconclusive) 0.2 %. On 20-Feb-2021, Prothrombin time: 62% (Inconclusive) 62 %. On 20-Feb-2021, Red blood cell count: 3.82 (Inconclusive) 3.82. On 20-Feb-2021, Red cell distribution width: 47.4 (Inconclusive) RDW-SD 47.4 fl RDW-CV 13.6 %. On 20-Feb-2021, SARS-CoV-2 test: negative (Negative) negative. On 20-Feb-2021, Troponin T: 14.17 (Inconclusive) 14.17. On 20-Feb-2021, White blood cell count: 2.92 (Inconclusive) 2.92. On 20-Feb-2021, pH body fluid: 7.370 (Inconclusive) 7.370. On 21-Feb-2021, Blood culture: unknown (Inconclusive) Investigation was terminated on 24-Feb-2021. E. coli was grown in anaerobic culture Amoxicillin/clavulanic acid R (MIC >=32.0) Cefuroxime I (MIC4.0) Piperacillin / Tazobactam S (MIC <=4.0) Ceftazidime S (MIC <= 0.12) Cefotaxime S (MIC <= 0.25) Cefepim S (MIC <= 0.12) Imipenem S (MIC <= 0.25) Meropenem S (MIC <= 0.25) Gentamycyna S (MIC <= 1.0) Amikacin S (MIC <= 2.0) Ciprofloxacin S (MIC <= 0.25) Trimethoprim / Sulfamethoxazole S (MIC <= 20.0) and unknown (Inconclusive)

Case ID	Narrative (Complete)
	Investigation was terminated on 24-Feb-2021. E. coli was grown in aerobic culture Amoxicillin/clavulanic acid R (MIC >=32.0) Cefuroxime I (MIC4.0) Piperacillin / Tazobactam S (MIC <=4.0) Ceftazidime S (MIC <= 0.12) Cefotaxime S (MIC <= 0.25) Cefepim S (MIC <= 0.12) Imipenem S (MIC <= 0.25) Meropenem S (MIC <= 0.25) Gentamycyna S (MIC <= 1.0) Amikacin S (MIC <= 2.0) Ciprofloxacin S (MIC <= 0.25) Trimethoprim / Sulfamethoxazole S (MIC <= 20.0). On 21-Feb-2021, Blood glucose: 107 (Inconclusive) 7 am: 107mg% 5 pm: 82 mg%. On 24-Feb-2021, Autopsy: abnormal (Inconclusive) Initial diagnosis: a lardaceous tumor of the hilus and lower lobe of the right lung, 7x70 cm in size and surrounded by satellite nodules of various sizes. Metastases to the lymph nodes of the right hilum of the lung and to the lymph nodes of the tracheal bifurcation. The entire right lung, except for the tumor, is gray, poppy and disintegrates when touched. Left lung with signs of hyperemia and emphysema. High-grade generalized atherosclerosis. Left ventricular hypertrophy. Aortic valve calcification. Significant enlargement of the gallbladder. Small cysts of the kidney cortex (0.5 cm in diameter). Chronic cystitis. Prostatic hypertrophy.. For mRNA-1273 (COVID 19 Vaccine Moderna) (Intramuscular), the reporter considered DYSPNOEA (Dyspnoea), ACUTE KIDNEY INJURY (Acute renal failure) and PYREXIA (Fever) to be probably related and ESCHERICHIA SEPSIS (Escherishia coli sepsis), EMBOLISM (Suspicion of embolism), RENAL CYST (Small kidney cysts), LIVER INJURY (Liver damage), RESPIRATORY FAILURE (Respiratory failure), GALLBLADDER ENLARGEMENT (Gallbladder enlargement), LEFT VENTRICULAR HYPERTROPHY (Left ventricular of heart hypertrophy), HYPERURICAEMIA (Hyperuricemia), LEUKOPENIA (Leukopenia) and GENERAL PHYSICAL HEALTH DETERIORATION (Deterioration of general condition) to be possibly related. Additional medical history details included a tumor of the mediastinum and hilum of the right lung - in an ambulatory chest CT scan with contrast (09-Feb-2021), pathological infiltrative-nodal mass, also described peripherally from the tumor in the upper lobe at the apex of the segment 6 GGO density of atelectatic-inflammatory nature with accompan

Case ID	Narrative (Complete)
[redacted]	This case was received via an unknown source (no reference has been entered for a health authority or license partner) on 31-May-2021 and was forwarded to Moderna on 31-May-2021. This regulatory authority case was reported by a physician and describes the occurrence of HEPATOCELLULAR INJURY (Hepatocellular damage) in a 73-year-old female patient who received mRNA-1273 (COVID 19 Vaccine Moderna) for COVID-19 vaccination. Co-suspect products included non-company products RITUXIMAB ([redacted]CHO)) (TRUXIMA) for B-cell lymphoma, IBRUTINIB (IMBRUVICA) for B-cell lymphoma and LENALIDOMIDE (REVLIMID 10 mg, gélule) for B-cell lymphoma. The patient's past medical history included B-cell lymphoma in January 2020, Osteosynthesis and Oophorectomy. Concurrent medical conditions included Anxiodepressive syndrome and Hypercholesterolaemia. On 29-Mar-2021, the patient started RITUXIMAB ([redacted]CHO)) (TRUXIMA) (IV drip) 615 milligram and IBRUTINIB (IMBRUVICA) (Oral) 560 milligram once a day. On 30-Mar-2021, the patient started LENALIDOMIDE (REVLIMID 10 mg, [redacted](Oral) 20 milligram once a day. On 19-Apr-2021, the patient received first dose of mRNA-1273 (COVID 19 Vaccine Moderna) (Intramuscular) 1 dosage form. On 20-Apr-2021, the patient experienced HEPATOCELLULAR INJURY (Hepatocellular damage) (seriousness criterion medically significant). At the time of the report, HEPATOCELLULAR INJURY (Hepatocellular damage) was resolving. For mRNA-1273 (COVID 19 Vaccine Moderna) (Intramuscular), the reporter did not provide any causality assessments. No other concomitants and no treatment information were reported. Based on the current available information and strong temporal association between the use of mRNA-1273 and the onset of the events, a causal relationship cannot be excluded. Causality is also confounded by the concomitant treatment with Rituximab, lenalidomide and Ibrutinib. Senders case identifying number is [redacted]
[redacted]	This case was received via United States FDA VAERS (Reference number: [redacted] on 01-Jun-2021 and was forwarded to Moderna on 01-Jun-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of DEATH (Death), HEPATIC FAILURE (Hepatic failure) and RENAL FAILURE (Renal failure) in a 48-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 016C219) for COVID-19 vaccination. No medical history was provided by the reporter. Concomitant products included VENLAFAXINE, VENLAFAXINE, ESTRADIOL (DIVIGEL), PANTOPRAZOLE and AMFETAMINE ASPARTATE, AMFETAMINE SULFATE, DEXAMFETAMINE SACCHARATE, DEXAMFETAMINE SULFATE (ADDERALL) for an unknown indication. On 30-Apr-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 02-May-2021, the patient experienced HEPATIC FAILURE (Hepatic failure) (seriousness criteria death, hospitalization and medically significant) and RENAL FAILURE (Renal failure) (seriousness criteria death, hospitalization and medically significant). The patient died on 15-May-2021. The cause of death was not reported. An autopsy was performed, but no results were provided. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Treatment information was not provided. Action taken with mRNA-1273 (Moderna COVID-19 Vaccine) in response to the event was not applicable. Company Comment: Based on the current available information and temporal association between the use of mRNA-1273 and the start date of the events, a causal relationship cannot be excluded. Very limited information regarding this events has been provided at this time.

Case ID	Narrative (Complete)
[redacted]	This spontaneous case was reported by a patient (subsequently medically confirmed) and describes the occurrence of LIVER INJURY (liver damage due to dehydration), NAUSEA (nausea), VOMITING (vomiting) and DEHYDRATION (dehydrated) in a 25-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 008C21A and 030B21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Anxiety. Concomitant products included CLONAZEPAM for Anxiety, AMFETAMINE ASPARTATE, AMFETAMINE SULFATE, DEXAMFETAMINE SACCHARATE, DEXAMFETAMINE SULFATE (ADDERALL) for an unknown indication. On 07-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 05-May-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 2 dosage form. On 06-May-2021, the patient experienced NAUSEA (nausea) (seriousness criterion hospitalization), VOMITING (vomiting) (seriousness criterion hospitalization), DEHYDRATION (dehydrated) (seriousness criterion hospitalization), DYSPHAGIA (could not eat or drink and hold anything down) and PYREXIA (feverish). On 07-May-2021, the patient experienced LIVER INJURY (liver damage due to dehydration) (seriousness criteria hospitalization and medically significant). In May 2021, the patient experienced ALOPECIA (lost lot of hair). On an unknown date, the patient experienced IMPAIRED WORK ABILITY (could not go to work because of illness). The patient was hospitalized until 12-May-2021 due to DEHYDRATION, LIVER INJURY, NAUSEA and VOMITING. On 09-May-2021, NAUSEA (nausea), VOMITING (vomiting) and DYSPHAGIA (could not eat or drink and hold anything down) had resolved. On 12-May-2021, DEHYDRATION (dehydrated) had resolved. At the time of the report, LIVER INJURY (liver damage due to dehydration) had resolved and ALOPECIA (lost lot of hair), IMPAIRED WORK ABILITY (could not go to work because of illness) and PYREXIA (feverish) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 06-May-2021, Blood pressure measurement: unknown (Low) blood pressure dropped. On 07-May-2021, Liver function test: unknown (High) Elevated liver enzymes. Patient was also reported to be taking birth control pills as concomitant medications. Patient reported that several tests were done in the hospital. Patient was reported to stay in the ICU on 07-MAY-2021. Patient was treated with iv fluids, iv potassium and anti-nausea medication. Patient was reported to specifically ask if she can get some refund for the money spent for treatment at the hospital and wanted to talk to somebody from Moderna safety team and was expecting call from safety team to clarify if any refund policy for the injury and answer her questions. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. This case was linked to [redacted] (Patient Link).

Case ID	Narrative (Complete)
[redacted]	This case was received via [redacted] Reference number: [redacted] on 08-Jun-2021 and was forwarded to Moderna on 08-Jun-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of ACUTE KIDNEY INJURY (Acute kidney injury), DISSEMINATED INTRAVASCULAR COAGULATION (Disseminated intravascular coagulation), HAEMOPHAGOCYTIC LYMPHOHISTIOCYTOSIS (Haemophagocytic lymphohistiocytosis), HEPATIC FAILURE (Hepatic failure), MULTIPLE ORGAN DYSFUNCTION SYNDROME (Multiple organ dysfunction syndrome), RESPIRATORY FAILURE (Respiratory failure), THROMBOCYTOPENIA (Thrombocytopenia), SHOCK (Shock), GENERAL PHYSICAL HEALTH DETERIORATION (General physical health deterioration), HYPONATRAEMIA (Hyponatraemia), MALAISE (Malaise), CHILLS (Chills), FATIGUE (Fatigue) and PYREXIA (Pyrexia) in a 62-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. Concurrent medical conditions included Hyperlipidaemia and Seasonal allergy. On 12-Apr-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 16-Apr-2021, the patient experienced ACUTE KIDNEY INJURY (Acute kidney injury) (seriousness criteria hospitalization, medically significant and life threatening), DISSEMINATED INTRAVASCULAR COAGULATION (Disseminated intravascular coagulation) (seriousness criteria hospitalization, medically significant and life threatening), HAEMOPHAGOCYTIC LYMPHOHISTIOCYTOSIS (Haemophagocytic lymphohistiocytosis) (seriousness criteria hospitalization, medically significant and life threatening), HEPATIC FAILURE (Hepatic failure) (seriousness criteria hospitalization, medically significant and life threatening), MULTIPLE ORGAN DYSFUNCTION SYNDROME (Multiple organ dysfunction syndrome) (seriousness criteria hospitalization, medically significant and life threatening), RESPIRATORY FAILURE (Respiratory failure) (seriousness criteria hospitalization, medically significant and life threatening), THROMBOCYTOPENIA (Thrombocytopenia) (seriousness criteria hospitalization, medically significant and life threatening), SHOCK (Shock) (seriousness criteria hospitalization, medically significant and life threatening), GENERAL PHYSICAL HEALTH DETERIORATION (General physical health deterioration) (seriousness criteria hospitalization and life threatening), HYPONATRAEMIA (Hyponatraemia) (seriousness criteria hospitalization and life threatening), MALAISE (Malaise) (seriousness criteria hospitalization and life threatening), CHILLS (Chills) (seriousness criteria hospitalization and life threatening), FATIGUE (Fatigue) (seriousness criteria hospitalization and life threatening) and PYREXIA (Pyrexia) (seriousness criteria hospitalization and life threatening). The patient was hospitalized on sometime in April 2021 due to ACUTE KIDNEY INJURY, CHILLS, DISSEMINATED INTRAVASCULAR COAGULATION, FATIGUE, GENERAL PHYSICAL HEALTH DETERIORATION, HAEMOPHAGOCYTIC LYMPHOHISTIOCYTOSIS, HEPATIC FAILURE, HYPONATRAEMIA, MALAISE, MULTIPLE ORGAN DYSFUNCTION SYNDROME, PYREXIA, RESPIRATORY FAILURE, SHOCK and THROMBOCYTOPENIA. The patient was treated with IBUPROFEN on 16-Apr-2021 for Fever, Chills, Fatigue and Malaise, at a dose of UNK dosage form and ACETAMINOPHEN on 16-Apr-2021 for Fever, Chills, Fatigue and Malaise, at a dose of UNK dosage form. At the time of the report, ACUTE KIDNEY INJURY (Acute kidney injury), DISSEMINATED INTRAVASCULAR COAGULATION (Disseminated intravascular coagulation), HAEMOPHAGOCYTIC LYMPHOHISTIOCYTOSIS (Haemophagocytic lymphohistiocytosis), HEPATIC FAILURE (Hepatic failure), MULTIPLE ORGAN DYSFUNCTION SYNDROME (Multiple organ dysfunction syndrome), RESPIRATORY FAILURE (Respiratory failure), THROMBOCYTOPENIA (Thrombocytopenia), SHOCK (Shock), GENERAL PHYSICAL HEALTH DETERIORATION (General physical health deterioration), HYPONATRAEMIA (Hyponatraemia), MALAISE (Malaise), CHILLS (Chills), FATIGUE (Fatigue) and PYREXIA (Pyrexia) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 16-Apr-2021, Biopsy bone marrow: abnormal (abnormal) Positive for hemophagocytosis on smear. On 16-Apr-2021, Computerised tomogram head normal: normal (normal) Negative for thrombosis. On 16-Apr-2021, Ultrasound Doppler normal: normal (normal) LE dopplers negative for thrombosis. On 16-Apr-2021, Ventilation/perfusion scan: normal (normal) Normal. On 22-Apr-2021, Platelet count: 122 (Low) decreased - 122. On 26-Apr-2021, Alanine aminotransferase: 813 (High) increased - 813. On 26-Apr-2021, Aspartate aminotransferase: 1,106 (High) increased - 1,106. On 26-Apr-2021, Bilirubin conjugated: 2.3 (High) direct bilirubin increased - 2.3. On 26-Apr-2021, Blood bilirubin: 3.3 (High) total bilirubin increased - 3.3. On 26-Apr-2021, Haemoglobin: 10.8 (Low) decreased - 10.8. On 26-Apr-2021, Lipase: 360 (High) increased - 360. On 26-Apr-2021, Serum ferritin: 12,531 (High) increased - highly elevated suggestive of hemophagocytic lymphhistiocytosis (HLH). On 27-Apr-2021, Fibrin D dimer: 8.28 (High) increased - 8.28. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medications were reported. The patient presented to the (emergency room) ER where he was admitted to the hospital and rapidly deteriorated. The patient developed respiratory failure requiring endotracheal intubation and shock requiring vasopressors. At the time of this report, the patient had been transferred to the cancer center for HLH (hemophagocytic lymphohistiocytosis) treatment and was in the intensive care unit (ICU), intubated, sedated and on pressors (vasopressors). Heparin PF4 (heparin-induced thrombocytopenia (HIT)) antibody tests were pending. Although a temporal association exists, provided information is not adequate to assess the causal association between the event and mRNA-1273. According to the reporter, the patient had been transferred to the cancer center for HLH (hemophagocytic lymphohistiocytosis) treatment confounding the causality.

Case ID	Narrative (Complete)
[redacted]	This case was initially received via [redacted] (Reference number: [redacted] on 08-Jun-2021. The most recent information was received on 08-Jun-2021 and was forwarded to Moderna on an unknown date. This regulatory authority case was reported by an other health care professional and describes the occurrence of DEATH (Death), PNEUMONIA LEGIONELLA (Pneumonia legionella), ACUTE HEPATIC FAILURE (Acute hepatic failure), HAEMOPHAGOCYTIC LYMPHOHISTIOCYTOSIS (Haemophagocytic lymphohistiocytosis), HYPERFERRITINAEMIA (Hyperferritinaemia), SLEEP DISORDER (Sleep disorder), PRURITUS (Pruritus) and FATIGUE (Fatigue) in a 65-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. Concurrent medical conditions included Allergy (Iodinated contrast), Leukemia, Atrial fibrillation, Aortic stenosis, Hypertension, GERD and CVA (Prior embolic CVA). Concomitant products included ALLOPURINOL, FLECAINIDE, VITAMIN D3, FOLIC ACID, MAGNESIUM OXIDE, OMEPRAZOLE, PENTAMIDINE, VALACYCLOVIR [VALACICLOVIR], DILTIAZEM, MELATONIN and DECITABINE for an unknown indication. On 20-Jan-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 24-Jan-2021, the patient experienced PNEUMONIA LEGIONELLA (Pneumonia legionella) (seriousness criteria hospitalization, medically significant and life threatening), ACUTE HEPATIC FAILURE (Acute hepatic failure) (seriousness criteria hospitalization, medically significant and life threatening), HAEMOPHAGOCYTIC LYMPHOHISTIOCYTOSIS (Haemophagocytic lymphohistiocytosis) (seriousness criteria hospitalization, medically significant and life threatening), HYPERFERRITINAEMIA (Hyperferritinaemia) (seriousness criteria hospitalization and life threatening), SLEEP DISORDER (Sleep disorder) (seriousness criteria hospitalization and life threatening), PRURITUS (Pruritus) (seriousness criteria hospitalization and life threatening) and FATIGUE (Fatigue) (seriousness criteria hospitalization and life threatening). The patient died on 16-Mar-2021. The cause of death was not reported. It is unknown if an autopsy was performed. At the time of death, PNEUMONIA LEGIONELLA (Pneumonia legionella) had not resolved and ACUTE HEPATIC FAILURE (Acute hepatic failure), HAEMOPHAGOCYTIC LYMPHOHISTIOCYTOSIS (Haemophagocytic lymphohistiocytosis), HYPERFERRITINAEMIA (Hyperferritinaemia), SLEEP DISORDER (Sleep disorder), PRURITUS (Pruritus) and FATIGUE (Fatigue) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 23-Feb-2021, Alanine aminotransferase normal: 2366 (High) high. On 23-Feb-2021, Aspartate aminotransferase increased: 1260 (High) high. On 23-Feb-2021, Coagulation time shortened: abnormal (abnormal) abnormal-0.63. On 23-Feb-2021, Interleukin-2 receptor increased: 3003 (Low) low. On 23-Feb-2021, Serum ferritin: abnormal (abnormal) 32000. On 25-Feb-2021, Alanine aminotransferase normal: 2168 (High) high. On 25-Feb-2021, Aspartate aminotransferase increased: 1114 (High) high. On 25-Feb-2021, Blood bilirubin: abnormal (abnormal) Abnormal-2.4. On 25-Feb-2021, Haemoglobin: abnormal (abnormal) abnormal-9.6. On 25-Feb-2021, Platelet count: low (Low) low-21. On 25-Feb-2021, Serum ferritin: abnormal (abnormal) abnormal-30,400. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Treatment information is not provided. Company Comment: This is a case of death in a 65-year-old male subject with a medical history of Allergy (Iodinated contrast), Leukemia, Atrial fibrillation, Aortic stenosis, Hypertension, GERD and CVA (Prior embolic CVA), who died 55 days after receiving the first dose of vaccine. Based on patient's age and comorbid conditions the death and other events are assessed as unlikely related to mRNA-1273. Most recent FOLLOW-UP information incorporated above includes: On 08-Jun-2021: Upon internal review on 17-Aug-2021, onset of the event of death was updated from 24-Jan-2021 to 16-Mar-2021. Action taken and dechallenge were updated to not applicable.

Case ID	Narrative (Complete)
[redacted]	This case was received via United States FDA VAERS (Reference number: [redacted] on 08-Jun-2021 and was forwarded to Moderna on 08-Jun-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of DEATH (Death), ACUTE RESPIRATORY FAILURE (Acute respiratory failure), CARDIOGENIC SHOCK (Cardiogenic shock), RENAL FAILURE (Renal failure), ANGINA PECTORIS (Angina pectoris) and HEPATIC FAILURE (Hepatic failure) in an 82-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 042L20A) for COVID-19 vaccination. Concurrent medical conditions included Penicillin allergy, Sulfonamide allergy, COPD and AFib. On 10-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 19-Feb-2021, the patient experienced DEATH (Death) (seriousness criteria death, hospitalization, medically significant and life threatening), ACUTE RESPIRATORY FAILURE (Acute respiratory failure) (seriousness criteria death, hospitalization prolonged, medically significant and life threatening), CARDIOGENIC SHOCK (Cardiogenic shock) (seriousness criteria death, hospitalization prolonged, medically significant and life threatening), RENAL FAILURE (Renal failure) (seriousness criteria death, hospitalization prolonged, medically significant and life threatening), ANGINA PECTORIS (Angina pectoris) (seriousness criteria death, hospitalization, medically significant and life threatening) and HEPATIC FAILURE (Hepatic failure) (seriousness criteria death, hospitalization prolonged, medically significant and life threatening). The patient died on 03-Mar-2021. The reported cause of death was Acute hypoxic respiratory failure and Cardiogenic shock. It is unknown if an autopsy was performed. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. On 27-Feb-2021, the patient with complain of Heart pain was transferred to Emergency room 2 times in 2 days. Within two days their liver and kidney function failed. The cause of death listed were acute hypoxic respiratory failure and cardiogenic shock on 03-Mar-2021. No Concomitant product use was reported. No treatment information was provided. Action taken with mRNA-1273 in response to the event was not applicable. Company Comment: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Concomitant medical conditions could be potentially confounders/co-suspects for the events.

Case ID	Narrative (Complete)
[redacted]	This case was received via [redacted] (Reference number: [redacted] on 08-Jun-2021 and was forwarded to Moderna on 08-Jun-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of ACUTE HEPATIC FAILURE (Acute hepatic failure), LOSS OF CONSCIOUSNESS (Loss of consciousness) and HEPATIC PAIN (Hepatic pain) in a 38-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 04642IA) for COVID-19 vaccination. Concurrent medical conditions included Von Willebrand's disease. Concomitant products included VENLAFAXINE HYDROCHLORIDE (EFFEXOR), COLECALCIFEROL (VITAMIN D3 1000) and OMEGA-3 FATTY ACIDS for an unknown indication. On 12-Apr-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 13-Apr-2021, the patient experienced ACUTE HEPATIC FAILURE (Acute hepatic failure) (seriousness criteria hospitalization, medically significant and life threatening), LOSS OF CONSCIOUSNESS (Loss of consciousness) (seriousness criteria hospitalization, medically significant and life threatening) and HEPATIC PAIN (Hepatic pain) (seriousness criteria hospitalization and life threatening). The patient was hospitalized from 13-Apr-2021 to 16-Apr-2021 due to ACUTE HEPATIC FAILURE, HEPATIC PAIN and LOSS OF CONSCIOUSNESS. At the time of the report, ACUTE HEPATIC FAILURE (Acute hepatic failure), LOSS OF CONSCIOUSNESS (Loss of consciousness) and HEPATIC PAIN (Hepatic pain) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 13-Apr-2021, Blood test: inconclusive (Inconclusive) results unknown. On 13-Apr-2021, Computerised tomogram: inconclusive (Inconclusive) results unknown. On 13-Apr-2021, Magnetic resonance cholangiopancreatography: inconclusive (Inconclusive) results unknown. On 13-Apr-2021, Ultrasound scan: inconclusive (Inconclusive) results unknown. On 13-Apr-2021, Urine analysis: inconclusive (Inconclusive) Inconclusive. On 13-Apr-2021, X-ray: inconclusive (Inconclusive) Inconclusive. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. The patient reported 14 hours after the 2nd Moderna vaccine she experienced extreme and severe liver pain followed by loss of consciousness at home. She was rushed to local Emergency Room (ER,) and then life flighted out of state by helicopter in acute liver failure. She was hospitalized for 4 days. All lab results indicate adverse reaction to vaccine. The treatment information was not provided. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. However, patient's medical history of Von Willebrand's disease is a confounding factor.

Case ID	Narrative (Complete)
[redacted]	This case was received via [redacted] (Reference number [redacted]) on 08-Jun-2021 and was forwarded to Moderna on 08-Jun-2021. This regulatory authority case was reported by a health care professional and describes the occurrence of HEPATIC FAILURE (Hepatic failure), FEELING ABNORMAL (Feeling abnormal) and PAIN (Pain) in a 76-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 031A21A) for COVID-19 vaccination. The patient's past medical history included Bypass surgery (Quadruple bypass heart surgery.) and Pacemaker generated rhythm (pacemaker). Concurrent medical conditions included Liver failure. Concomitant products included ACETYLSALICYLIC ACID (BABY ASPIRIN) for Heart disease, unspecified, OMEPRAZOL [OMEPRAZOLE] for an unknown indication. On 24-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 24-Mar-2021, the patient experienced HEPATIC FAILURE (Hepatic failure) (seriousness criteria hospitalization and medically significant), FEELING ABNORMAL (Feeling abnormal) (seriousness criterion hospitalization) and PAIN (Pain) (seriousness criterion hospitalization). The patient was hospitalized from 26-Mar-2021 to 27-Mar-2021 due to FEELING ABNORMAL, HEPATIC FAILURE and PAIN. At the time of the report, HEPATIC FAILURE (Hepatic failure), FEELING ABNORMAL (Feeling abnormal) and PAIN (Pain) outcome was unknown. 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. Additional concomitant medication reported included unspecified blood pressure medication and water pill. It was reported that, within one hour, the patient began feeling "weird" and developed right sided pain. She went to local fire department and was transferred to hospital with severe right side pain. On 26-Mar-2021, the patient had a cholecystectomy the removal of her gallbladder. On 27-Mar-2021, the patient was discharged to home. Since discharge the patient consulted with her liver specialist regarding her gallbladder attack, her liver failure and the effect that the vaccine had on her condition. No treatment medication was not provided. Company Comment: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.

Case ID	Narrative (Complete)
[redacted]	This case was received via [redacted] (Reference number: [redacted]) on 15-Jun-2021 and was forwarded to Moderna on 15-Jun-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of DRUG-INDUCED LIVER INJURY (Drug-induced liver injury), AUTOIMMUNE HEPATITIS (Autoimmune hepatitis) and JAUNDICE (Jaundice) in a 68-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. Concurrent medical conditions included Diabetes and GERD. On 07-May-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 13-May-2021, the patient experienced DRUG-INDUCED LIVER INJURY (Drug-induced liver injury) (seriousness criteria hospitalization and medically significant), AUTOIMMUNE HEPATITIS (Autoimmune hepatitis) (seriousness criteria hospitalization and medically significant) and JAUNDICE (Jaundice) (seriousness criterion hospitalization). At the time of the report, DRUG-INDUCED LIVER INJURY (Drug-induced liver injury), AUTOIMMUNE HEPATITIS (Autoimmune hepatitis) and JAUNDICE (Jaundice) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 13-May-2021, Alanine aminotransferase: increased (High) Alanine aminotransferase increased. On 13-May-2021, Aspartate aminotransferase: increased (High) Aspartate aminotransferase increased. On 13-May-2021, Biopsy liver: abnormal (abnormal) Biopsy liver abnormal. On 13-May-2021, Blood bilirubin: increased (High) Blood bilirubin increased. On 28-May-2021, Alanine aminotransferase: 1500 (abnormal) AST and ALT approx 1500 on 5/28. On 28-May-2021, Aspartate aminotransferase: 1500 (abnormal) AST and ALT approx 1500 on 5/28. On 29-May-2021, Biopsy liver: inconclusive (Inconclusive) DILI vs autoimmune hepatitis, thought to be more related to AIH.. On 30-May-2021, Blood bilirubin: 25 (abnormal) Total Bilirubin highest peak 25 INR 1.4 5/30. On 30-May-2021, International normalised ratio: 1.4 (High) 1.4. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Concomitant product use was not provided by the reporter. Treatment included steroids with improvement. Company Comment: Very limited information regarding these events has been provided at this time. No further information is expected.

Case ID	Narrative (Complete)
[redacted]	This case was initially received via [redacted] (Reference number: [redacted] on 15-Jun-2021. The most recent information was received on 15-Jun-2021 and was forwarded to Moderna on an unknown date. This regulatory authority case was reported by an other health care professional and describes the occurrence of AUTOIMMUNE HEPATITIS (Autoimmune hepatitis), CHROMATURIA (dark urine), FATIGUE (Fatigue), NAUSEA (Nausea) and MYALGIA (aches) in a 37-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. On 04-May-2021, the patient received dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 05-May-2021, the patient experienced AUTOIMMUNE HEPATITIS (Autoimmune hepatitis) (seriousness criteria disability and medically significant), CHROMATURIA (dark urine) (seriousness criterion disability), FATIGUE (Fatigue) (seriousness criterion disability), NAUSEA (Nausea) (seriousness criterion disability) and MYALGIA (aches) (seriousness criterion disability). At the time of the report, AUTOIMMUNE HEPATITIS (Autoimmune hepatitis), CHROMATURIA (dark urine), FATIGUE (Fatigue), NAUSEA (Nausea) and MYALGIA (aches) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 05-May-2021, Blood bilirubin: high (High) High. On 05-May-2021, Ultrasound scan: abnormal (abnormal) abnormal. On 24-May-2021, Blood bilirubin: high (High) extremely elevated bilirubin levels. On 25-May-2021, Ultrasound scan: abnormal (abnormal) ultrasound confirmed inflamed liver. On 27-May-2021, Ultrasound scan: abnormal (abnormal) liver specialist confirmed autoimmune hepatitis. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown) was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter considered FATIGUE (Fatigue) and NAUSEA (Nausea) to be possibly related. No further causality assessments were provided for AUTOIMMUNE HEPATITIS (Autoimmune hepatitis), CHROMATURIA (dark urine) and MYALGIA (aches). No concomitant medication was reported. No treatment medications were reported. It was reported that the treatment plan was with steroids followed by nonsteroidal immunosuppressants for 3-5yrs. Company Comment: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded Most recent FOLLOW-UP information incorporated above includes: On 15-Jun-2021: Upon internal review on 06-Jan-2022, significant correction was performed: Treatment information was updated in the narrative and narrative was updated accordingly

Case ID	Narrative (Complete)
[redacted]	This case was received via [redacted] (Reference number: [redacted] on 15-Jun-2021 and was forwarded to Moderna on 15-Jun-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of CARDIAC FAILURE (Cardiac failure), INTENSIVE CARE (Intensive care), LIVER INJURY (Liver injury), LOSS OF CONSCIOUSNESS (Loss of consciousness), MECHANICAL VENTILATION (Mechanical ventilation), NAUSEA (Nausea), PNEUMONIA (Pneumonia), RENAL INJURY (Renal injury), SEPSIS (Sepsis) and THROMBOSIS (Thrombosis) in a 73-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 014M20A) for COVID-19 vaccination. The patient's past medical history included Asthma. Concurrent medical conditions included Drug allergy (tetracycline) and Drug allergy (Sulfa). Concomitant products included METOPROLOL, TRAMADOL, TRAZODONE, SALBUTAMOL SULFATE ([redacted] [SALBUTAMOL SULFATE]), ATORVASTATIN, CYANOCOBALAMIN (VITAMIN B-12), GABAPENTIN, GLUCOSAMINE, MULTIVITAMINS [VITAMINS NOS], OLMESARTAN, OMEPRAZOLE, TAMSULOSIN and VITAMIN D3 for an unknown indication. On 26-Feb-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to I dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 07-Mar-2021, the patient experienced CARDIAC FAILURE (Cardiac failure) (seriousness criteria hospitalization, medically significant and life threatening), INTENSIVE CARE (Intensive care) (seriousness criteria hospitalization and life threatening), LIVER INJURY (Liver injury) (seriousness criteria hospitalization, medically significant and life threatening), LOSS OF CONSCIOUSNESS (Loss of consciousness) (seriousness criteria hospitalization, medically significant and life threatening), MECHANICAL VENTILATION (Mechanical ventilation) (seriousness criteria hospitalization and life threatening), NAUSEA (Nausea) (seriousness criteria hospitalization and life threatening), PNEUMONIA (Pneumonia) (seriousness criteria hospitalization, medically significant and life threatening), RENAL INJURY (Renal injury) (seriousness criteria hospitalization, medically significant and life threatening), SEPSIS (Sepsis) (seriousness criteria hospitalization, medically significant and life threatening) and THROMBOSIS (Thrombosis) (seriousness criteria hospitalization, medically significant and life threatening). The patient was treated with APIXABAN (ELIQUIS) ongoing since an unknown date at an unspecified dose and frequency. At the time of the report, CARDIAC FAILURE (Cardiac failure), INTENSIVE CARE (Intensive care), LIVER INJURY (Liver injury), LOSS OF CONSCIOUSNESS (Loss of consciousness), MECHANICAL VENTILATION (Mechanical ventilation), NAUSEA (Nausea), PNEUMONIA (Pneumonia), RENAL INJURY (Renal injury), SEPSIS (Sepsis) and THROMBOSIS (Thrombosis) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 07-Mar-2021, Blood test abnormal: abnormal (abnormal) abnormal. On 07-Mar-2021, Cardiac stress test: abnormal (abnormal) Abnormal. On 07-Mar-2021, Chest X-ray: abnormal (abnormal) Abnormal. On 07-Mar-2021, Computerised tomogram thorax: abnormal (abnormal) Abnormal. On 07-Mar-2021, Electrocardiogram: abnormal (abnormal) Abnormal. On 07-Mar-2021, Liver scan: abnormal (abnormal) Abnormal. On 07-Mar-2021, Renal function test: abnormal (abnormal) Abnormal. On 07-Mar-2021, X-ray: inconclusive (Inconclusive) Inconclusive. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No treatment drug information provided. Action taken with mRNA-1273 in response to the events was not applicable. The patient after 1st shot, unconscious, blood sepsis, nausea, on a ventilator, severe pneumonia in right lung. In ICU for 3 days, normal ward 3 days, treated with antibiotics, 2nd shoot unconscious, blood sepsis, blood clot, heart failure, kidney & liver damage, treated with Eliquis and antibiotics. At hospital in ICU for 2 days, normal ward 3 days. Continuing with Eliquis, increased Metoprolol. Follow-up with kidney specialist and Cardiologist PA. Company Comment Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.

Case ID	Narrative (Complete)
[redacted]	This case was received via [redacted] (Reference number: [redacted]) on 15-Jun-2021 and was forwarded to Moderna on 15-Jun-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of ACUTE KIDNEY INJURY (Acute kidney injury), HEART INJURY (Heart injury) and LIVER INJURY (Liver injury) in a 40-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 011J20A and 028L20A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No medical information history was reported. Concomitant products included TESTOSTERONE (ANDROGEL), LEVOTHYROXINE SODIUM (SYNTHROID) and MULTIVITAMINS [VITAMINS NOS] for an unknown indication. On 08-Jan-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 08-Jan-2021, the patient experienced ACUTE KIDNEY INJURY (Acute kidney injury) (seriousness criterion medically significant), HEART INJURY (Heart injury) (seriousness criterion medically significant), LIVER INJURY (Liver injury) (seriousness criterion medically significant), DYSPNOEA (Dyspnoea), PAIN (Pain) and FATIGUE (Fatigue). At the time of the report, ACUTE KIDNEY INJURY (Acute kidney injury), HEART INJURY (Heart injury), LIVER INJURY (Liver injury), DYSPNOEA (Dyspnoea), PAIN (Pain) and FATIGUE (Fatigue) had not resolved. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. On 08-Jan-2021, Blood test, Chest X-ray, Electrocardiogram were done. Results were not provided. Treatment information was not reported. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded
[redacted]	This case was received via [redacted] (Reference number: [redacted]) on 15-Jun-2021 and was forwarded to Moderna on 15-Jun-2021. This regulatory authority prospective pregnancy case was reported by an other health care professional and describes the occurrence of AUTOIMMUNE HEPATITIS (Autoimmune hepatitis) and HEPATITIS C (Hepatitis C) in a 40-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 025J20-2A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 30-Dec-2020, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. Last menstrual period and estimated date of delivery were not provided. On 17-Jan-2021, the patient experienced AUTOIMMUNE HEPATITIS (Autoimmune hepatitis) (seriousness criterion medically significant), HEPATITIS C (Hepatitis C) (seriousness criterion medically significant) and HEPATOMEGALY (Hepatomegaly). On an unknown date, the patient experienced EXPOSURE DURING PREGNANCY (Pregnancy). At the time of the report, AUTOIMMUNE HEPATITIS (Autoimmune hepatitis), HEPATITIS C (Hepatitis C) and HEPATOMEGALY (Hepatomegaly) had not resolved and EXPOSURE DURING PREGNANCY (Pregnancy) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 17-Jan-2021, Human chorionic gonadotropin: Positive. 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. Patient reported NKDA allergies. Lab Data includes on 01/22 = CBC, lipase, CMP, BHCG, Troponin, Acetaminophen, Acute Hep Panel, PT/INR, UA, Urine Culture, CT abdomen pelvis, US abdomen On 01/24 = CBC, CMP, Lipase, PT/INR, Hep C 01/26 = Epstein Barr, CBC, CMP 02/02 = CMP 02/05 = CMP 02/22 = CMP 05/17 = ANA, CMP, CBC No concomitant medication was reported. No treatment was reported. Company comment: Very limited information regarding this event (autoimmune hepatitis) has been provided at this time. However, based on the mechanism of action of mRNA-1273, the event (Hepatitis c) is unlikely related to mRNA-1273. However, results of all the labs/diagnostics are necessary for further assessment. This is a case of possible product exposure during pregnancy with no associated AEs. There is no contact details to contact to confirm pregnancy and to monitor AEs during the pregnancy.

Case ID	Narrative (Complete)
[redacted]	This case was received via [redacted] (Reference number: [redacted] on 15-Jun-2021 and was forwarded to Moderna on 15-Jun-2021. This case was received via [redacted] (Reference number: [redacted]) on 15-Jun-2021 and was forwarded to Moderna on 15-Jun-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of AUTOIMMUNE HEPATITIS (Autoimmune hepatitis) in a 35-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. On 25-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 02-Apr-2021, the patient experienced AUTOIMMUNE HEPATITIS (Autoimmune hepatitis) (seriousness criterion medically significant). At the time of the report, AUTOIMMUNE HEPATITIS (Autoimmune hepatitis) had not resolved. 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. On 02-Apr-2021, patient underwent liver biopsy and Ultrasound scan (results were not provided for both), also had done diagnostic investigations including blood immunoglobulin G (results were not provided), Liver function test (results were not provided) and unspecified blood test (results were not provided). Approximately one month after vaccination patient was diagnosed with auto-immune hepatitis. No concomitant medication was provided. Treatment details were not provided. Company Comment: Very limited information regarding this event has been provided at this time. All the results of tests/diagnostics are required for further evaluation.
[redacted]	This case was received via [redacted] (Reference number: [redacted] on 15-Jun-2021 and was forwarded to Moderna on 15-Jun-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of PERITONITIS (Peritonitis), PORTAL FIBROSIS (Portal fibrosis), HEPATITIS ACUTE (Hepatitis acute), ASTHMA (Asthma), CHRONIC OBSTRUCTIVE PULMONARY DISEASE (Chronic obstructive pulmonary disease), CONDITION AGGRAVATED (Condition aggravated), HEPATIC LYMPHOCYTIC INFILTRATION (Hepatic lymphocytic infiltration), BLOOD ALKALINE PHOSPHATASE INCREASED (Blood alkaline phosphatase increased), INTERNATIONAL NORMALISED RATIO INCREASED (International normalised ratio increased), LIVER IRON CONCENTRATION INCREASED (Liver iron concentration increased), PROTHROMBIN TIME PROLONGED (Prothrombin time prolonged), BLOOD BILIRUBIN INCREASED (Blood bilirubin increased) and LEUKAEMIC INFILTRATION HEPATIC (Leukemic involvement of the liver) in a 65-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 012L20A and 013M20A) for COVID-19 vaccination. The patient's past medical history included Renal failure. Concurrent medical conditions included CLL, Drug allergy (Simvastatin), COPD and Asthma. Concomitant products included [redacted] [SALBUTAMOL], FLUTICASONE, BUDESONIDE, OMEPRAZOLE, FUROSEMIDE (LASIX [FUROSEMIDE]), WARFARIN SODIUM (COUMADIN), VITAMIN D NOS and METOPROLOL for an unknown indication. On 14-Jan-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 11-Feb-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 18-Feb-2021, the patient experienced PERITONITIS (Peritonitis) (seriousness criteria hospitalization and medically significant), PORTAL FIBROSIS (Portal fibrosis) (seriousness criteria hospitalization and medically significant), HEPATITIS ACUTE (Hepatitis acute) (seriousness criteria hospitalization and medically significant), ASTHMA (Asthma) (seriousness criterion hospitalization prolonged), CHRONIC OBSTRUCTIVE PULMONARY DISEASE (Chronic obstructive pulmonary disease) (seriousness criterion hospitalization prolonged) and CONDITION AGGRAVATED (Condition aggravated) (seriousness criterion hospitalization prolonged). 18-Feb-2021, the patient experienced HEPATIC LYMPHOCYTIC INFILTRATION (Hepatic lymphocytic infiltration) (seriousness criterion hospitalization), BLOOD ALKALINE PHOSPHATASE INCREASED (Blood alkaline phosphatase increased) (seriousness criterion hospitalization), INTERNATIONAL NORMALISED RATIO INCREASED (International normalised ratio increased) (seriousness criterion hospitalization), LIVER IRON CONCENTRATION INCREASED (Liver iron concentration increased) (seriousness criterion hospitalization), PROTHROMBIN TIME PROLONGED (Prothrombin time prolonged) (seriousness criterion hospitalization), BLOOD BILIRUBIN INCREASED (Blood bilirubin increased) (seriousness criterion hospitalization) and LEUKAEMIC INFILTRATION HEPATIC (Leukemic involvement of the liver) (seriousness criteria hospitalization and medically significant). The patient was hospitalized from sometime in February 2021 to sometime in 2021 due to ASTHMA, CHRONIC OBSTRUCTIVE PULMONARY DISEASE, CONDITION AGGRAVATED, HEPATITIS ACUTE, PERITONITIS and PORTAL FIBROSIS. At the time of the report, PERITONITIS (Peritonitis), PORTAL FIBROSIS (Portal fibrosis), HEPATITIS ACUTE (Hepatitis acute), ASTHMA (Asthma), CHRONIC OBSTRUCTIVE PULMONARY DISEASE (Chronic obstructive pulmonary disease), CONDITION AGGRAVATED (Condition aggravated), HEPATIC LYMPHOCYTIC INFILTRATION (Hepatic lymphocytic infiltration), BLOOD ALKALINE PHOSPHATASE INCREASED (Blood alkaline phosphatase increased), INTERNATIONAL NORMALISED RATIO INCREASED (International normalised ratio increased), LIVER IRON CONCENTRATION INCREASED (Liver iron concentration increased), PROTHROMBIN TIME PROLONGED (Prothrombin time prolonged), BLOOD BILIRUBIN INCREASED (Blood bilirubin increased) and LEUKAEMIC INFILTRATION HEPATIC (Leukemic involvement of the liver) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 18-Feb-2021, Alanine aminotransferase (29-33): 660 ui/l (High) Abnormal. On 18-Feb-2021, Aspartate aminotransferase (8-48): 353 ui/l (High) increased. On 18-Feb-2021, Biopsy liver: hepatic lymphocytic infiltration (abnormal) Significant numbers of plasma cells, eosinophils or neutrophils are not seen. Activity in the form of extension beyond the limiting plate or hepatocellular necrosis is not seen. No granulomas are present. The lymphoid infiltrate is not nodular or atypical within the hepatocellular parenchyma. The iron stain reveals a modest increase in hepatocellular iron. The PAS stain reveals well glycogenated hepatocellular parenchyma without PAS positive, diastase resistant material other than pigment which appears to be lipofuscin. Bile pigment is not seen. The reticulin and trichrome stains do not show evidence of fibrosis or cirrhosis.. On 18-Feb-2021, Blood alkaline phosphatase (44-147): 663 ui/l (High) increased. On 18-Feb-2021, Blood bilirubin (0.3-1.2): 1.2 mg/dl (normal) 1.2 mg/dL.

Case ID	Narrative (Complete)
	On 18-Feb-2021, Hepatitis B DNA assay: negative (normal) Negative for Hepatitis B. On 18-Feb-2021, Peritoneal dialysis: cronic renal failure (Inconclusive) Current procedure due to CRF. On 18-Feb-2021, Prothrombin time prolonged: 31 (High) Abnormal Corrected with Vit K. On 14-May-2021, Biopsy liver: portal fibrosis (abnormal) A number of the portal tracts are expanded by rather well circumscribed lymphoid cell aggregates. This may be related to the patient's chronic viral hepatitis. However, in a patient with chronic lymphocytic leukemia, the possibility of leukemic involvement of the liver cannot be excluded on the current materials. A small number of hepatocytes may be ballooned. A proportion of the Kupffer cells contain cytoplasmic debris, as is well seen with the PASD stain. This may be related to the recent serum elevation of transaminases. That this may be associated temporally with the vaccine inoculation is intersting. With the iron stain, a mild increase in iron in Kupffer cells and hepatocytes is noted. Portal fibrosis is noted with the trichrome stain. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. The reporter stated that it isn't clear exactly when the abnormal lab findings began, but noted that labs on 14-Jan-21 were essentially the patient's baseline and then the next routine check on 18-Feb-21 found a significant elevation from his previous baseline that continued until peak around first week of May. The reporter also stated that the patient was admitted for this and that ultimately underwent a liver biopsy. The reporter stressed that these findings did not suggest CLL, autoimmune hepatitis and that the other lab work up was negative. Per report, the patient's labs abnormalities started to decrease by May 17th and he is still currently followed in the Hepatology Clinic. No treatment information was provided by the reporter. Action taken with mRNA-1273 was not applicable. Company Comment: The case has several confounders including patient's history of CLL, CRF on peritoneal dialysis, Drug allergy, COPD and Asthma, however based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded

Case ID	Narrative (Complete)
[redacted]	This case was initially received via European Medicines Agency (Reference number: [redacted] on 21-Jun-2021. The most recent information was received on 25-Aug-2021 and was forwarded to Moderna on 25-Aug-2021. This regulatory authority case was reported by a physician and describes the occurrence of HAEMORRHAGIC ASCITES (Hemorrhagic ascites), SHOCK HAEMORRHAGIC (Haemorrhagic shock), TRUNCUS COELIACUS THROMBOSIS (Truncus coeliacus thrombosis) and ACUTE HEPATIC FAILURE (Acute hepatic failure) in a 63-year-old female patient who received mRNA-1273 (COVID 19 Vaccine Moderna) (batch no. 3002620) for Prophylactic vaccination. No Medical History information was reported. On 29-Apr-2021, the patient received first dose of mRNA-1273 (COVID 19 Vaccine Moderna) (unknown route) 1 dosage form. On 10-Jun-2021, received second dose of mRNA-1273 (COVID 19 Vaccine Moderna) (unknown route) dosage was changed to 1 dosage form. On 12-Jun-2021, the patient experienced HAEMORRHAGIC ASCITES (Hemorrhagic ascites) (seriousness criteria death, hospitalization, medically significant and life threatening), SHOCK HAEMORRHAGIC (Haemorrhagic shock) (seriousness criteria death, hospitalization, medically significant and life threatening), TRUNCUS COELIACUS THROMBOSIS (Truncus coeliacus thrombosis) (seriousness criteria death, hospitalization, medically significant and life threatening) and ACUTE HEPATIC FAILURE (Acute hepatic failure) (seriousness criteria death, hospitalization, medically significant and life threatening). The reported cause of death was Hemorrhagic shock. It is unknown if an autopsy was performed. For mRNA-1273 (COVID 19 Vaccine Moderna) (Unknown), the reporter considered HAEMORRHAGIC ASCITES (Hemorrhagic ascites), SHOCK HAEMORRHAGIC (Haemorrhagic shock), TRUNCUS COELIACUS THROMBOSIS (Truncus coeliacus thrombosis) and ACUTE HEPATIC FAILURE (Acute hepatic failure) to have an unknown relationship. Concomitant medications were not provided. Treatment information was not provided. This case refers to a 63-year-old female patient who experienced the serious unexpected events Haemorrhagic ascites, Haemorrhagic shock, Haemorrhagic shock and Acute hepatic failure events 2 days after receiving the mRNA vaccine. Very limited information regarding the events has been provided at this time. The events are probably related to the patient's comorbidities. Additional information required. Most recent FOLLOW-UP information incorporated above includes: On 21-Jun-2021: Seriousness criteria was changed to 'hospitalisation' and 'life threatening' from 'death' and outcome of the events changed to 'unknown' and 'not recovered' from fatal. On 25-Aug-2021: Follow up received contains no significant information. On 25-Aug-2021: Follow-up information received contain significant information. Updated event outcome and cause of the death.
[redacted]	This case was received via United States FDA VAERS (Reference number: [redacted] on 22-Jun-2021 and was forwarded to Moderna on 22-Jun-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of CARDITIS (heart inflammation), CONFUSIONAL STATE (confusion), DYSARTHRIA (Slurred speech), HEPATIC FAILURE (liver failure) and MOBILITY DECREASED (loss of use of limbs) in a 65-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The patient's past medical history included Kidney disorder (Kidney disease.) since an unknown date. On 22-Feb-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 22-Feb-2021, the patient experienced CARDITIS (heart inflammation) (seriousness criteria death, hospitalization and medically significant), CONFUSIONAL STATE (confusion) (seriousness criteria death and hospitalization), DYSARTHRIA (Slurred speech) (seriousness criterion death), HEPATIC FAILURE (liver failure) (seriousness criteria death, hospitalization and medically significant) and MOBILITY DECREASED (loss of use of limbs) (seriousness criterion death). The patient was hospitalized on 22-Feb-2021 due to CARDITIS, CONFUSIONAL STATE and HEPATIC FAILURE. The patient died on 17-May-2021. It is unknown if an autopsy was performed. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. No concomitant medications were reported. Patient had lab done on 23-Feb-2021 -17-May-2021 but no results were reported. No treatment information was reported. Based on current available information and the temporal association between product use and the start date of the events a causal relationship cannot be excluded.

Case ID	Narrative (Complete)
[redacted]	This literature-non-study case was reported in a literature article and describes the occurrence of AUTOIMMUNE HEPATITIS (SARS-CoV-2 vaccine induced-AIH) in a 41-year-old female patient who received mRNA-1273 (COVID 19 Vaccine Moderna) for COVID-19 vaccination. LITERATURE REFERENCE: Londono MC, Gines JG, Penataro JS. Another case of autoimmune hepatitis after SARS-CoV-2 vaccination - still casualty?. J Hepatol. 2021;75(5):1248-9 Concurrent medical conditions included Premature ovarian failure (undergoing substitutive hormonal therapy with no side effect.). 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 an unknown date, the patient experienced AUTOIMMUNE HEPATITIS (SARS-CoV-2 vaccine induced-AIH) (seriousness criterion medically significant). The patient was treated with PREDNISONE for Autoimmune hepatitis, at a dose of 1 milligram/kilogram. At the time of the report, AUTOIMMUNE HEPATITIS (SARS-CoV-2 vaccine induced-AIH) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In 2021, Alanine aminotransferase: 1,312 iu/l 1,312 IU/L. In 2021, Antinuclear antibody: positive (Positive) Positive. In 2021, Aspartate aminotransferase: 993 iu/l 993 IU/L. In 2021, Biopsy liver: abnormal (abnormal) The liver biopsy (2.5 cm, 19 portal tracts) showed a marked expansion of the portal tracts with a dense inflammatory infiltrate composed by lymphocytes and plasma cells, severe interface hepatitis and lobular inflammation with disperse necro inflammatory foci, apoptotic bodies and hepatocyte ballooning.. In 2021, Blood alkaline phosphatase: 190 iu/l 190 IU/L. In 2021, Blood bilirubin: 2.3 mg/dl 2.3 mg/dl (peak of 8.5 mg/dl). In 2021, Blood immunoglobulin G: 20.8 g/l (High) IgG levels were elevated (20.8 g/L).. In 2021, Cytomegalovirus test: negative (Negative) Negative. In 2021, Epstein-Barr virus test: negative (Negative) Negative. In 2021, Gamma-glutamyltransferase: 209 iu/l 209 IU/L. In 2021, Hepatitis A virus test: negative (Negative) Negative. In 2021, Hepatitis B virus test: negative (Negative) Negative. In 2021, Hepatitis C virus test: negative (Negative) Negative. In 2021, Hepatitis E virus test: negative (Negative) Negative. In 2021, Herpes simplex test: negative (Negative) herpes simplex virus type 1 and 2 and herpes 6 virus were negative. In 2021, Histology: no signs of parenchymal or perisinusoidal fibrosis Masson's trichrome staining showed no signs of parenchymal or perisinusoidal fibrosis.. In 2021, Smooth muscle antibody: positive (Positive) Positive. In 2021, Ultrasound liver: normal (normal) normal. For mRNA-1273 (COVID 19 Vaccine Moderna) (Unknown), the reporter considered AUTOIMMUNE HEPATITIS (SARS-CoV-2 vaccine induced-AIH) to be possibly related. After receiving the first dose of SARS-CoV-2 Moderna vaccine (mRNA-1273) the patient presented epigastric pain, nausea and vomiting. These symptoms lasted for 3 weeks and then decreased in intensity. Seven days after the second dose, symptoms reappeared with higher intensity and were associated with choluria and jaundice. Laboratory tests also included anti-soluble liver antigen (anti-SLA) and anti-liver cytosol tests which were positive The score of simplified diagnostic criteria of the International Autoimmune Hepatitis Group was 8 (definite diagnosis of AIH) and the patient was diagnosed with SARS-CoV-2 vaccine induced-AIH. Corticosteroid treatment with high-dose prednisone (1 mg/kg) was started with rapid normalization of liver enzymes. Authors stated that they believe that more than casualty, the association between SARS-CoV-2 vaccines and AIH is causality. Author concluded that the benefits of vaccination are far higher than the potential risks of the vaccines and therefore the report of these 2 cases should not be used as an argument against vaccination. It should be noted that these reports illustrate a rare adverse event that has only been detected after the administration of millions of doses of mRNA vaccines in a "real-world" setting. Most recent FOLLOW-UP information incorporated above includes: On 22-Jun-2021: Upon review performed on 10-Feb-2022, literature reference details, author contact information, laboratory tests, outcome of event were updated, dose 1 and dose 2 cases were merged On 22-Jun-2021: Upon internal review on 17-Feb-2022, a non-significant amendment was performed in the case: Company Comment corrected. On 23-Jun-2021: Follow up received by safety 23-JUN-2021 has Email with FTA received and does not contain any new information. On 25-Nov-2021: Follow up received by safety 25-NOV-2021 has Email with FTA received from SARA team and does not contain any new information. Company comment: This literature case describes the occurrence of serious AESI of Autoimmune hepatitis (SARS-CoV-2 vaccine induced-AIH) in a 41-year-old female patient with relevant medical history of premature ovarian failure with undergoing substitutive hormonal therapy. On unknown date patient received the first dose of mRNA-1273 and then presented (latency unknown) epigastric pain, nausea and vomiting. These symptoms lasted for 3 weeks and then decreased in intensity. Seven days after the second dose of mRNA-1273 symptoms reappeared with higher intensity and were associated with choluria and jaundice. Based on available tests results (very well documented) patient was diagnosed with SARS-CoV-2 vaccine induced-AIH. Corticosteroid treatment with high-dose prednisone (1 mg/kg) was started with rapid normalization of liver enzymes. Author of article believes that is the more than causality between the mRNA-1273 and reported event, however author is also stating that his article describes rare adverse event and only 2 such cases were documented so far after the millions of doses of mRNA-1273. Patient's medical history of premature ovarian failure with undergoing substitutive hormonal therapy seems to be confounding factor. The benefit-risk relationship of the Moderna mRNA-1273 vaccine is not affected by this report.

Case ID	Narrative (Complete)
[redacted]	This case was received via [redacted] (Reference number: [redacted] on 22-Jun-2021 and was forwarded to Moderna on 22-Jun-2021. This regulatory authority case was reported by a health care professional and describes the occurrence of DRUG-INDUCED LIVER INJURY (Drug-induced liver injury), HEPATITIS CHOLESTATIC (Hepatitis cholestatic) and CHROMATURIA (Chromaturia) in a 43-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. Concomitant products included IBUPROFEN for an unknown indication. On 11-Feb-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 15-Mar-2021, the patient experienced DRUG-INDUCED LIVER INJURY (Drug-induced liver injury) (seriousness criteria hospitalization, medically significant and life threatening), HEPATITIS CHOLESTATIC (Hepatitis cholestatic) (seriousness criteria hospitalization, medically significant and life threatening), CHROMATURIA (Chromaturia) (seriousness criteria hospitalization and life threatening) and PYREXIA (Pyrexia). At the time of the report, DRUG-INDUCED LIVER INJURY (Drug-induced liver injury), HEPATITIS CHOLESTATIC (Hepatitis cholestatic), CHROMATURIA (Chromaturia) and PYREXIA (Pyrexia) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 15-Mar-2021, Alanine aminotransferase: high (High) High. On 15-Mar-2021, Biopsy liver: abnormal (abnormal) abnormal. On 15-Mar-2021, Blood bilirubin: high (High) High. On 15-Mar-2021, Liver function test: high (High) High. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Action taken with mRNA-1273 in response to the events was not Applicable. Company Comment Based on the information provided which includes a temporal association and excluding other etiology. a causal association between the reported events and the administration of the mRNA-1273 cannot be excluded. Fever is consistent with the product known safety profile.
[redacted]	This regulatory authority case was reported by a physician and describes the occurrence of HEPATOCELLULAR INJURY (Hepatocellular damage) in a 73-year-old female patient who received mRNA-1273 (COVID 19 Vaccine Moderna) (batch no. 3001413) for COVID-19 vaccination. Co-suspect product included non-company product PARACETAMOL for Fever. The patient's past medical history included Uterine fibromyoma (UTERINE FIBROID + HYSTEROSCOPIC ENDOMETRIAL RESECTION) on 05-Oct-1998. Concurrent medical conditions included Degeneration macular and Hypothyroidism. On 01-Apr-2021, the patient received first dose of mRNA-1273 (COVID 19 Vaccine Moderna) (Intramuscular) 1 dosage form. On 18-Apr-2021, the patient started PARACETAMOL (Oral) 3 gram. On 21-Apr-2021, the patient experienced HEPATOCELLULAR INJURY (Hepatocellular damage) (seriousness criterion medically significant). At the time of the report, HEPATOCELLULAR INJURY (Hepatocellular damage) had resolved. The action taken with mRNA-1273 (COVID 19 Vaccine Moderna) (Intramuscular) was unknown. For mRNA-1273 (COVID 19 Vaccine Moderna) (Intramuscular), the reporter did not provide any causality assessments. Concomitant product use was not provided by the reporter. Treatment information was not provided. Safety Report Unique Identifier [redacted] Company Comment: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. Concomitant medication could be potentially co-suspect for the event Most recent FOLLOW-UP information incorporated above includes: On 25-Jun-2021: Translation document received on 25 Jun 2021, medical history comments, medicinal Product Name as reported by the primary source was translated to English with no new information.

Case ID	Narrative (Complete)
[redacted]	This regulatory authority case was reported by a physician and describes the occurrence of IMMUNE THROMBOCYTOPENIA (Immune thrombocytopenia), ACUTE HEPATIC FAILURE (Acute hepatic failure) and EPSTEIN-BARR VIRUS INFECTION REACTIVATION (Epstein-Barr virus infection reactivation) in a 46-year-old female patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for SARS-CoV-2 immunisation. The occurrence of additional non-serious events is detailed below. Family history included Autoimmune disorder NOS (Positive family history for auto-immune disease in the sister (SAPHO- synovitis, acne, pustulosis, hyperostosis, osteitis from the age of 30).). Concurrent medical conditions included Endometriosis and Alcohol use (alcohol consumption of 2 glasses of wine 3x/week. Labeled "medically important" because the patient had to be seen on several occasions). Concomitant products included DIENOGEST (VISANNE) for Endometriosis, PARACETAMOL from 24-Apr-2021 to 10-May-2021, MEFENAMIC ACID (PONSTAN) from 24-Apr-2021 to 10-May-2021 and TIZANIDINE HYDROCHLORIDE (SIRDALUD) from 24-Apr-2021 to 10-May-2021 for Pain. On 01-May-2021, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form. On 06-May-2021, the patient experienced ASTHENIA (asthenia), DIZZINESS (dizziness), PYREXIA (Fever), MYALGIA (myalgia) and HEADACHE (intense headaches). On 10-May-2021, the patient experienced IMMUNE THROMBOCYTOPENIA (Immune thrombocytopenia) (seriousness criterion medically significant) and ACUTE HEPATIC FAILURE (Acute hepatic failure) (seriousness criterion medically significant). 10-May-2021, the patient experienced EPSTEIN-BARR VIRUS INFECTION REACTIVATION (Epstein-Barr virus infection reactivation) (seriousness criterion medically significant). On an unknown date, the patient experienced INFLUENZA LIKE ILLNESS (flu-like illness), DYSPNOEA (dyspnea), PAIN IN EXTREMITY (lower right limb pain), CHEST PAIN (chest pain) and OFF LABEL USE (Off label dosing frequency). The patient was treated with PREDNISONE on 17-May-2021 for Thrombocytopenia, at an unspecified dose and frequency. On 21-May-2021, IMMUNE THROMBOCYTOPENIA (Immune thrombocytopenia) had resolved. At the time of the report, ACUTE HEPATIC FAILURE (Acute hepatic failure) and EPSTEIN-BARR VIRUS INFECTION REACTIVATION (Epstein-Barr virus infection reactivation) was resolving, INFLUENZA LIKE ILLNESS (flu-like illness), ASTHENIA (asthenia), DIZZINESS (dizziness), DYSPNOEA (dyspnea), PAIN IN EXTREMITY (lower right limb pain), CHEST PAIN (chest pain), PYREXIA (Fever), MYALGIA (myalgia) and HEADACHE (intense headaches) outcome was unknown and OFF LABEL USE (Off label dosing frequency) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 16-Nov-2020, Heparin-induced thrombocytopenia test: positive (Positive) Positive. On 10-May-2021, Blood bilirubin: normal (normal) Normal. On 12-May-2021, Hepatitis viral: negative (Negative) Negative. On 12-May-2021, Herpes simplex test: positive (Positive) Positive. On 12-May-2021, Polymerase chain reaction: positive (Positive) POSITIVE. On 13-May-2021, Ultrasound scan abnormal: abnormal (abnormal) Abnormal showed hepatosplenomegaly. On 14-May-2021, Antinuclear antibody: positive (Positive) Positive. On 14-May-2021, Heparin-induced thrombocytopenia test: positive (Positive) Positive. On 14-May-2021, Smooth muscle antibody: positive (Positive) Positive. On 19-May-2021, Heparin-induced thrombocytopenia test: positive (Positive) Positive. On 21-May-2021, Epstein-Barr virus antibody: positive (Positive) Positive and positive (Positive) Positive. On 21-May-2021, Heparin-induced thrombocytopenia test: positive (Positive) Positive. On 31-May-2021, Heparin-induced thrombocytopenia test: positive (Positive) Positive. On 24-Jun-2021, Epstein-Barr virus antibody: positive (Positive) Positive and positive (Positive) Positive. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered IMMUNE THROMBOCYTOPENIA (Immune thrombocytopenia), ACUTE HEPATIC FAILURE (Acute hepatic failure) and EPSTEIN-BARR VIRUS INFECTION REACTIVATION (Epstein-Barr virus infection reactivation) to be possibly related. No further causality assessments were provided for INFLUENZA LIKE ILLNESS (flu-like illness), ASTHENIA (asthenia), DIZZINESS (dizziness), DYSPNOEA (dyspnea), PAIN IN EXTREMITY (lower right limb pain), CHEST PAIN (chest pain), OFF LABEL USE (Off label dosing frequency), PYREXIA (Fever), MYALGIA (myalgia) and HEADACHE (intense headaches). Laboratory details was mentioned as follows On 10-May-2021, Alanine aminotransferase, Aspartate aminotransferase, Blood alkaline phosphatase, Gamma-glutamyltransferase and Platelet count and Hepatitis with cytolysis (ALAT 1423, ASAT 663 U/L) and cholestasis (y-GT 518, PAL 601,was detected) results not provided. On 12-May-2021, Alanine aminotransferase, Aspartate aminotransferase, Blood alkaline phosphatase, Epstein-Barr virus test, Gamma-glutamyl transferase,Platelet count and chest, cerebral CT scan, ultrasound of lower limbs and abdomen result not provided. On 14-May-2021, Alanine aminotransferase, Aspartate aminotransferase, Blood alkaline phosphatase, and Gamma-glutamyltransferase; result was not provided. On 17-May-2021, Alanine aminotransferase, Aspartate aminotransferase, Blood alkaline phosphatase, Platelet count and Gamma-glutamyltransferase: result was not provided. On 19-May-2021, Alanine aminotransferase, Aspartate aminotransferase, Blood alkaline phosphatase, and Gamma-glutamyltransferase: result was not provided. On 21-May-2021, Alanine aminotransferase, Aspartate aminotransferase, Blood alkaline phosphatase, and Gamma-glutamyltransferase: result was not provided. On 24-JUN-2021, EBV serologies were positive, compatible with EBV reactivation or a primary EBV infection, due to which the patient was Liver impairment, thrombocytopenia and splenomegaly. On 13-May-2021 abdominal ultrasound revealed Hepatomegaly. On 24-JUN-2021, EBNA was negative. Second dose of mRNA-1273 was not administered. This regulatory authority case concerns a 46-year-old female patient with relevant family medical history of autoimmune disease and concurrent use of alcohol, who experienced serious unexpected events of immune thrombocytopenia, acute hepatic failure and Epstein-Barr infection

Case ID	Narrative (Complete)
	reactivation. The events occurred approximately 5 days after the first dose of Spikevax. Reportedly. 5 days after vaccination, the patient developed a flu-like illness with fever, asthenia, myalgia and intense headaches accompanied by dizziness. Later, she complained of dyspnea, chest pain and right lower limb pain. The laboratory work-up revealed thrombocytopenia, hepatitis with cytolysis, recent EBV infection and HSV1 infection based on antibody positivity The patient received prednisone for immune thrombocytopenia. The second dose will not be administered and thus, rechallenge was not applicable. The benefit-risk relationship of drug is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 15-Oct-2021: Follow up received on 15-Oct-2021 contains additional event and lab data. On 15-Oct-2021: Translation received on 19-OCT-2021. Updated case narrative on laboratory data, dose 2 information and event description.

Case ID	Narrative (Complete)
[redacted]	This case was received via [redacted] (Reference number: [redacted]) on 29-Jun-2021 and was forwarded to Moderna on 29-Jun-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of HEPATITIS ACUTE (Hepatitis acute) and JAUNDICE (Jaundice) in a 38-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. On 01-Apr-2021, the patient received dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 05-Apr-2021, the patient experienced HEPATITIS ACUTE (Hepatitis acute) (seriousness criteria medically significant and life threatening) and JAUNDICE (Jaundice) (seriousness criterion life threatening). At the time of the report, HEPATITIS ACUTE (Hepatitis acute) and JAUNDICE (Jaundice) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 05-Apr-2021, Alanine aminotransferase: 2165 (High) Increased. On 05-Apr-2021, Aspartate aminotransferase: 1288 (High) Increased. On 05-Apr-2021, Liver function test: normal (normal) normal. On 05-Apr-2021, Mycobacterium tuberculosis complex test: 6.5 (Positive) Positive. On 05-Apr-2021, Serology test: negative (Negative) Negative. 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 concomitant medications were given by the reporter. No Treatment information were provided by the reporter. Patient with an acute hepatitis with Tb 6.5, ALT 2165, AST 1288. Serologies for all chronic liver disease negative. Autoimmune serologies negative. LFTs normalized by June 2021. Jaundice resolved. Very limited information regarding this event/s has been provided at this time. Further information has been requested. Further information is not expected.
[redacted]	This case was received via [redacted] (Reference number: [redacted]) on 29-Jun-2021 and was forwarded to Moderna on 29-Jun-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of LIVER INJURY (Liver injury) in a 38-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Penicillin allergy, Drug allergy (Aspirin (acetyl salicylic acid) allergy), Blood pressure high and Depression. Concomitant products included METOPROLOL, CLONAZEPAM ([redacted]) and DIPHENHYDRAMINE HYDROCHLORIDE (BENADRYL [DIPHENHYDRAMINE HYDROCHLORIDE]) for an unknown indication. On 07-Apr-2021, the patient received dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) unknown. On 08-Apr-2021, the patient experienced LIVER INJURY (Liver injury) (seriousness criterion medically significant), ABDOMINAL DISTENSION (Abdominal distension), ABDOMINAL PAIN UPPER (Abdominal pain upper), MUSCULOSKELETAL PAIN (Musculoskeletal pain), DIZZINESS (Dizziness), CHILLS (Chills), HEADACHE (Headache) and NAUSEA (Nausea). At the time of the report, LIVER INJURY (Liver injury), ABDOMINAL DISTENSION (Abdominal distension), ABDOMINAL PAIN UPPER (Abdominal pain upper), MUSCULOSKELETAL PAIN (Musculoskeletal pain), DIZZINESS (Dizziness), CHILLS (Chills), HEADACHE (Headache) and NAUSEA (Nausea) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 08-Apr-2021, Scan with contrast: abnormal (abnormal) abnormal. On 24-Apr-2021, Metabolic function test: liver damage (Inconclusive) Liver damage. On 26-Apr-2021, Alanine aminotransferase: 50 (High) ALT (SGPT) 50. On 26-Apr-2021, Aspartate aminotransferase: 49 (High) increased (SGOT) 49. 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 treatment medication was provided. company comment Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.

Case ID	Narrative (Complete)
[redacted]	This case was received via [redacted] (Reference number: [redacted]) on 29-Jun-2021 and was forwarded to Moderna on 29-Jun-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of HEPATITIS ACUTE (Hepatitis acute) in a 39-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 001C21A) for COVID-19 vaccination. No Medical History information was reported. On 04-May-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 17-May-2021, the patient experienced HEPATITIS ACUTE (Hepatitis acute) (seriousness criterion medically significant). At the time of the report, HEPATITIS ACUTE (Hepatitis acute) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 17-May-2021, Blood test: unknown (Inconclusive) Not provided. On 17-May-2021, Liver function test: normal (normal) Liver function test normal. On 17-May-2021, Ultrasound abdomen: unknown (Inconclusive) Not provided. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medication were provided by the reporter. Treatment information includes supportive care. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) was not applicable. Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.
[redacted]	This case was received via [redacted] (Reference number: [redacted] on 29-Jun-2021 and was forwarded to Moderna on 29-Jun-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of DRUG-INDUCED LIVER INJURY (Drug-induced liver injury), EAR INFECTION (Ear infection), TONSILLITIS (Tonsillitis), ANXIETY (Anxiety), DEPRESSION (Depression), MALAISE (Malaise), IMPAIRED WORK ABILITY (Impaired work ability), LOSS OF PERSONAL INDEPENDENCE IN DAILY ACTIVITIES (Loss of personal independence in daily activities), RESTLESSNESS (Restlessness) and FATIGUE (Fatigue) in a 46-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 013M20A) for COVID-19 vaccination. The patient's past medical history included Triglycerides high, Anxiety, Depression and Acid reflux (esophageal). Concurrent medical conditions included Penicillin allergy and Allergy to antibiotic. Concomitant products included FENOFIBRATE, VITAMIN D NOS, ESTRADIOL and OMEPRAZOLE for an unknown indication, CITALOPRAM and IBUPROFEN for product used for unknown indication. On 26-Feb-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 02-Mar-2021, the patient experienced DRUG-INDUCED LIVER INJURY (Drug-induced liver injury) (seriousness criteria hospitalization, medically significant and life threatening), EAR INFECTION (Ear infection) (seriousness criterion hospitalization), TONSILLITIS (Tonsillitis) (seriousness criterion hospitalization), ANXIETY (Anxiety) (seriousness criterion hospitalization), MALAISE (Malaise) (seriousness criterion hospitalization), IMPAIRED WORK ABILITY (Impaired work ability) (seriousness criterion hospitalization), LOSS OF PERSONAL INDEPENDENCE IN DAILY ACTIVITIES (Loss of personal independence in daily activities) (seriousness criterion hospitalization), RESTLESSNESS (Restlessness) (seriousness criterion hospitalization) and FATIGUE (Fatigue) (seriousness criterion hospitalization). 02-Mar-2021, the patient experienced DEPRESSION (Depression) (seriousness criterion hospitalization). At the time of the report, DRUG-INDUCED LIVER INJURY (Drug-induced liver injury), EAR INFECTION (Ear infection), TONSILLITIS (Tonsillitis), ANXIETY (Anxiety), DEPRESSION (Depression), MALAISE (Malaise), IMPAIRED WORK ABILITY (Impaired work ability), LOSS OF PERSONAL INDEPENDENCE IN DAILY ACTIVITIES (Loss of personal independence in daily activities), RESTLESSNESS (Restlessness) and FATIGUE (Fatigue) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 18-Mar-2021, Liver function test: increased (abnormal) Increased. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Labs include blood tests since march,repeating every month, Echocardiogram in Mar-2021, Liver biopsy on 24-May-2021, CT scan in May-2021,EGD on 25-May-2021 whose results are not provided.Treatment information not provided .

Case ID	Narrative (Complete)
[redacted]	This regulatory authority case was reported by an other health care professional and describes the occurrence of DEAFNESS NEUROSENSORY (Deafness neurosensory), COGNITIVE DISORDER (Cognitive disorder), BRADYPHRENIA (Bradyphrenia), LIVER INJURY (Liver Injury), ANXIETY (Anxiety), FEELING ABNORMAL (Feeling abnormal), ASTHENIA (Asthenia), BALANCE DISORDER (Balance disorder), CONDITION AGGRAVATED (Condition aggravated), DEPRESSION (Depression), DISCOMFORT (Discomfort), HEMIPARESIS (Hemiparesis), GLUCOSE TOLERANCE IMPAIRED (Glucose tolerance impaired), HYPERSOMNIA (Hypersomnia), IMPAIRED WORK ABILITY (Impaired work ability), LIVER INJURY (Liver injury), NYSTAGMUS (Nystagmus), SKIN EXFOLIATION (Skin exfoliation), SKIN LESION (Skin lesion), TINNITUS (Tinnitus), FATIGUE (Fatigue), VISION BLURRED (Vision blurred), VITAMIN D DEFICIENCY (Vitamin D deficiency), PAIN (Pain), RASH (Rash), PYREXIA (Pyrexia), VESTIBULAR DISORDER (Vestibular disorder), HEADACHE (Headache) and NAUSEA (Nausea) in a 54-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 002A21A) for COVID-19 vaccination. The patient's past medical history included Post-traumatic stress disorder, Toxoplasmosis (Toxoplasmosis with uveitis), Sporotrichosis (Sporotrichosis from cat(Sporothrix brasiliensis),) and Cold sores ((Herpes simplex)). Concurrent medical conditions included Penicillin allergy. On 03-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 04-Mar-2021, the patient experienced DEAFNESS NEUROSENSORY (Deafness neurosensory) (seriousness criteria disability and medically significant), COGNITIVE DISORDER (Cognitive disorder) (seriousness criterion disability), BRADYPHRENIA (Bradyphrenia) (seriousness criterion disability), ANXIETY (Anxiety) (seriousness criterion disability), FEELING ABNORMAL (Feeling abnormal) (seriousness criterion disability), ASTHENIA (Asthenia) (seriousness criterion disability), BALANCE DISORDER (Balance disorder) (seriousness criterion disability), CONDITION AGGRAVATED (Condition aggravated) (seriousness criterion disability), DEPRESSION (Depression) (seriousness criterion disability), DISCOMFORT (Discomfort) (seriousness criterion disability), HEMIPARESIS (Hemiparesis) (seriousness criteria disability and medically significant), GLUCOSE TOLERANCE IMPAIRED (Glucose tolerance impaired) (seriousness criterion disability), HYPERSOMNIA (Hypersomnia) (seriousness criterion disability), IMPAIRED WORK ABILITY (Impaired work ability) (seriousness criterion disability), LIVER INJURY (Liver injury) (seriousness criteria disability and medically significant), NYSTAGMUS (Nystagmus) (seriousness criterion disability), SKIN EXFOLIATION (Skin exfoliation) (seriousness criterion disability), SKIN LESION (Skin lesion) (seriousness criterion disability), TINNITUS (Tinnitus) (seriousness criterion disability), FATIGUE (Fatigue) (seriousness criterion disability), VISION BLURRED (Vision blurred) (seriousness criterion disability), VITAMIN D DEFICIENCY (Vitamin D deficiency) (seriousness criterion disability), PAIN (Pain) (seriousness criterion disability), RASH (Rash) (seriousness criterion disability), PYREXIA (Pyrexia) (seriousness criterion disability), VESTIBULAR DISORDER (Vestibular disorder) (seriousness criterion disability), HEADACHE (Headache) (seriousness criterion disability) and NAUSEA (Nausea) (seriousness criterion disability). 04-Mar-2021, the patient experienced LIVER INJURY (Liver Injury) (seriousness criteria disability and medically significant). The patient was treated with FLUOXETINE HYDROCHLORIDE (PROZAC) ongoing since an unknown date for Symptomatic treatment, at a dose of 20 mg; IBUPROFEN (ADVIL [IBUPROFEN]) for Symptomatic treatment, at an unspecified dose and frequency; MECLOZINE HYDROCHLORIDE (MECLIZINE [MECLOZINE HYDROCHLORIDE]) for Symptomatic treatment, at an unspecified dose and frequency; ONDANSETRON for Symptomatic treatment, at an unspecified dose and frequency and TRAMADOL for Symptomatic treatment, at an unspecified dose and frequency. At the time of the report, DEAFNESS NEUROSENSORY (Deafness neurosensory), COGNITIVE DISORDER (Cognitive disorder), BRADYPHRENIA (Bradyphrenia), LIVER INJURY (Liver Injury), ANXIETY (Anxiety), FEELING ABNORMAL (Feeling abnormal), ASTHENIA (Asthenia), BALANCE DISORDER (Balance disorder), CONDITION AGGRAVATED (Condition aggravated), DEPRESSION (Depression), DISCOMFORT (Discomfort), HEMIPARESIS (Hemiparesis), GLUCOSE TOLERANCE IMPAIRED (Glucose tolerance impaired), HYPERSOMNIA (Hypersomnia), IMPAIRED WORK ABILITY (Impaired work ability), LIVER INJURY (Liver injury), NYSTAGMUS (Nystagmus), SKIN EXFOLIATION (Skin exfoliation), SKIN LESION (Skin lesion), TINNITUS (Tinnitus), FATIGUE (Fatigue), VISION BLURRED (Vision blurred), VITAMIN D DEFICIENCY (Vitamin D deficiency), PAIN (Pain), RASH (Rash), PYREXIA (Pyrexia), VESTIBULAR DISORDER (Vestibular disorder), HEADACHE (Headache) and NAUSEA (Nausea) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 04-Mar-2021, Body temperature: 100.4 (High) not over 100.4. On 06-Apr-2021, Blood thyroid stimulating hormone: normal (normal) normal. On 06-Apr-2021, C-reactive protein: normal (normal) normal. On 06-Apr-2021, Differential white blood cell count: normal (normal) normal. On 06-Apr-2021, Full blood count: normal (normal) normal. On 06-Apr-2021, Haemoglobin: prediabetic (High) Glycosylated hemoglobin increased. On 06-Apr-2021, Lipids: normal (normal) normal. On 06-Apr-2021, Metabolic function test: liver damage (abnormal) Comprehensive metabolic panel(Blood sugar, liver,kidney tests) - Liver damage. On 06-Apr-2021, Urine analysis: normal (normal) normal. On 06-Apr-2021, Vitamin D: deficiency (Low) Blood 25-hydroxy cholecalciferol deficiency. On 21-May-2021, Toxoplasma serology: inconclusive (Inconclusive) Past activity atleast 6 months ago. On 26-May-2021, Computerised tomogram head: normal (normal) Imaging CT scan of head with or without contrast was normal. On 26-May-2021, Differential white blood cell count: normal (normal) normal. On 26-May-2021, Full blood count: normal (normal) normal. On 26-May-2021, Metabolic function test: normal (normal) Basic metabolic panel-normal. On 26-May-2021, Scan with contrast: normal (normal) normal. On 02-Jun-2021, Audiogram: pure tone audiometry (abnormal) Mild sensorineural hearing loss at 250-500 Hz. Rising to normal 1000-4000 Hz. Sloping to severe hearing loss at 8000 HZ. On 02-Jun-2021, Electronystagmogram: abnormal (abnormal) Findings consistent with peripheral vestibular dysfunction(unilateral weakness to the right). On 02-Jun-2021, Oculomotor study: abnormal (abnormal) abnormal. On 02-Jun-2021, Vestibular nystagmus: abnormal (abnormal) Findings consistent with central vestibular dysfunction if occular motor dysfunction can be ruled out. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments.

Case ID	Narrative (Complete)
	Concomitant medication include vitamins. Treatment information also include anti-histaminic drugs. Action taken with mRNA-1273 in response to the event was not applicable. Company Comment : Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. No further information is expected at this time.

Case ID	Narrative (Complete)
[redacted]	This case was received via [redacted] (Reference number: [redacted] on 29-Jun-2021 and was forwarded to Moderna on 29-Jun-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of AUTOIMMUNE CHOLANGITIS (Autoimmune cholangitis), CHOLANGITIS INFECTIVE (Cholangitis infective), HEPATOCELLULAR INJURY (Hepatocellular injury), BILIARY TRACT DISORDER (Biliary tract disorder), CHOLANGITIS ACUTE (Cholangitis acute), CHROMATURIA (dark urine), FATIGUE (Fatigue), IDIOSYNCRATIC DRUG REACTION (Idiosyncratic drug reaction), NAUSEA (Nausea) and VOMITING (Vomiting) in a 35-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 005C21A) for COVID-19 vaccination. The patient's past medical history included Depression and Gallbladder removal in December 2013. Concurrent medical conditions included Constipation chronic and Sulfonamide allergy (Sulfa drugs). Concomitant products included ESCITALOPRAM OXALATE (LEXAPRO), DOCUSATE SODIUM (COLACE) and BISACODYL (DULCOLAX [BISACODYL]) from 09-May-2021 to an unknown date for an unknown indication. On 21-May-2021, the patient received dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 29-May-2021, the patient experienced AUTOIMMUNE CHOLANGITIS (Autoimmune cholangitis) (seriousness criteria hospitalization and medically significant), CHOLANGITIS INFECTIVE (Cholangitis infective) (seriousness criteria hospitalization and medically significant), HEPATOCELLULAR INJURY (Hepatocellular injury) (seriousness criteria hospitalization and medically significant), BILIARY TRACT DISORDER (Biliary tract disorder) (seriousness criterion hospitalization), CHOLANGITIS ACUTE (Cholangitis acute) (seriousness criteria hospitalization and medically significant), CHROMATURIA (dark urine) (seriousness criterion hospitalization), FATIGUE (Fatigue) (seriousness criterion hospitalization), IDIOSYNCRATIC DRUG REACTION (Idiosyncratic drug reaction) (seriousness criterion hospitalization), NAUSEA (Nausea) (seriousness criterion hospitalization) and VOMITING (Vomiting) (seriousness criterion hospitalization). The patient was treated with NALTREXONE HYDROCHLORIDE (NALTREXONE [NALTREXONE HYDROCHLORIDE]) on 16-Jun-2021 for Itching, at a dose of 50 mg and URSODIOL on 16-Jun-2021 at a dose of 300 mg three times a day. At the time of the report, AUTOIMMUNE CHOLANGITIS (Autoimmune cholangitis), CHOLANGITIS INFECTIVE (Cholangitis infective), HEPATOCELLULAR INJURY (Hepatocellular injury), BILIARY TRACT DISORDER (Biliary tract disorder), CHOLANGITIS ACUTE (Cholangitis acute), CHROMATURIA (dark urine), FATIGUE (Fatigue), IDIOSYNCRATIC DRUG REACTION (Idiosyncratic drug reaction), NAUSEA (Nausea) and VOMITING (Vomiting) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 29-May-2021, Alanine aminotransferase: alanine aminotransferase increased (High) Alanine aminotransferase increased. On 29-May-2021, Aspartate aminotransferase: increased (High) Aspartate aminotransferase increased. On 29-May-2021, Biopsy liver: abnormal (abnormal) Biopsy liver abnormal. On 29-May-2021, Blood alkaline phosphatase: increased (High) Blood alkaline phosphatase increased. On 29-May-2021, Blood bilirubin: increased (High) Blood bilirubin increased. On 29-May-2021, Computerised tomogram: normal (normal) Computerised tomogram normal. On 29-May-2021, Eosinophil count: increased (High) Eosinophil count increased. On 01-Jun-2021, Alanine aminotransferase: 396 (High) Alanine aminotransferase increased. On 01-Jun-2021, Aspartate aminotransferase: 142 (High) Aspartate aminotransferase increased. On 01-Jun-2021, Blood alkaline phosphatase: 186 (High) Blood alkaline phosphatase increased. On 01-Jun-2021, Blood bilirubin: 4.2 (High) Blood bilirubin increased. On 01-Jun-2021, Computerised tomogram: normal (normal) Computerised tomogram normal. On 01-Jun-2021, Magnetic resonance cholangiopancreatography: normal (normal) normal. On 02-Jun-2021, Computerised tomogram: normal (normal) Computerised tomogram normal. On 02-Jun-2021, Magnetic resonance cholangiopancreatography: normal (normal) normal. On 04-Jun-2021, Biopsy liver: abnormal (abnormal) abnormal. On 12-Jun-2021, Alanine aminotransferase: 184 (High) 184. On 12-Jun-2021, Aspartate aminotransferase: 80 (High) 80. On 12-Jun-2021, Blood alkaline phosphatase: 186 (High) Blood alkaline phosphatase increased. On 12-Jun-2021, Blood bilirubin: 7.4 (High) Blood bilirubin increased. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown) was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Patient past medical history included Gallbladder removal in December 2013. Treatment information included high dose steriods of 60mg.

Case ID	Narrative (Complete)
[redacted]	This spontaneous case was reported by a physician (subsequently medically confirmed) and describes the occurrence of HEPATITIS ACUTE (Acute hepatitis) in a 78-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Hypothyroidism. Concomitant products included LEVOTHYROXINE SODIUM (SYNTHROID) for Hypothyroidism. In May 2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On an unknown date, the patient experienced HEPATITIS ACUTE (Acute hepatitis) (seriousness criterion medically significant), DIARRHOEA (Diarrhea) and FATIGUE (Fatigue). At the time of the report, HEPATITIS ACUTE (Acute hepatitis) was resolving, DIARRHOEA (Diarrhea) had resolved and FATIGUE (Fatigue) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 29-Jun-2021, Alanine aminotransferase: 653 (Inconclusive) 653. On 29-Jun-2021, Aspartate aminotransferase: 283 (Inconclusive) 283. On 29-Jun-2021, Bilirubin conjugated: 0.3 (Inconclusive) 0.3. On 29-Jun-2021, Blood alkaline phosphatase: 90 (normal) 90. On 29-Jun-2021, Blood bilirubin: 1.3 (Inconclusive) Gilbert's. On 29-Jun-2021, International normalised ratio: 1.03 (Inconclusive) 1.03. On 29-Jun-2021, Ultrasound liver: abnormal (abnormal) +ANA chronic for years , low suspicion. On an unknown date, Alanine aminotransferase: high (High) 20 -> 250 -> 950. On an unknown date, Aspartate aminotransferase: high (High) 20 -> 147 -> 256. On an unknown date, Blood bilirubin: 1.2 (Inconclusive) 1.2. On an unknown date, International normalised ratio: <1.2 (Inconclusive) <1.2. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Other laboratory included test for Acute hepatitis- Negative for Hep A/B/C , IgG Treatment information was not provided. The physician reported that previous labs suggest underlying Gilbert's Company Comment: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.

Case ID	Narrative (Complete)
[redacted]	This case was received via [redacted] (Reference number: [redacted]) on 13-Jul-2021 and was forwarded to Moderna on 13-Jul-2021. This regulatory authority case was reported by a health care professional and describes the occurrence of ACUTE RESPIRATORY FAILURE (Acute respiratory failure), COVID-19 PNEUMONIA (COVID-19 pneumonia), DELIRIUM (Delirium), HEPATIC CIRRHOSIS (Hepatic cirrhosis), HEPATIC ENCEPHALOPATHY (Hepatic encephalopathy), HEPATIC FAILURE (Hepatic failure), LACTIC ACIDOSIS (Lactic acidosis), NON-HODGKIN'S LYMPHOMA (Non-Hodgkin's lymphoma), THROMBOCYTOPENIA (Thrombocytopenia), COVID-19 (COVID-19), AGGRESSION (Aggression), AGITATION (Agitation), ARTERIOSCLEROSIS (Arteriosclerosis), CONFUSIONAL STATE (Confusional state), COUGH (Cough), LUNG HYPERINFLATION (Lung hyperinflation), LUNG OPACITY (Lung opacity), MALAISE (Malaise), NEUROPATHY PERIPHERAL (Neuropathy peripheral), PORTAL HYPERTENSION (Portal hypertension), PORTAL HYPERTENSIVE COLOPATHY (Portal hypertensive colopathy) and RESPIRATORY TRACT CONGESTION (Respiratory tract congestion) in a 67-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The patient's past medical history included Alcohol abuse since an unknown date. Concurrent medical conditions included Drug allergy (atorvastatin), Drug allergy (Hydrochlorothiazide), Drug allergy (lisinopril), Drug allergy (meloxicam), Drug allergy (propafenone), Liver cirrhosis, Esophageal varices, Gastric varices, Atrial fibrillation, Congestive heart failure, Coronary artery disease (last stent placed in 12/7/2012), Type 2 diabetes mellitus, Gastroesophageal reflux disease, Hyperlipidemia, Hypertension, Peripheral neuropathy, Hypothyroidism, Non-Hodgkin's lymphoma and Obstructive sleep apnea syndrome. Concomitant products included HALOPERIDOL for Agitation, INSULIN DEGLUDEC (TRESIBA), INSULIN and METFORMIN for Type 2 diabetes mellitus, DEXAMETHASONE from 27-Jun-2021 to an unknown date, REMDESIVIR from 27-Jun-2021 to an unknown date, RIFAXIMIN and GABAPENTIN for an unknown indication. On 28-Feb-2021, the patient received dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 29-Jun-2021, the patient experienced ACUTE RESPIRATORY FAILURE (Acute respiratory failure) (seriousness criteria hospitalization and medically significant), COVID-19 PNEUMONIA (COVID-19 pneumonia) (seriousness criteria hospitalization and medically significant), DELIRIUM (Delirium) (seriousness criteria hospitalization and medically significant), HEPATIC CIRRHOSIS (Hepatic cirrhosis) (seriousness criteria hospitalization and medically significant), HEPATIC ENCEPHALOPATHY (Hepatic encephalopathy) (seriousness criteria hospitalization and medically significant), HEPATIC FAILURE (Hepatic failure) (seriousness criteria hospitalization and medically significant), LACTIC ACIDOSIS (Lactic acidosis) (seriousness criteria hospitalization and medically significant), NON-HODGKIN'S LYMPHOMA (Non-Hodgkin's lymphoma) (seriousness criteria hospitalization and medically significant), THROMBOCYTOPENIA (Thrombocytopenia) (seriousness criteria hospitalization and medically significant), AGGRESSION (Aggression) (seriousness criterion hospitalization), AGITATION (Agitation) (seriousness criterion hospitalization), ARTERIOSCLEROSIS (Arteriosclerosis) (seriousness criterion hospitalization), CONFUSIONAL STATE (Confusional state) (seriousness criterion hospitalization), COUGH (Cough) (seriousness criterion hospitalization), LUNG HYPERINFLATION (Lung hyperinflation) (seriousness criterion hospitalization), LUNG OPACITY (Lung opacity) (seriousness criterion hospitalization), MALAISE (Malaise) (seriousness criterion hospitalization), NEUROPATHY PERIPHERAL (Neuropathy peripheral) (seriousness criteria hospitalization and medically significant), PORTAL HYPERTENSION (Portal hypertension) (seriousness criteria hospitalization and medically significant), PORTAL HYPERTENSIVE COLOPATHY (Portal hypertensive colopathy) (seriousness criteria hospitalization and medically significant) and RESPIRATORY TRACT CONGESTION (Respiratory tract congestion) (seriousness criterion hospitalization). 29-Jun-2021, the patient experienced COVID-19 (COVID-19) (seriousness criterion hospitalization). At the time of the report, ACUTE RESPIRATORY FAILURE (Acute respiratory failure), COVID-19 PNEUMONIA (COVID-19 pneumonia), DELIRIUM (Delirium), HEPATIC CIRRHOSIS (Hepatic cirrhosis), HEPATIC ENCEPHALOPATHY (Hepatic encephalopathy), HEPATIC FAILURE (Hepatic failure), LACTIC ACIDOSIS (Lactic acidosis), NON-HODGKIN'S LYMPHOMA (Non-Hodgkin's lymphoma), THROMBOCYTOPENIA (Thrombocytopenia), COVID-19 (COVID-19), AGGRESSION (Aggression), AGITATION (Agitation), ARTERIOSCLEROSIS (Arteriosclerosis), CONFUSIONAL STATE (Confusional state), COUGH (Cough), LUNG HYPERINFLATION (Lung hyperinflation), LUNG OPACITY (Lung opacity), MALAISE (Malaise), NEUROPATHY PERIPHERAL (Neuropathy peripheral), PORTAL HYPERTENSION (Portal hypertension), PORTAL HYPERTENSIVE COLOPATHY (Portal hypertensive colopathy) and RESPIRATORY TRACT CONGESTION (Respiratory tract congestion) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 27-Jun-2021, Chest X-ray: abnormal (abnormal) Progressive pulmonary opacities suggestive of COVID-19, hyperinflated lungs and arthrosclerotic vascular disease. On 29-Jun-2021, Ammonia: increased (High) increased. On 29-Jun-2021, Chest X-ray: abnormal (abnormal) abnormal. On 29-Jun-2021, Computerised tomogram: abnormal (abnormal) abnormal and abnormal (abnormal) abnormal. On 29-Jun-2021, SARS-CoV-2 test: positive (Positive) positive. On 29-Jun-2021, Scan with contrast: abnormal (abnormal) abnormal. On 29-Jun-2021, Transaminases increased: increased (High) increased. 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. Lab data was pending for EKG, troponin, respiratory culture and BNP. DVT prophylaxis on hold due to thrombocytopenia. CT of the abdomen and pelvis with contrast indicated compatible with hepatic upper gastric body, most likely due to surgical changes. High density material within the dependent portion of the body of the stomach that could represent gastric bleeding. Thickening of the ascending and transverse colon likely represented a portal colopathy. Lungs consistent with inflammatory process like Covid. The patient did not received a dose of Tocilizumab. Very limited information regarding the events has been provided at this time. Further information is not expected.

Case ID	Narrative (Complete)
[redacted]	This regulatory authority case was reported by a physician and describes the occurrence of HEPATIC FAILURE [redacted] in a 60-year-old female patient who received mRNA-1273 (COVID 19 Vaccine Moderna) for COVID-19 vaccination. No Medical History information was reported. On 07-Jun-2021, the patient received first dose of mRNA-1273 (COVID 19 Vaccine Moderna) (unknown route) 1 dosage form. On 08-Jun-2021, the patient experienced HEPATIC FAILURE [redacted] (seriousness criterion medically significant). At the time of the report, HEPATIC FAILURE [redacted] was resolving. 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. Concomitant medication was not provided by the reporter. Treatment information was not provided by the reporter. Very limited information regarding this event has been provided at this time. No further follow-up information is expected. Most recent FOLLOW-UP information incorporated above includes: On 14-Jul-2021: Translated received on 21 Jul 2021 included correction in drug stat date.
[redacted]	This spontaneous case was reported by a consumer and describes the occurrence of ILLNESS (got very sick and ended up in the hospital), HEPATIC FAILURE (liver, kidneys, and pancreas shut down), ACUTE KIDNEY INJURY (liver, kidneys, and pancreas shut down) and PANCREATIC FAILURE (liver, kidneys, and pancreas shut down) in a male patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No medical history was provided. On an unknown date, the patient received dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On an unknown date, the patient experienced ILLNESS (got very sick and ended up in the hospital) (seriousness criterion hospitalization), HEPATIC FAILURE (liver, kidneys, and pancreas shut down) (seriousness criteria hospitalization, medically significant and life threatening), ACUTE KIDNEY INJURY (liver, kidneys, and pancreas shut down) (seriousness criteria hospitalization, medically significant and life threatening) and PANCREATIC FAILURE (liver, kidneys, and pancreas shut down) (seriousness criteria hospitalization, medically significant and life threatening). The patient was hospitalized for 14 days due to ACUTE KIDNEY INJURY, HEPATIC FAILURE, ILLNESS and PANCREATIC FAILURE. At the time of the report, ILLNESS (got very sick and ended up in the hospital), HEPATIC FAILURE (liver, kidneys, and pancreas shut down), ACUTE KIDNEY INJURY (liver, kidneys, and pancreas shut down) and PANCREATIC FAILURE (liver, kidneys, and pancreas shut down) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. No concomitant medications were reported. No treatment information was provided. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.

Case ID	Narrative (Complete)
[redacted]	This regulatory authority case was reported by a physician and describes the occurrence of DRUG-INDUCED LIVER INJURY (Drug-induced liver injury) in a 34-year-old male patient who received mRNA-1273 (COVID 19 Vaccine Moderna) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event. On 21-Jun-2021, the patient received first dose of mRNA-1273 (COVID 19 Vaccine Moderna) (Intramuscular) 1 dosage form. In 2021, the patient experienced DRUG-INDUCED LIVER INJURY (Drug-induced liver injury) (seriousness criterion medically significant). On 23-Jun-2021, after starting mRNA-1273 (COVID 19 Vaccine Moderna), the patient experienced PYREXIA (pyrexia). The patient was treated with ACETYLSALICYLIC ACID (BUFFERIN [ACETYLSALICYLIC ACID]) for Pyrexia, at an unspecified dose and frequency. At the time of the report, DRUG-INDUCED LIVER INJURY (Drug-induced liver injury) and PYREXIA (pyrexia) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 23-Jun-2021, Body temperature: 37.8 degree Celsius (High) 37.8 degrees Celsius. On 01-Jul-2021, Alanine aminotransferase: 418 (abnormal) 418. On 01-Jul-2021, Aspartate aminotransferase: 119 (abnormal) 119. On 01-Jul-2021, Gamma-glutamyltransferase: 147 (abnormal) 147. On 07-Jul-2021, Alanine aminotransferase: 122 (normal) 122. On 07-Jul-2021, Aspartate aminotransferase: 35 (normal) 35. On 07-Jul-2021, Gamma-glutamyltransferase: 105 (normal) 105. For mRNA-1273 (COVID 19 Vaccine Moderna) (Intramuscular), the reporter considered DRUG-INDUCED LIVER INJURY (Drug-induced liver injury) to be possibly related. No further causality assessment was provided for PYREXIA (pyrexia). No concomitant medications were provided by the reporter. Adverse reaction to COVID-19 vaccine or drug-induced liver injury due to oral drugs were suspected as the cause. The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.Based on the current available information and temporal association between the use of the product and the start date of the events [Pyrexia and DILI), a causal relationship cannot be excluded.

Case ID	Narrative (Complete)
[redacted]	This case was initially received via [redacted] (Reference number: [redacted] on 11-May-2021. The most recent information was received on 11-May-2021 and was forwarded to Moderna on an unknown date. This regulatory authority case was reported by an other health care professional and describes the occurrence of FOETAL HYPOKINESIA (Foetal hypokinesia), FOETAL MOVEMENT DISORDER (baby stopped moving), ACUTE HEPATIC FAILURE (DIC due to acute hepatic failure) and LOW BIRTH WEIGHT BABY (Birth weight was 1770 grams) in a neonate of an unknown age and gender exposed to mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 030L20A and 025J20A) , while the mother received the product for COVID-19 vaccination. MEDICAL HISTORY (Parent): The mother's past medical history included Exposure during pregnancy on 21-Jan-2021 and Endometrial ablation. Concurrent medical conditions included Hypercoagulation (Thrombophilia A1 deficiency) and Drug allergy (Atropine). No Medical History information was reported. On 06-Jan-2021, the mother received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 06-Jan-2021, received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. The mother's last menstrual period was on an unknown date and the estimated date of delivery was 08-May-2021. On 21-Jan-2021, the neonate was diagnosed with FOETAL HYPOKINESIA (Foetal hypokinesia) (seriousness criteria hospitalization, medically significant and life threatening). On an unknown date, the neonate was diagnosed with FOETAL MOVEMENT DISORDER (baby stopped moving) (seriousness criterion hospitalization), ACUTE HEPATIC FAILURE (DIC due to acute hepatic failure) (seriousness criteria hospitalization and medically significant) and LOW BIRTH WEIGHT BABY (Birth weight was 1770 grams) (seriousness criterion hospitalization). The Neonate was exposed to mRNA-1273 (Moderna COVID-19 Vaccine) during pregnancy. The cesarean delivery occurred on 16-Mar-2021, which was reported as Abnormal Pregnancy Outcome. For neonate 1, the birth weight was 1770 grams (3lbs 14oz). The outcome was reported as Pre-Term Birth w Complications. On 16 Mar 2021, the baby stopped moving. Patient went to the emergency room. Heart rate of fetus was declining. An emergent cesarean section was done. When the baby was born, she was in disseminated vascular coagulation due to acute hepatic failure. The baby received multiple different blood products along with antibiotics, intravenous (IV) immunoglobulin, IV dopamine, IV furosemide, and total parenteral nutrition. She was on the ventilator, had a central line, arterial line, multiple IVs and a nasogastric tube. At the time of the report, FOETAL HYPOKINESIA (Foetal hypokinesia), FOETAL MOVEMENT DISORDER (baby stopped moving), ACUTE HEPATIC FAILURE (DIC due to acute hepatic failure) and LOW BIRTH WEIGHT BABY (Birth weight was 1770 grams) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Heart rate: unknown (Low) Heart was declined. On an unknown date, Ultrasound foetal: unknown (abnormal) Infant in uterine showed liver calcification measuring 5.9, 4.2, 1.7 mm.. For mRNA-1273 (Moderna COVID-19 Vaccine) (Transplacental), the reporter did not provide any causality assessments. The concomitant medications on use were not provided. Treatment information was not provided by the reporter. Infant in uterine showed liver calcification measuring 5.9, 4.2, 1.7 mm. On 16-Mar-2021, parent scheduled to consult a neurologist. On the same day parent went to ER. An emergent C-section was done. Company Comment: This case concerns neonate patient with Foetal exposure during pregnancy to mRNA-1273 vaccine, whose mother was 42 years old and had thrombophilia (treated with aspirin and other medication), who experienced the unexpected serious events of Foetal hypokinesia and Foetal heart rate decreased. It is reported that the mother had an emergency cesarean section due to these events (approximately two months before the due date) and that the child had other events: acute hepatic failure and DIC (Disseminated intravascular coagulation). The events occurred approximately 2 weeks after a dose of mRNA-1273 vaccine. The rechallenge was not applicable since due to the nature of the events. The medical history of mother was 42 years old and had thrombophilia (treated with aspirin and other medication), remain as confounders. 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 as life-threatening and hospitalization. This case was linked to [redacted] (Parent-Child Link). See case [redacted] for details regarding the Parent case. Most recent FOLLOW-UP information incorporated above includes: On 11-May-2021: Upon internal review on 17 Nov 2021 pregnancy exposure added in medical history of the parent and Premature delivery removed from event in child case.

Case ID	Narrative (Complete)
[redacted]	This case was received via [redacted] (Reference number: [redacted]) on 27-Jul-2021 and was forwarded to Moderna on 27-Jul-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of ACUTE HEPATIC FAILURE (Acute hepatic failure), AUTOIMMUNE HEPATITIS (Autoimmune hepatitis), DRUG-INDUCED LIVER INJURY (Drug-induced liver injury), HEPATITIS VIRAL (Hepatitis viral), ISCHAEMIC HEPATITIS (Ischaemic hepatitis) and VACCINATION COMPLICATION (Vaccination complication) in a 57-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. Concurrent medical conditions included Non-small cell lung cancer (new diagnosis, not started treatment yet), Hypertension and Neuropathy. On 05-Jun-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 02-Jul-2021, the patient experienced ACUTE HEPATIC FAILURE (Acute hepatic failure) (seriousness criteria hospitalization and medically significant), AUTOIMMUNE HEPATITIS (Autoimmune hepatitis) (seriousness criteria hospitalization and medically significant), DRUG-INDUCED LIVER INJURY (Drug-induced liver injury) (seriousness criteria hospitalization and medically significant), HEPATITIS VIRAL (Hepatitis viral) (seriousness criteria hospitalization and medically significant), ISCHAEMIC HEPATITIS (Ischaemic hepatitis) (seriousness criteria hospitalization and medically significant) and VACCINATION COMPLICATION (Vaccination complication) (seriousness criterion hospitalization). At the time of the report, ACUTE HEPATIC FAILURE (Acute hepatic failure), AUTOIMMUNE HEPATITIS (Autoimmune hepatitis), DRUG-INDUCED LIVER INJURY (Drug-induced liver injury), HEPATITIS VIRAL (Hepatitis viral), ISCHAEMIC HEPATITIS (Ischaemic hepatitis) and VACCINATION COMPLICATION (Vaccination complication) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 02-Jul-2021, Alcohol test: negative (Negative) Negative. On 02-Jul-2021, Analgesic drug level: inconclusive (Inconclusive) Inconclusive. On 02-Jul-2021, Ultrasound Doppler: normal (normal) normal. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter considered ACUTE HEPATIC FAILURE (Acute hepatic failure), AUTOIMMUNE HEPATITIS (Autoimmune hepatitis), DRUG-INDUCED LIVER INJURY (Drug-induced liver injury), HEPATITIS VIRAL (Hepatitis viral), ISCHAEMIC HEPATITIS (Ischaemic hepatitis) and VACCINATION COMPLICATION (Vaccination complication) to be possibly related. No concomitant medications were reported. It was reported in GI team documentation that patient presented fulminant liver failure and do not have an etiology for this acute liver injury. Acetaminophen and salicylate levels were negative. Although patient does abuse alcohol on a daily basis, her presentation was not consistent with acute alcoholic hepatitis. Serologies were sent to evaluate the differential diagnosis and other potential causes of acute liver injury. Liver imaging including Doppler ultrasound did not reveal any abnormality and there was no evidence of chronic liver disease. Four case reports of hepatitis/autoimmune hepatitis related to mRNA vaccines and a case of fulminant liver failure were reported in the community were reported a few months back of which no other etiology was identified other then mRNA vaccine. With no other identifiable cause, patients acute sudden liver failure was considered vaccine induced. No treatment information was reported. Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. Concurrent illness of viral hepatitis, history of alcohol use are a potential confounder.

Case ID	Narrative (Complete)
[redacted]	This regulatory authority case was reported by a non-health professional (subsequently medically confirmed) and describes the occurrence of HEPATITIS ACUTE (acute hepatitis), SEPTIC SHOCK (septic shock) and BACTERIAL INFECTION (bacterial infection) in a 74-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. On 03-Jul-2021, the patient received dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 05-Jul-2021, the patient experienced HEPATITIS ACUTE (acute hepatitis) (seriousness criteria hospitalization and medically significant). On 06-Jul-2021, the patient experienced SEPTIC SHOCK (septic shock) (seriousness criteria hospitalization and medically significant). 06-Jul-2021, the patient experienced BACTERIAL INFECTION (bacterial infection) (seriousness criterion hospitalization). The patient was hospitalized on 06-Jul-2021 due to BACTERIAL INFECTION, HEPATITIS ACUTE and SEPTIC SHOCK. At the time of the report, HEPATITIS ACUTE (acute hepatitis), SEPTIC SHOCK (septic shock) and BACTERIAL INFECTION (bacterial infection) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 05-Jul-2021, Liver function test: 2000 abnormal. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. No concomitant medications were reported. On 05-Jul-2021, the patient was sent to the hospital due to fever, and examination showed liver index 2000 and acute hepatitis. Very limited information regarding these events have been provided at this time. No further information is expected. Most recent FOLLOW-UP information incorporated above includes: On 22-Jul-2021: Translated document for initial version received: new events added.

Case ID	Narrative (Complete)
[redacted]	This literature-non-study case was reported in a literature article and describes the occurrence of AUTOIMMUNE HEPATITIS (Acute Autoimmune-like Hepatitis) in a 63-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. LITERATURE REFERENCE: Ghielmetti M, Schaufelberger HD, Mieli-Vergani G, Cerny A, Dayer E, Vergani D, et al. Acute autoimmune-like hepatitis with atypical anti-mitochondrial antibody after mRNA COVID-19 vaccination: A novel clinical entity?. J Autoimmun. 2021;123:102706 Concurrent medical conditions included Type 2 diabetes mellitus, Ischemic heart disease and Alcohol use (daily consumption of 10g). Concomitant products included ACETYLSALICYLIC ACID and ROSUVASTATIN for Ischemic heart disease, METFORMIN for Type 2 diabetes mellitus. On an unknown date, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form. On an unknown date, after starting mRNA-1273 (COVID-19 Vaccine Moderna), the patient experienced AUTOIMMUNE HEPATITIS (Acute Autoimmune-like Hepatitis) (seriousness criterion medically significant) and PRODUCT DOSE OMISSION ISSUE (The second vaccine dose was temporally suspended). The patient was treated with PREDNISONE for Adverse event, at a dose of 40 milligram once a day and PREDNISONE for Adverse event, at a dose of 40 mg once a day. At the time of the report, AUTOIMMUNE HEPATITIS (Acute Autoimmune-like Hepatitis) and PRODUCT DOSE OMISSION ISSUE (The second vaccine dose was temporally suspended) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 15-Jun-2021, Alanine aminotransferase: 1038 (abnormal) 1038 U/l. On 15-Jun-2021, Antimitochondrial antibody: negative (Negative) negative. On 15-Jun-2021, Antineutrophil cytoplasmic antibody: negative (Negative) negative. In 2021, Antinuclear antibody: negative (Negative) Negative, positive (Positive) Positive with rim-like indirect immunofluorescence pattern on liver HEp2 cell substrates, similar to PBC-specific ANA. On 15-Jun-2021, Antinuclear antibody negative (Negative) negative, negative (Negative) negative, negative (Negative) Negative, negative (Negative) negative, negative (Negative) negative and negative (Negative) negative. On 15-Jun-2021, Aspartate aminotransferase: 1127 1127 U/l. On 15-Jun-2021, Autoantibody test: negative (Negative) negative, negative (Negative) negative and negative (Negative) negative. On 15-Jun-2021, Biopsy liver: hepatitis (abnormal) expanded portal tracts with intense lymphoplasmacytic infiltrate with scattered eosinophils, and interface hepatitis. intense lobular activity associated with centrilobular necrosis. On 15-Jun-2021, Blood alkaline phosphatase (40-150): 192 192 U/l. On 15-Jun-2021, Blood bilirubin: 204.8 204.8 micro mol/l. In 2021, Blood immunoglobulin G: elevated (High) Elevated and. On 15-Jun-2021, Blood immunoglobulin G 19.96 (High) 19.96 g/l. On 15-Jun-2021, Body mass index: 28 (High) Increased to 28. On 15-Jun-2021, Gamma-glutamyltransferase: 536 536 U/l. On 15-Jun-2021, Haemoglobin: 14.8 14.8 g/dl. In 2021, Histology: abnormal (abnormal) showed inflammatory portal infiltrate with interface hepatitis, lobular and centrilobular inflammation with centrilobular necrosis, in absence of fibrosis and steatosis.. In 2021, International normalised ratio: 1.16 1.16 and. On 15-Jun-2021, International normalised ratio 1.4 worsening to 1.4. On 15-Jun-2021, Platelet count: 309 x10e9/l platelets 309 x10 e9/l. On 15-Jun-2021, Polymerase chain reaction: negative (Negative) negative. In 2021, Primary biliary cholangitis: negative (Negative) Negative. On 15-Jun-2021, SARS-CoV-2 antibody test: positive (Positive) 24 days after the first vaccine dose was positive (1392 AU/ml, positivity cut-off: 50 AU/ml).. In 2021, Serology test: ama (abnormal) showed an indirect immunofluorescence pattern on triple rodent tissue compatible with anti-mitochondrial antibody (AMA) and. On 15-Jun-2021, Serology test ana (abnormal) anti-nuclear antibody (ANA) at a titer of 1:640 with fine speckled indirect immunofluorescencepattern on HEp2 cells, positive anti-gastric parietal cells antibody at a titer of 1:320. repeated 12 days after first testing; Indirect immunofluorescence on HEp2 and VSM47 cells (Euroimmun) showed positive nuclear staining with a speckled pattern and a faint rim-like pattern, coupled with positive cytoplasmic staining with a trabecular pattern.. On 15-Jun-2021, Smooth muscle antibody: negative (Negative) negative. On 15-Jun-2021, Ultrasound abdomen: normal (normal) Normal Liver parenchyma, normal portal vein flow, no ascites, normal spleen size (11 cm).. On 15-Jun-2021, White blood cell count: 6.3 6.3 x10e9/l. mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) was temporarily withheld on an unknown date. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered AUTOIMMUNE HEPATITIS (Acute Autoimmune-like Hepatitis) to be possibly related. No further causality assessment was provided for PRODUCT DOSE OMISSION ISSUE (The second vaccine dose was temporally suspended). Patient presented with symptoms of jaundice, fatigue and loss of appetite. Additional diagnostic tests : results are as follow Molecular-based assay for Scl-70: negative. Molecular-based assay forJo-1: negative. Molecular-based assay for Sm: negative. Molecular-based assay for dsDNA: negative. Molecular-based assay for Fibrillarin: negative. Molecular-based assay for RNA Pol III: negative. Molecular-based assay for Rib-P: negative.

Case ID	Narrative (Complete)
	Molecular-based assay for PM-Scl: negative. Molecular-based assay for PCNA: negative. Molecular-based assay for Mi2: negative. Anti-native pyruvate dehydrogenase complex E2 sudunit (PDC-E2): negative. Anti-recombinant PDC subunit E2: negative. Anti-2-oxoglutarate dehydrogenase complex E2 subunit (OGDC-E2): negative. Anti-branched-chain 2-oxo acid dehydrogenase complex E2-subunit (BCOADC-E2): negative. MIT-3 based Elisa (INOVA): negative. Immunoblot for anti-SLA: negative. Immunoblot for anti-LC1: negative. Immunoblot anti -LKM1: negative. Immunoblot anti-sp100: negative. Immunoblot anti-gp210 (Alphadia): negative. Immunoblot anti-transglutaminase IgA (Elisa, Thermofisher Scientific): negative. ANCA: negative. Anti-cardiolipin IgG: negative. IgM antibodies: negative. IgA: positive (26.1 CU, positivity cut-off 20CU). Anti-β-2 glycoprotein IgA: positive (51.3 CU, positivity cut-off 20). Anti-β-2 glycoprotein IgM: negative. Anti-β-2 glycoprotein IgG: negative. Human leukocyte antigen (HLA) testing showed DRB1*01:01 11:01, DQA1*01:01 05:01, and DQB1*03:01 05:01. Serum ceruloplasmin and alfa-I-antitrypsin levels: normal. Response from the reporter included that the patient was still on steroidal treatment and at the time of presentation with symptoms, the patient was not tested with SARS-CoV-2 RT-PCR or SARS-CoV-2 antigen. The case was reported to regulatory authority [redacted]. Local evaluator comment:This literature non-study case from [redacted] reported in a literature concerns a 63-year-old, male patient, who experienced according to [redacted] SmPC, the unexpected serious event of autoimmune hepatitis. The event occurred 7 days after the first dose of mRNA-1273. The patient presented to his practitioner with jaundice, fatigue and loss of appetite with tender hepatomegaly without ascites upon examination. AST, ALT, GGT and AP were significantly increased and autoimmune liver serology showed anti-nuclear antibody (ANA). Prednisone 40 mg/day was started, which was well tolerated and induced a good response during a follow-up of 2 weeks and was subsequently rapidly tapered to 20 mg/day. The event was considered as related per both the reporter's and Company's assessment. Until present no risk minimization measures were implemented to the events according to the latest version. The benefit-risk relationship of mRNA-1273 is not affected by this report. Company comment: This literature non-study case concerns a 63-year-old, male patient, who experienced the unexpected serious event of aut

Case ID	Narrative (Complete)
[redacted]	This case was initially received via European Medicines Agency (Reference number: [redacted] on 29-Jul-2021. 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 an other health care professional and describes the occurrence of MALAISE (Malaise following the first vaccination), AUTOIMMUNE HEPATITIS (Toxic hepatitis with autoimmune similarities.), JAUNDICE (debut with Icterus after vaccination), FATIGUE (Tiredness after the first vaccine), DECREASED APPETITE (Decreased appetite), SCLERAL DISCOLOURATION (yellowcolored sclera following the first vaccination) and HEPATIC ENZYME INCREASED (Sudden severely elevated liver counts) in a 57-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 3002338 and 3004493) for COVID-19 vaccination. The patient was previously been healthy and well. Patient had no medical history. On 21-May-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 01-Aug-2021, received dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to 1 dosage form. On 09-Jun-2021, the patient experienced HEPATIC ENZYME INCREASED (Sudden severely elevated liver counts) (seriousness criterion hospitalization). In 2021, the patient experienced MALAISE (Malaise following the first vaccination) (seriousness criterion hospitalization), JAUNDICE (debut with Icterus after vaccination) (seriousness criterion hospitalization), FATIGUE (Tiredness after the first vaccine) (seriousness criterion hospitalization), DECREASED APPETITE (Decreased appetite) (seriousness criterion hospitalization) and SCLERAL DISCOLOURATION (yellowcolored sclera following the first vaccination) (seriousness criterion hospitalization). In June 2021, the patient experienced AUTOIMMUNE HEPATITIS (Toxic hepatitis with autoimmune similarities.) (seriousness criterion hospitalization). On 19-Jul-2021, HEPATIC ENZYME INCREASED (Sudden severely elevated liver counts) had resolved. At the time of the report, MALAISE (Malaise following the first vaccination), JAUNDICE (debut with Icterus after vaccination), FATIGUE (Tiredness after the first vaccine), DECREASED APPETITE (Decreased appetite) and SCLERAL DISCOLOURATION (yellowcolored sclera following the first vaccination) outcome was unknown and AUTOIMMUNE HEPATITIS (Toxic hepatitis with autoimmune similarities.) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In 2021, Alanine aminotransferase: 2000 not specified 2000 Not specified and. In June 2021, Alanine aminotransferase elevated (not otherwise speci 09Jun2021-19Jul2021: Elevated (not otherwise speci. In June 2021, Blood alkaline phosphatase: elevated (not otherwise speci 09Jun2021-19Jul2021: Elevated (not otherwise speci. In 2021, Blood test: no results provided No results provided. In June 2021, Gamma-glutamyltransferase: elevated (not otherwise speci 09Jun2021-19Jul2021: Elevated (not otherwise speci. In June 2021, Hepatic enzyme: elevated (not otherwise speci 09Jun2021-19Jul2021: Elevated liver enzymes.. In 2021, International normalised ratio: up to 1.5 not specified Up to 1.5 Not specified and. In June 2021, International normalised ratio elevated (not otherwise speci 09Jun2021-19Jul2021: Elevated (not otherwise speci. On 21-Jun-2021, Biopsy liver: severe activity, fibrosis Severe activity, fibrosis, chronic active inflammation Chronic active inflammation and compatible with acute autoimmune hepatitis. Compatible with Acute Autoimmune hepatitis.. In July 2021, Alanine aminotransferase: elevated (not otherwise speci 09Jun2021-19Jul2021: Elevated (not otherwise speci. In July 2021, Blood alkaline phosphatase: elevated (not otherwise speci 09Jun2021-19Jul2021: Elevated (not otherwise speci. In July 2021, Gamma-glutamyltransferase: elevated (not otherwise speci 09Jun2021-19Jul2021: Elevated (not otherwise speci. In July 2021, International normalised ratio: elevated (not otherwise speci 09Jun2021-19Jul2021: Elevated (not otherwise speci. mRNA-1273 (Spikevax) (Intramuscular) dosing remained unchanged. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Concomitant medications were not reported. No treatment information was provided by the reporter. FOLLOW-UP (version 003): New information received on 16Aug2021 from a physician in duplicate case [redacted], which has been merged with this master case before submission to EV Company Comment : This case concerns a 57-year-old male patient with no reported medical history, who experienced the unexpected serious (seriousness criteria Hospitalization) events of Autoimmune hepatitis (AESI), Hepatic enzymes increased, Jaundice, Scleral discoloration, Malaise, Fatigue and Decreased appetite. The onset of the event Hepatic enzymes increased occurred approximately 19 days and for other events unknown days after the first dose of mRNA-1273 Vaccine. A liver biopsy was performed which showed chronic active inflammation, severe activity, and fibrosis, compatible with Acute Autoimmune Hepatitis. Hepatic enzymes increased resolved after 40 days of onset. Second dose was administered approximately 71 days after the first dose (inappropriate schedule). The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Seriousness of the events retained as per Regulatory Authority reporting. Most recent FOLLOW-UP information incorporated above includes: On 21-Mar-2022: Follow-up received with Lab test details updated, Suspect product coding (COVID-19 Moderna Vaccine to Spikevax), Indication updated, Event details (Autoimmune hepatitis) updated.

Case ID	Narrative (Complete)
[redacted]	This regulatory authority case was reported by a physician and describes the occurrence of HEPATITIS ACUTE (Hepatitis acute), LEUKOPENIA (Leucopenia) and THROMBOCYTOPENIA (Thrombopenia) in a 24-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination. Concurrent medical conditions included Alcohol use (Occasional alcohol consumption (1-2 beers/week)). Concomitant products included IBUPROFEN (IBUPROFENE) from 06-Jun-2021 to 10-Jun-2021 and PARACETAMOL (DAFALGAN) from 06-Jun-2021 to 10-Jun-2021 for an unknown indication. On 05-Jun-2021, the patient received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form. On 11-Jun-2021, the patient experienced HEPATITIS ACUTE (Hepatitis acute) (seriousness criterion medically significant), LEUKOPENIA (Leucopenia) (seriousness criterion medically significant) and THROMBOCYTOPENIA (Thrombopenia) (seriousness criterion medically significant). On 17-Jun-2021, THROMBOCYTOPENIA (Thrombopenia) had resolved. On 21-Jun-2021, LEUKOPENIA (Leucopenia) had resolved. At the time of the report, HEPATITIS ACUTE (Hepatitis acute) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 11-Jun-2021, Platelet count: 87 (Low) Minimal thrombocytopenia at 87 G/L. On 12-Jun-2021, Serum ferritin: 3800 (High) Considerable high serum ferritin at 3800 U/L (reference 30-400). On 12-Jun-2021, White blood cell count: 2.5 (Low) Moderate leukopenia at 2.5 G/L were observed. In 2021, SARS-CoV-2 test: negative (Negative) Negative. On 17-Jun-2021, Alanine aminotransferase: 447 (abnormal) Considerable hepatic cytolysis with ALT at 447. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered HEPATITIS ACUTE (Hepatitis acute), LEUKOPENIA (Leucopenia) and THROMBOCYTOPENIA (Thrombopenia) to be possibly related. On 11-Jun-2021, the patient underwent Aspartate aminotransferase, Alanine aminotransferase, Bilirubin total, Leucocyte count, and results were not provided for these tests. The patient also underwent Fibrin D-Dimer test and the value noted for the D-dimer was at 2964 (reference <500). On 12-Jun-2021, Aspartate aminotransferase, Alanine aminotransferase and Platelet count test and the results of these test was not provided. On 13-Jun-2021, the patient underwent Fibrin D Dimer test and results were not provided.On 16-Jun-2021, Aspartate aminotransferase, Alanine aminotransferase, Leucocyte count, Platelet count and Ferritin Laboratory tests. On 17-Jun-2021, Alanine aminotransferase test and results revealed considerable hepatic cytolysis with ALT at 447. On 18-Jun-2021, the patient underwent Aspartate aminotransferase, Lactate dehydrogenase and Ferritin tests and results were not provided. On 21-Jun-2021, Aspartate aminotransferase, Alanine aminotransferase, Bilirubin total, Lactate dehydrogenase, Leucocyte count, Platelet count and Ferritin tests and results were not provided. the patient's aspartate aminotransferase was noted at 237 U/L. The patient visited the emergency room on 11-Jun-2021 for fever with nausea, vomiting and bloating. The patient underwent a chest CT Scan which ruled out a pulmonary embolism and an abdominal ultrasound (16.06) which was unremarkable, except for an enlarged spleen. Reportedly, on 21-Jun-2021, the patient was asymptomatic, and a lab work-up ruled out viral or bacterial hepatitis (HBV, HAV, HCV, HEV, HIV, CMV, EBV, parvovirus, Coxiella, Bartonella negative, leptospirosis pending). Differential diagnosis of Para infectious liver and hematologic involvement was suggested or even macrophage activation syndrome. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Most recent FOLLOW-UP information incorporated above includes: On 28-Jul-2021: Translation received on 05Aug2021 includes: Medical history, lab data, changed the previously captured dose number of suspect drug from first to second and event description.

Case ID	Narrative (Complete)
[redacted]	This case was initially received via [redacted] (Reference number: [redacted] on 27-Jul-2021. The most recent information was received on 27-Jul-2021 and was forwarded to Moderna on an unknown date. This regulatory authority case was reported by a physician and describes the occurrence of AUTOIMMUNE HEPATITIS (Autoimmune hepatitis) in a male patient of an unknown age who received mRNA-1273 (Moderna CoviD-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. On an unknown date, the patient received second dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) at an unspecified dose. On an unknown date, received first dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) dosage was changed to at an unspecified dose. On an unknown date, the patient experienced AUTOIMMUNE HEPATITIS (Autoimmune hepatitis) (seriousness criterion hospitalization). At the time of the report, AUTOIMMUNE HEPATITIS (Autoimmune hepatitis) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In 2021, SARS-CoV-2 test: negative (Negative) Negative. The action taken with mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown) was unknown. For mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Concomitant medications were not reported. Treatment medications were not reported. The patient had not tested positive for COVID-19 since having the vaccine. Company Comment: This case concerns a male patient of unknown age with no medical history reported, who experienced the unexpected serious AESI Autoimmune hepatitis at an unknown date. The patient received the second dose of mRNA-1273 vaccine at an unknown date. There is no information available to establish the temporal relation of the events. 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. Most recent FOLLOW-UP information incorporated above includes: On 27-Jul-2021: Upon internal review on 07-Jan-2022, significant correction was performed. Lab result, company comment and narrative were updated.

Case ID	Narrative (Complete)
[redacted]	This case was received via United States FDA VAERS (Reference number: [redacted] on 03-Aug-2021 and was forwarded to Moderna on 03-Aug-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of ACUTE HEPATIC FAILURE (Acute hepatic failure), ACUTE MYOCARDIAL INFARCTION (Acute myocardial infarction), AORTIC STENOSIS (Aortic stenosis), BRAIN HYPOXIA (Brain hypoxia), CARDIAC ARREST (Cardiac arrest), CARDIOGENIC SHOCK (Cardiogenic shock), CARDIOMYOPATHY (Cardiomyopathy), CONDITION AGGRAVATED (Condition aggravated), DYSPNOEA (Dyspnoea), GENERAL PHYSICAL HEALTH DETERIORATION (General physical health deterioration), LACTIC ACIDOSIS (Lactic acidosis), MALAISE (Malaise), PULMONARY EMBOLISM (Pulmonary embolism), RASH (Rash), RASH ERYTHEMATOUS (Rash erythematous), RENAL FAILURE (Renal failure) and RHEUMATOID ARTHRITIS (Rheumatoid arthritis) in a 58-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The patient's past medical history included Anxiety and Rheumatoid arthritis. Concomitant products included ACETYLSALICYLIC ACID (ASPRIN), CITALOPRAM, PREDNISONE and FUROSEMIDE for an unknown indication. On 02-Jun-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 03-Jun-2021, the patient experienced ACUTE HEPATIC FAILURE (Acute hepatic failure) (seriousness criteria death and medically significant), ACUTE MYOCARDIAL INFARCTION (Acute myocardial infarction) (seriousness criteria death and medically significant), AORTIC STENOSIS (Aortic stenosis) (seriousness criteria death and medically significant), BRAIN HYPOXIA (Brain hypoxia) (seriousness criteria death and medically significant), CARDIAC ARREST (Cardiac arrest) (seriousness criteria death and medically significant), CARDIOGENIC SHOCK (Cardiogenic shock) (seriousness criteria death and medically significant), CARDIOMYOPATHY (Cardiomyopathy) (seriousness criteria death and medically significant), CONDITION AGGRAVATED (Condition aggravated) (seriousness criterion death), DYSPNOEA (Dyspnoea) (seriousness criterion death), GENERAL PHYSICAL HEALTH DETERIORATION (General physical health deterioration) (seriousness criterion death), LACTIC ACIDOSIS (Lactic acidosis) (seriousness criteria death and medically significant), MALAISE (Malaise) (seriousness criterion death), PULMONARY EMBOLISM (Pulmonary embolism) (seriousness criteria death and medically significant), RASH (Rash) (seriousness criterion death), RASH ERYTHEMATOUS (Rash erythematous) (seriousness criterion death), RENAL FAILURE (Renal failure) (seriousness criteria death and medically significant) and RHEUMATOID ARTHRITIS (Rheumatoid arthritis) (seriousness criteria death and medically significant). The patient died on 10-Jul-2021. The cause of death was not reported. It is unknown if an autopsy was performed. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No treatment drug information was provided. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was not applicable For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Company Comment Very limited information regarding these events has been provided at this time. No further follow up information is expected.

Case ID	Narrative (Complete)
[redacted]	This case was initially received via European Medicines Agency (Reference number: [redacted]) on 03-Aug-2021. The most recent information was received on 03-Aug-2021 and was forwarded to Moderna on 18-Aug-2021. This regulatory authority case was reported by a physician and describes the occurrence of AUTOIMMUNE HEPATITIS ([redacted] LIVER DISORDER [redacted] and TRANSAMINASES INCREASED (Transaminases increased) in a 33-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 3003183) for Prophylactic vaccination. Concurrent medical conditions included Crohn's disease. Concomitant products included ADALIMUMAB for Crohn's disease. On 18-Jun-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 18-Jun-2021, the patient experienced AUTOIMMUNE HEPATITIS [redacted] (seriousness criteria hospitalization and medically significant), LIVER DISORDER ([redacted] (seriousness criterion hospitalization) and TRANSAMINASES INCREASED (Transaminases increased) (seriousness criterion hospitalization). At the time of the report, AUTOIMMUNE HEPATITIS [redacted], LIVER DISORDER [redacted] and TRANSAMINASES INCREASED (Transaminases increased) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 18-Jun-2021, Transaminases: high (High) Transaminases increased.. On 02-Jul-2021, Antibody test: Patient is negative for SplOO antibody, PMK antibody, LKM-l antibody, LC-l antibody, SLA antibody, Ro-52 antibody negative, ds-DNA-antibody, p-ANCA, c-ANCA negative and negative Negative. On 02-Jul-2021, Antimitochondrial antibody: negative (Negative) M2-3E negative. On 02-Jul-2021, Antinuclear antibody: 1:1289 (High) units: titer serological exclusion of viral hepatitides. On 02-Jul-2021, Cytomegalovirus test: negative Negative. On 02-Jul-2021, Epstein-Barr virus test: negative Negative. On 02-Jul-2021, Haematocrit: negative Negative. On 02-Jul-2021, Herpes simplex test: negative Negative. On 06-Jul-2021, Biopsy liver: without clear pathological findings normal. On 08-Jul-2021, Magnetic resonance imaging: normal (normal) no signs of advanced parenchymal damage. On 08-Jul-2021, Ultrasound scan: normal (normal) No cholestasis, exclusion, portal vein thrombosis.. The action taken with mRNA-1273 (Spikevax) (Intramuscular) was unknown. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. On 02 Jul 2021 patient had Adalimumab GPT (ALT) test whose result was 1758 U/l, GOT (AST) test whose result was 777 U/l, gamma GT test which showed a result of 124 U/l, CRP test whose result was 31.5 mg/dL. On 03 Jul 2021 patient underwent GPT (ALT) test which showed a result of 1947 U/L, GOT (AST) test whose result was 867 U/l and gamma GT test data showed a result of 121 U/l. On 04 Jul 2021 patient had GPT (ALT) test whose result was 2025 U/l, GOT (AST) test data showed a result of 882 U/l and gamma GT test which showed a result of 132 U/l. On 05 Jul 2021 patient underwent GPT (ALT) test, GOT (AST) test, gamma GT test and CRP test which showed a result of 1857 U/l, 699 U/l, 134 U/l and 13.4 mg/dl. On 06 Jul 2021 patient had GPT (ALT) test, GOT (AST) test and gamma GT test whose result was 1799 U/l, 652 U/l and 142 U/l respectively. On 07 Jul 2021 patient underwent GPT (ALT) test, GOT (AST) test and gamma CT test data showed a result of 2138 U/l, 784 U/l and 172 U/l respectively. On 08 Jul 2021 Patient had total bilirubin test, GPT (ALT) test GOT (AST) test which showed a results of 1.66 mg/dl, 1952 U/L and 595 U/l respectively and On 09 Jul 2021 patient underwent GPT (ALT) test, GOT (AST) test, and gamma GT test whose results were 1650 U/l, 393 U/l and 214 U/l respectively. On an unknown date patient Ceruloplasmin was not elevated. Causality for all the events were reported as Unclassifiable. Company comment: This is a RA report of Autoimmune hepatitis (and liver disorder) that required hospitalization, after an unknown dose of the product, in a 33 years old female under treatment with Adalimumab for Chron´s Disease. Based on the current available information and temporal association between the use of the product and the onset of the events, a causal relationship cannot be excluded. Concomitant medical conditions and medication could be potentially confounders/co-suspects for the reported events. Most recent FOLLOW-UP information incorporated above includes: On 03-Aug-2021: Translation document received on 18-Aug-2021 and included Concomitant drug was added, information regarding patient's current condition, laboratory test patient had and anatomical location of vaccination. On 25-Aug-2021: Follow-up received included no new information.

Case ID	Narrative (Complete)
[redacted]	This spontaneous case was reported by a consumer and describes the occurrence of PORTAL VEIN THROMBOSIS (developed a clot in her portal vein) and HEPATIC FAILURE (liver failure) in an 85-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 002A21A and 041L20A) for COVID-19 vaccination. Concurrent medical conditions included Hypertension and Diabetes. On 28-Jan-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 26-Feb-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient experienced PORTAL VEIN THROMBOSIS (developed a clot in her portal vein) (seriousness criteria death, hospitalization and medically significant) and HEPATIC FAILURE (liver failure) (seriousness criteria death, hospitalization and medically significant). The reported cause of death was Liver failure. It is unknown if an autopsy was performed. It was reported that the reporter believed that her mother passed away as a result of a complication with the vaccine. Patient's mother received first dose on 28-JAN-2021. Patient received second dose one 26-FEB-2021. The patient was 85-year-old with hypertension and diabetes and developed a clot in her portal vein. Patient was hospitalized. The clot made her go into liver failure which was the cause of death. The date of the reported events remained unknown at the time of the report. Treatment information were not provided by the reporter. Concomitant medications were not reported by reporter. Company Comment: This is the case of an 85-year-old female subject with a history of hypetension and diabetes who died due to hepatic falure. Reportedly, the patient initially developed thrombosis in portal vein (a clot in her portal vein), however a temporal association between the use of the product and the start date of the event was not reported. The patient subsequently developed liver failure and died due to liver failure, as reported, however, the date of death was not provided. It is unknown if an autopsy was performed. Very limited information regarding these events has been provided at this time. Causality is confounded with the patient's advanced age, hypertension and diabetes.
[redacted]	This case was initially received via European Medicines Agency (Reference number: [redacted] on 04-Aug-2021. The most recent information was received on 04-Aug-2021 and was forwarded to Moderna on 11-Aug-2021. This regulatory authority case was reported by a physician and describes the occurrence of HEPATOCELLULAR INJURY (Hepatocellular damage), LEUKOPENIA (Leucopenia), HYPERTENSION (Hypertensive episode), ASTHENIA (Asthenia), ERYTHEMA (Erythema) and ARTHRALGIA (Arthralgia) in a 71-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The patient's past medical history included Cancer of lung (lung adenocarcinoma) in 2018 and Lung lobectomy (right lobectomy) in December 2018. Concomitant products included ESOMEPRAZOLE SODIUM (NEXIUM [ESOMEPRAZOLE SODIUM]) for an unknown indication. On 26-Mar-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 04-Apr-2021, the patient experienced ARTHRALGIA (Arthralgia) (seriousness criterion medically significant). On 13-Apr-2021, the patient experienced HYPERTENSION (Hypertensive episode) (seriousness criterion medically significant), ASTHENIA (Asthenia) (seriousness criterion medically significant) and ERYTHEMA (Erythema) (seriousness criterion medically significant). On 14-Apr-2021, the patient experienced HEPATOCELLULAR INJURY (Hepatocellular damage) (seriousness criterion medically significant) and LEUKOPENIA (Leucopenia) (seriousness criterion medically significant). On 16-Apr-2021, LEUKOPENIA (Leucopenia) had resolved. On 26-Apr-2021, HEPATOCELLULAR INJURY (Hepatocellular damage) had resolved. At the time of the report, HYPERTENSION (Hypertensive episode), ASTHENIA (Asthenia), ERYTHEMA (Erythema) and ARTHRALGIA (Arthralgia) had resolved. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Treatment information was not provided. Company Comment: Very limited information regarding these events has been provided at this time. Most recent FOLLOW-UP information incorporated above includes: On 04-Aug-2021: Translation received (Medical history comments)

Case ID	Narrative (Complete)
[redacted]	This case was initially received via [redacted] (Reference number: [redacted] on 08-Aug-2021. The most recent information was received on 26-Oct-2021 and was forwarded to Moderna on 26-Oct-2021. This regulatory authority case was reported by a physician and describes the occurrence of LIVER INJURY (myocarditic injury), CHEST PAIN (chest pain) and MYOCARDITIS (Myopericarditis) in a 25-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for COVID-19 vaccination. The patient's past medical history included Chest pain, Cardiac MRI and Clinical trial participant (Study details: Local imaging trial of myocarditis). On 04-Jul-2021, the patient received first dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 26-Jul-2021, the patient experienced MYOCARDITIS (Myopericarditis) (seriousness criteria hospitalization and medically significant). On an unknown date, the patient experienced LIVER INJURY (myocarditic injury) (seriousness criteria hospitalization and medically significant) and CHEST PAIN (chest pain) (seriousness criteria hospitalization and medically significant). On 06-Aug-2021, MYOCARDITIS (Myopericarditis) was resolving. At the time of the report, LIVER INJURY (myocarditic injury) and CHEST PAIN (chest pain) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 31-Jul-2021, SARS-CoV-2 test: no - negative covid-19 test (Negative) No - Negative COVID-19 test. On an unknown date, Electrocardiogram: abnormal (abnormal) Pericarditic injury pattern. On an unknown date, Magnetic resonance imaging heart: abnormal (abnormal) Myocarditic injury pattern. On an unknown date, Troponin I: 50,000 ng/l (abnormal) 50,000 ng/l. For mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Concomitant product was not provided by the reporter It was reported that patient's diagnostic test included cardiac ultrasound and Left ventricular function was normal, Florid myopericarditis picture with chest pain .The patient was managed conservatively with colchicine. Based on the current available information and temporal association between the use of the product and the start date of these events, a causal relationship cannot be excluded Company comment: This case concerns a 25-year-old male patient with relevant past medical history of chest pain (cardiac MRI and local imaging trial of myocarditis), who experienced the unexpected events liver injury and chest pain and expected event of myocarditis The events occurred 22 days after the first dose of mRNA-1273 (Moderna COVID-19 Vaccine). The rechallenge was unknown as no details about second dose was disclosed. Causality assessment with product use was not provided by the reporter. Myocarditis is consistent with the current understanding of the mechanism of action of the vaccine. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report. Events are assessed as serious (medically significant/hospitalization) per regulatory reporting. Myocarditis is an an important medical event and an adverse event of special interest. Most recent FOLLOW-UP information incorporated above includes: On 15-Aug-2021: Follow up received included no new Information On 26-Oct-2021: Added lab data , updated action taken and added additional information in I-narrative supplement.

Case ID	Narrative (Complete)
[redacted]	This regulatory authority case was reported by a physician and describes the occurrence of AUTOIMMUNE HEPATITIS (Autoimmune hepatitis) in a 62-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Diabetes mellitus (Type 2 diabetes) and Ischemic cardiomyopathy (Ischemic heart disease). Concomitant products included METFORMIN HYDROCHLORIDE [redacted], ACETYLSALICYLIC ACID (ASA SANDOZ) and ROSUVASTATIN for Type 2 diabetes mellitus and Ischemic heart disease, ROSUVASTATIN CALCIUM (CRESTOR) for an unknown indication. On 04-May-2021, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form. On 11-May-2021, after starting mRNA-1273 (COVID-19 Vaccine Moderna), the patient experienced AUTOIMMUNE HEPATITIS (Autoimmune hepatitis) (seriousness criterion medically significant). On an unknown date, the patient experienced PRODUCT DOSE OMISSION ISSUE (Product dose omission issue). The patient was treated with PREDNISONE for Adverse event, at a dose of 40 mg once a day. At the time of the report, AUTOIMMUNE HEPATITIS (Autoimmune hepatitis) was resolving and PRODUCT DOSE OMISSION ISSUE (Product dose omission issue) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Alanine aminotransferase (Unknown-55): 1038 (abnormal) 1038 U/L (upper limit of normal (ULN) was reported as 55. On an unknown date, Alpha-1 anti-trypsin: normal (normal) Tested normal. On an unknown date, Antimitochondrial antibody: negative (Negative) Tested negative. On an unknown date, Antineutrophil cytoplasmic antibody: negative (Negative) Tested negative. On an unknown date, Aspartate aminotransferase (Unknown-34): 1127 (abnormal) 1127 U/L (upper limit of normal (ULN) 34 U/l. On an unknown date, Autoantibody test: positive (Positive) antibody (ANA) at a titer of 1:640 with fine speckled indirect immunofluorescence pattern on HEp2 cells, positive anti-gastric parietal cells antibody at a titer of 1:320. Anti-smooth muscle antibody (ASMA), anti neutrophil cytoplasmic antibody (ANCA), anti-soluble liver antigen (SLA) antibody, anti-liver kidney microsomal type 1 antibody (anti-LKM1), anti-liver cytosol type 1 (anti- LC1) antibody and anti mitochondrial antibody (AMA) were all negative. and positive (Positive) Autoimmune liver serology was repeated at 12 days after first testing. On an unknown date, Blood alkaline phosphatase (40-150): 192 (High) 192 U/L. On an unknown date, Blood bilirubin (Unknown-20.4): 204.8 (abnormal) 204.8 8 µmol/l (ULN 20.4 µmol/l). On an unknown date, Blood immunoglobulin G (5.4-18.22): 19.96 (High) 19.96 g/l. On an unknown date, Ceruloplasmin: normal (normal) Tested normal. On an unknown date, Gamma-glutamyltransferase (Unknown-55): 536 (normal) 536 U/l ULN 55 U/l. On an unknown date, Haemoglobin: 14.8 (normal) 14.8 g/dL. On an unknown date, Histology: abnormal (abnormal) Liver histology showed inflammatory portal infiltrate with interface hepatitis, lobular and centrilobular inflammation with centrilobular necrosis, in absence of fibrosis and steatosis.. On an unknown date, Immunology test: negative (Negative) Immunoblot for anti-SLA, anti-LC1, anti-LKM1, anti-sp100 and anti-gp210 (Alphadia), anti-transglutaminase IgA (Elisa, Thermofisher Scientific), ANCA, tested by indirect immunofluorescence on fixed human neutrophils (INOVA), anti-myeloperoxidase and anti-proteinase 3 (Elisa, Thermofisher Scientific) were all reported as negative. and positive (Positive) Indirect immunofluorescence on HEp2 and VSM47 cells (Euroimmun) showed positive nuclear staining with a speckled pattern and a faint rim-like pattern, coupled with positive cytoplasmic staining with a trabecular pattern.. On an unknown date, International normalised ratio: 1.16 (normal) 1.16 and 1.4 (normal) The patient did not develop signs of encephalopathy, and after a transient worsening of INR to 1.4, he showed spontaneous improvement of serum bilirubin, INR and transaminase levels.. On an unknown date, Physical examination: tender hepatomegaly tender hepatomegaly without ascites. On an unknown date, Platelet count: 309 (normal) 309 x 109/l. On an unknown date, Polymerase chain reaction: negative (Negative) Polymerase chain reaction for hepatitis B, C, E, anti hepatitis A virus and IgM were negative. On an unknown date, SARS-CoV-2 antibody test: 1392 Anti-SARS-Cov2 IgG spike 1 antibody 24 days after the first vaccine dose was positive (1392 AU/ml, positivity cut off: 50 AU/ml).. On an unknown date, Ultrasound abdomen: normal (normal) An abdominal ultrasound showed normal liver parenchyma, normal portal vein flow, no ascites, normal spleen size (11 cm).. On an unknown date, White blood cell count: 6.3 (normal) 6.3 x 109/l. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered AUTOIMMUNE HEPATITIS (Autoimmune hepatitis) to be possibly related. No further causality assessment was provided for PRODUCT DOSE OMISSION ISSUE (Product dose omission issue). The reporter stated that patient had presented to his general practitioner and did not take herbal remedies or other drugs, and his daily amount of alcohol consumption was 10g. Patient had no history of clinical apparent COVID-19. On examination,patient was jaundiced, and had tender hepatomegaly without ascites. The second vaccine dose was temporarily suspended. The lab test reported also included Anti-smooth muscle antibody (ASMA), anti-soluble liver antigen (SLA) antibody, anti-liver kidney microsomal type 1 antibody (anti-LKM1), anti-liver cytosol type 1 (anti- LC1) antibody and were reported as negative. Anti-SARS-Cov2 IgG spike 1 antibody was undergone 24 days after the first vaccine dose and reported as positive (1392 AU/ml, positivity cut-off: 50 AU/ml). Molecular-based assays for U1-snRNP, SSA/Ro, SSB/La, CENP-B, Scl-70, Jo-1, Sm, dsDNA, Fibrillarin, RNA Pol III, Rib-P, PM-Scl, PCNA, Mi2 were negative (CTD screen, Thermofisher Scientific). Anti-native pyruvate dehydrogenase complex E2 sudunit (PDC-E2), anti-recombinant PDC subunit E2, anti-2-oxoglutarate dehydrogenase complex E2 subunit (OGDC-E2) and anti-branched-chain 2-oxo acid dehydrogenase complex E2-subunit (BCOADC-E2) were negative (Alphadia). MIT-3 based Elisa (INOVA) was also negative. The reported lab results also included anti-cardiolipin IgG and IgM antibodies were negative IgA was positive (26.1 CU, positivity cut-off 20CU); similarly, anti-beta-2 glycoprotein IgA was positive (51.3 CU, positivity cut-off 20), with negative anti-beta-2 glycoprotein IgM and IgG. Human leukocyte antigen (HLA) testing showed DRB101:01 11:01, DQA1 01:01 05:01, and DQB1 03:01 05:01 The reporter also stated that the patient was on long term statin therapy.

Case ID	Narrative (Complete)
	Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. Product dose omission issue is assessed as not applicable for causality.

Case ID	Narrative (Complete)
[redacted]	This literature-non-study case was reported in a literature article and describes the occurrence of IMMUNE THROMBOCYTOPENIA (Immune thrombocytopenic purpura (ITP)) and LIVER INJURY (Acute liver injury) in a 26-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: Hines A, Shen JG, Olazagasti C, Shams S. Immune thrombocytopenic purpura and acute liver injury after COVID-19 vaccine. BMJ Case Rep. 2021;14(7):e242678 The patient's past medical history included Menses irregular (Patient was on oral contraceptives was sent to the emergency room by her primary care physician for a petechial rash of 6 days). Previously administered products included for Menstrual cramps: Acetaminophen (Drug-induced liver injury: the patient reported taking acetaminophen infrequently for menstrual cramps and last ingested a week prior to hospitalisation. Acetaminophen level and salicylate level were negative). Past adverse reactions to the above products included No adverse reaction with Acetaminophen. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On an unknown date, the patient experienced IMMUNE THROMBOCYTOPENIA (Immune thrombocytopenic purpura (ITP)) (seriousness criteria hospitalization and medically significant), LIVER INJURY (Acute liver injury) (seriousness criterion medically significant) and VACCINATION SITE PAIN (Arm soreness at the injection site). The patient was hospitalized for 5 days due to IMMUNE THROMBOCYTOPENIA. The patient was treated with DEXAMETHASONE (intravenous) for Immune thrombocytopenic purpura, at a dose of 40 milligram once a day; N-ACETYLCYSTEINE for Adverse event, at an unspecified dose and frequency and PREDNISONE (oral) for Urticaria, at a dose of 40 milligram once a day. At the time of the report, IMMUNE THROMBOCYTOPENIA (Immune thrombocytopenic purpura (ITP)), LIVER INJURY (Acute liver injury) and VACCINATION SITE PAIN (Arm soreness at the injection site) outcome was unknown. Possible DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Alanine aminotransferase (10-45): 707 u/l (High) 707 U/L on HD 1, 1257 u/l (High) 1257 U/L on HD 3, increased to greater than one thousand, 2 weeks later of vaccine and 763 u/l On HD 5 763 U/L. On an unknown date, Aspartate aminotransferase (10-40): 284 u/l (High) 284 U/L on HD 1, 446 u/l (High) 446 U/L on HD 3, increased to greater than one thousand, 2 weeks later of vaccine and 175 u/l On HD 5 175 U/L. On an unknown date, Biopsy liver: normal (normal) no granulomas, steatosis or evidence of necroinflammatory injury, on HD 4. On an unknown date, Blood alkaline phosphatase: 82 u/l (normal) 82 U/L on HD 1. On an unknown date, Blood bilirubin (0.2-1.2): 1.0 mg/dl (normal) 1.0 mg/dl, on HD 1, 2.1 mg/dl 2.1 mg/dL HD 3 with mixed component of direct and indirect bilirubin. and 1.1 mg/dl On HD 5, her total bilirubin was normal at 1.1 mg/dL. On an unknown date, Blood creatinine: normal (normal) normal. On an unknown date, Blood fibrinogen: normal (normal) normal. On an unknown date, Blood folate: normal (normal) normal. On an unknown date, Blood immunoglobulin G (2-96): 100 mg/dl (High) specifically IgG4 measuring 100 mg/dL. On an unknown date, Blood immunoglobulin M: negative (Negative) negative, on HD 3. On an unknown date, Blood lactic acid (0.7-2.0): 3.3 mmol/l serum lactate that was transiently elevated on HD 3 to 3.3 mmol/L (0.7–2.0 mmol/L) but normalised to 1.9 mmol/L by HD 5. and 1.9 mmol/l 1.9 mmol/L by HD 5.. On an unknown date, Blood smear test: rare schistocytes, giant platelets, no platelet (abnormal) rare schistocytes, giant platelets, no platelet clumping, toxic neutrophils and atypical lymphocytes without immature WBCs or blasts. On an unknown date, Body temperature: normal (normal) normal. On an unknown date, Coagulation test: normal (normal) normal. On an unknown date, Cytomegalovirus test: not detected Epstein-Bar virus (EBV), parvovirus (PV), herpes simplex virus (HSV) 1/2 and cytomegalovirus (CMV) were not detected by means of serologic antibody and PCR testing.. On an unknown date, Epstein-Barr virus test: not detected Epstein-Bar virus (EBV), parvovirus (PV), herpes simplex virus (HSV) 1/2 and cytomegalovirus (CMV) were not detected by means of serologic antibody and PCR testing. On an unknown date, Fibrin D dimer: normal (normal) normal. On an unknown date, Full blood count: 19×10^9/l repeat complete blood count (CBC) showed a platelet ount of 19×109/L and 28×109/l On hospital day (HD) 1, the patient's CBC revealed a platelet count of 28×109/L with normal hemoglobin and white blood cell (WBC) levels.. On an unknown date, HIV antibody: undetectable HIV antigen, antibody and viral load were undetectable and negative (Negative) HIV1 and 2 antibodies were negative along with an undetectable transcription mediated amplification of RNA (viral load).. On an unknown date, HIV antigen: undetectable HIV antigen, antibody and viral load were undetectable. On an unknown date, HIV test: negative (Negative) HIV1 and 2 antibodies were negative along with an undetectable transcription mediated amplification of RNA (viral load).. On an unknown date, Haemoglobin: normal (normal) normal. On an unknown date, Hepatitis B antigen: negative (Negative) HBV e-antigen/ antibody were negative with an undetectable viral load. On an unknown date, Hepatitis B surface antibody positive: 1387.7 miu/ ml HBV surface antibody was positive at 1387.7 mIU/ mL indicating immunity. On an unknown date, Hepatitis B virus test: positive (Positive) The hepatitis panel was positive for hepatitis B virus (HBV) total core antibody. On an unknown date, Hepatitis C antibody: undetectable hepatitis C antibody and viral load were undetectable. On an unknown date, Herpes simplex test: not detected Epstein-Bar virus (EBV), parvovirus (PV), herpes simplex virus (HSV) 1/2 and cytomegalovirus (CMV) were not detected by means of serologic antibody and PCR testing.. On an unknown date, Parvovirus B19 test: not detected Epstein-Bar virus (EBV), parvovirus (PV), herpes simplex virus (HSV) 1/2 and cytomegalovirus (CMV) were not detected by means of serologic antibody and PCR testing.. On an unknown date, Platelet count (150-400): 91 (abnormal) 91x 10^9/L, abnormal, 28 (Low) 28x10^9/L, On hospital day (HD) 1, 213 (normal) 213x10^9/L On hospital day (HD) 5 and 19×10^9/l (abnormal) abnormal platelet count of 19×10^9/L. On an unknown date, Polymerase chain reaction: negative (Negative) EBV antibodies were consistent with past infection and confirmed with a negative PCR. On an unknown date, Pregnancy test: negative (Negative) negative. On an unknown date, SARS-CoV-2 test: negative (Negative) negative. On an unknown date, Serology test: negative (Negative) including microsomal antibody, antismooth muscle antibody, antimitochondrial antibody, ANA were negative. On an unknown date, Smooth muscle antibody: negative (Negative) negative.

Case ID	Narrative (Complete)
	On an unknown date, Thyroid hormones test: normal (normal) normal. On an unknown date, Ultrasound abdomen: normal (normal) with Doppler showed normal liver and spleen morphology with no identifiable thrombus. On an unknown date, Viral load: undetectable HBV e-antigen/ antibody were negative with an undetectable viral load, undetectable hepatitis C antibody and viral load were undetectable and undetectable HIV antigen, antibody and viral load were undetectable. On an unknown date, Vitamin B12: normal (normal) normal. On an unknown date, White blood cell count: normal (normal) normal. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter considered IMMUNE THROMBOCYTOPENIA (Immune thrombocytopenic purpura (ITP)), LIVER INJURY (Acute liver injury) and VACCINATION SITE PAIN (Arm soreness at the injection site) to be related. It was reported that the patient only had initial side effect after vaccination was arm soreness at the injection site. P

Case ID	Narrative (Complete)
[redacted]	This literature-non-study case was reported in a literature article and describes the occurrence of AUTOIMMUNE HEPATITIS (Autoimmune hepatitis) in a 76-year-old female patient who received mRNA-1273 (COVID-19 Vaccine Moderna) (batch no. 300042460) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. LITERATURE REFERENCE: Vuille-Lessard E, Montani M, Bosch J, Semmo N. Autoimmune hepatitis triggered by SARS-CoV-2 vaccination. J Autoimmun. 2021;123:102710 The patient's past medical history included COVID-19 (Three months prior (mild disease not requiring hospitalization)) on 30-Oct-2020, Urothelial carcinoma in 2019 and Low blood pressure. Concurrent medical conditions included Hypothyroidism since 2016. Concomitant products included LEVOTHYROXINE for Hypothyroidism, MIDODRINE for Low blood pressure, ZOLPIDEM for Sleepy. On 02-Feb-2021 at 3:30 PM, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form. On 15-Feb-2021, the patient experienced AUTOIMMUNE HEPATITIS (Autoimmune hepatitis) (seriousness criterion medically significant). On an unknown date, the patient experienced HERPES VIRUS INFECTION (nasal herpes simplex virus infection). The patient was treated with PREDNISOLONE (oral) from 16-Mar-2021 to 25-May-2021 for Autoimmune hepatitis, at a dose of 40 mg and AZATHIOPRINE from 30-Mar-2021 to 19-Apr-2021 for Autoimmune hepatitis, at a dose of 50 mg. At the time of the report, AUTOIMMUNE HEPATITIS (Autoimmune hepatitis) had not resolved and HERPES VIRUS INFECTION (nasal herpes simplex virus infection) outcome was unknown. Possible DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 16-Mar-2021, Biopsy liver: positive (Positive) diagnosis of autoimmune hepatitis was suspected, with positive autoantibodies. The diagnosis was confirmed histologically on a liver biopsy performed on 16.03.2021. In 2021, Abdomen scan: normal (normal) Abdominal examination was remarkable for tender hepatomegaly. In 2021, Alanine aminotransferase: 579 (abnormal) Alanine transaminase of 579 U/L. In 2021, Anti-actin antibody: 84 (abnormal) anti-actin antibody 84 U (negativity cut-off less than 20 U). In 2021, Antimitochondrial antibody: negative (Negative) Anti-M2 antibody Negative. In 2021, Antineutrophil cytoplasmic antibody: positive (Positive) anti-neutrophil cytoplasmic antibodies (titer greater than 1:1280, perinuclear, MPO and PR3 negative) were strongly positive. In 2021, Antinuclear antibody: 1:1280 (Inconclusive) Anti-nuclear antibody (titer 1:1280, homogeneous, fine granular). In 2021, Aspartate aminotransferase: 811 (High) elevated aspartate transaminase of 811 U/L. In 2021, Biopsy liver: abnormal (abnormal) A liver biopsy showed a chronic markedly active hepatitis with interface hepatitis, plasma cells, feathery degeneration and pseudo rosettes typical findings of autoimmune hepatitis (AIH). The degree of fibrosis could not be assessed given the significant parenchymal collapse. Simplified AIH Score was 8 (definite diagnosis of AIH).. In 2021, Blood albumin: 28 (abnormal) albumin was 28 g/L. In 2021, Blood alkaline phosphatase: 124 (abnormal) Alkaline phosphatase of 124 U/L. In 2021, Blood bilirubin: 65 (abnormal) total bilirubin of 65 micro mol/L. In 2021, Blood creatinine: normal (normal) creatinine was normal. In 2021, Blood immunoglobulin G: 39.4 (abnormal) significantly increased (39.4 g/L). In 2021, Blood pressure measurement: low (Low) Low. In 2021, Full blood count: normal (normal) Complete blood count was normal. In 2021, Gamma-glutamyltransferase: 361 (abnormal) Gamma-glutamyltransferase of 361 U/L. In 2021, International normalised ratio: 1.23 (abnormal) INR was 1.23. In 2021, Liver function test: normal (normal) Liver enzymes were completely normal in a routine check-up three years prior, as well as two months after the COVID-19 infection, elevated (High) elevated liver enzymes when referred to Hepatology outpatient clinic and normal (normal) After four weeks of treatment, the liver enzymes had completely normalized and the patient's symptoms had significantly improved. In 2021, Ophthalmological examination: abnormal (abnormal) On examination, the patient had discrete scleral and sublingual icterus.. In 2021, Polymerase chain reaction: negative (Negative) PCR for hepatitis B and E viruses and for cytomegalovirus were negative. In 2021, Serology test: negative (Negative) Serologies for hepatitis A, B and C viruses were negative. In 2021, Ultrasound abdomen: abnormal (abnormal) Abdominal ultrasound showed a slightly enlarged and hyperechogenic liver without biliary duct dilatation. The action taken with mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) was unknown. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered AUTOIMMUNE HEPATITIS (Autoimmune hepatitis) to be possibly related. No further causality assessment was provided for HERPES VIRUS INFECTION (nasal herpes simplex virus infection). Patient was referred to Hepatology outpatient clinic with a 5-week history of dark urine, weight loss and fatigue, associated with elevated liver enzymes. Symptoms had begun two to three days after receiving the first dose of the mRNA-1273 SARS-CoV-2 vaccine. Laboratory test also included anti-smooth muscle antibody (titer 1:1280, against F-Actin, no specific immunofluorescence pattern observed), liver kidney microsome type 1 antibody and anti-soluble liver antigen antibody were negative. After four weeks of treatment, the liver enzymes had completely normalized and the patient's symptoms had significantly improved A decision was made to not administer the second dose of the vaccine. The patient discontinued azathioprine on her own after two months of therapy due to drug intolerance and development of a nasal herpes simplex virus infection. Six weeks after stopping therapy there were however no biochemical signs of an AIH relapse. Authors concluded that vaccination could lead to the development of autoimmune diseases, but proving such a relationship was challenging and given the close temporal relationship between the vaccination and onset of symptoms, they hypothesized that vaccination against COVID-19 could have triggered the development of Autoimmune hepatitis in their patient, with Hashimoto thyroiditis and prior COVID-19 infection acting as predisposing factors.

Case ID	Narrative (Complete)
	Company Comment: Based on the current available information and temporal association between the use of the product, and the start date of the events, a causal relationship cannot be excluded. Concomitant autoimmune disease could be potentially confounder for the events. The prednisolone was stopped on 25.05.2021 after liver enzymes normalized. The patient had a relapse of the autoimmune hepatitis 3 months after the stop of therapy (in 08.2021), treated with prednisolone and mycophenolat mofetil. Most recent FOLLOW-UP information incorporated above includes: On 10-Aug-2021: Follow up received by safety on 12-Aug-2021 included an email with FTA received from SARA team and does not contain any new information. On 13-Sep-2021: Significant Follow up. Follow up received by safety 14-Sep-2021 included an Email with ADR form. Author details, patient details, history and onset date were updated.

Case ID	Narrative (Complete)
[redacted]	This regulatory authority case was reported by a physician and describes the occurrence of HEPATIC NECROSIS (Hepatic necrosis) and AUTOIMMUNE HEPATITIS (Autoimmune hepatitis) in a 43-year-old female patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination. Co-suspect products included non-company products IBUPROFEN for Frontal headache, ACETYLSALICYLIC ACID for Frontal headache, DICLOFENAC SODIUM for Frontal headache, PARACETAMOL for Frontal headache and DICLOFENAC POTASSIUM for Frontal headache. The patient's past medical history included Frontal headache on 05-Jun-2021 and Parietal cell antibody positive in January 2021. Concomitant products included DESOGESTREL, ETHINYLESTRADIOL [redacted][DESOGESTREL;ETHINYLESTRADIOL]) for an unknown indication. On 22-May-2021, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form. On 06-Jun-2021, the patient started IBUPROFEN (Oral) 400 milligram. On 11-Jun-2021, the patient started PARACETAMOL (Oral) 1 gram. On 14-Jun-2021, the patient started DICLOFENAC SODIUM (Intramuscular) 75 milligram and DICLOFENAC POTASSIUM (Oral) 1 dosage form. On 17-Jun-2021, the patient started ACETYLSALICYLIC ACID (Oral) 500 milligram. On 19-Jun-2021, received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) dosage was changed to 1 dosage form. On 15-Jun-2021, the patient experienced HEPATIC NECROSIS (Hepatic necrosis) (seriousness criterion hospitalization) and AUTOIMMUNE HEPATITIS (Autoimmune hepatitis) (seriousness criterion hospitalization). At the time of the report, HEPATIC NECROSIS (Hepatic necrosis) and AUTOIMMUNE HEPATITIS (Autoimmune hepatitis) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 15-Jun-2021, Alanine aminotransferase (8-41): 1059 (abnormal) 1059 units/l. On 15-Jun-2021, Aspartate aminotransferase (11-34): 321 (abnormal) 321 units/l. On 15-Jun-2021, Blood alkaline phosphatase (35-105): 106 (abnormal) 106 U/l. On 15-Jun-2021, Blood bilirubin (Unknown-<15): 12.2 (abnormal) 12.2 mcmol/l. On 15-Jun-2021, International normalised ratio: increased (High) increased. On 24-Jun-2021, Alanine aminotransferase (8-41): 1950 (abnormal) 1950 units/l. On 24-Jun-2021, Aspartate aminotransferase (11-34): 1051 (abnormal) 1051 units/l. On 24-Jun-2021, Blood alkaline phosphatase (35-105): 101 (normal) 101 U/l. On 24-Jun-2021, Blood bilirubin (Unknown-<15): 23.5 (abnormal) 23.5 mcmol/l. On 06-Jul-2021, Aspartate aminotransferase (11-34): 30 (abnormal) 30 units/l. On 06-Jul-2021, Blood bilirubin (Unknown-<15): 11.8 (normal) 11.8 mcmol/l. On 12-Jul-2021, Alanine aminotransferase (8-41): 63 (abnormal) 63 units/l. On 12-Jul-2021, Blood alkaline phosphatase (35-105): 74 (normal) 74 U/l. On an unknown date, International normalised ratio: normal (normal) normal (after discharge date). For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered HEPATIC NECROSIS (Hepatic necrosis) and AUTOIMMUNE HEPATITIS (Autoimmune hepatitis) to be possibly related. Therapy with prednisone 60mg/day was started on 25-Jun-2021 Patient discharged on 09-Jul-2021. liver biopsy, 25-Jun-2021: Histopathological findings: Fulminant hepatitis with confluent necrosis (partly bridging necrosis) of approx. 50 percent of the parenchyma. Numerous apoptotic hepatocytes. Severe hepatocellular, necrotizing hepatopathy of unclear [etiology] injury. Suspected drugs : Ibuprofen was last administered on 10-Jun-2021, diclofenac on 15-Jun-2021, paracetamol on 13-Jun-2021; Acetylsalicylic acid was discontinued on admission on 24-Jun-2021. Company comment: This is a regulatory case concerning a 43-year-old, female patient with a history of treatment with ibuprofen, Diclofenac sodium, Diclofenac potassium and paracetamol for frontal headache, concomitant use of desogestrel, ethinylestradiol and Parietal cell antibody positive, who experienced, the serious (due to hospitalization) unexpected AESI of hepatic necrosis and autoimmune hepatitis. The events occurred 24 days after the first dose of the mRNA-1273 vaccine. A liver biopsy was performed showing Fulminant hepatitis with confluent necrosis of approximately 50% of the parenchyma. Multiple laboratory tests were performed with negative results regarding infection, autoimmunological underlying disease, metabolic disorder and ischemia. The patient received treatment with prednisone and the outcome of the events was reported as recovering. Patient was discharged home. The concomitant use of ibuprofen, Diclofenac sodium, Diclofenac potassium and paracetamol (which are co-suspects for the events), use of desogestrel, ethinylestradiol and Parietal cell antibody positive remain as confounders. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 10-Aug-2021: Upon internal review on 06-JAN-2022, following corrections were performed. Company comment was amended.

Case ID	Narrative (Complete)
[redacted]	This literature-non-study case was reported in a literature article and describes the occurrence of AUTOIMMUNE HEPATITIS (Autoimmune Hepatitis) and JAUNDICE (jaundice) in a 71-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. LITERATURE REFERENCE: McShane C, Kiat C, Rigby J, Crosbie O. The mRNA COVID-19 vaccine - a rare trigger of autoimmune hepatitis?. J Hepatol. 2021:1-5 The patient's past medical history included Osteoarthritis knee, Cholecystectomy (20 years previously) and Hip replacement. Concomitant products included PARACETAMOL for an unknown indication. On 16-Apr-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On an unknown date, the patient experienced AUTOIMMUNE HEPATITIS (Autoimmune Hepatitis) (seriousness criteria hospitalization prolonged and medically significant). an unknown date, the patient experienced JAUNDICE (jaundice) (seriousness criterion hospitalization prolonged). The patient was hospitalized from sometime in 2021 to sometime in 2021 due to AUTOIMMUNE HEPATITIS and JAUNDICE. The patient was treated with PREDNISOLONE for Adverse event, at a dose of 1 dosage form. At the time of the report, AUTOIMMUNE HEPATITIS (Autoimmune Hepatitis) and JAUNDICE (jaundice) was resolving. Possible DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In April 2021, Alanine aminotransferase: high (High) 1067U/L, 1143U/L. In April 2021, Aspartate aminotransferase: high (High) 1469U/L. In April 2021, Biopsy liver: abnormal (abnormal) Up to 20 portal tracts were present, each expanded with a marked polymorphous inflammatory cell infiltrate of plasma cells, lymphocytes, eosinophils, neutrophils and PASD positive ceroid laden macrophages; interface hepatitis was present and continuous in most tracts, with portal-portal and portal-central bridging necrosis. In April 2021, Blood alkaline phosphatase: high (High) 217U/L, 237U/L. In April 2021, Blood bilirubin: high (High) 270umol/L, 332umol/L. In April 2021, Blood immunoglobulin G: high (High) markedly raised at 21.77g/L. In April 2021, Computerised tomogram: abnormal (abnormal) showed distal common bile duct dilation of 1.4cm consistent with prior cholecystectomy. In April 2021, Hepatitis A antibody: positive (Positive) Hepatitis A IgG was positive with a negative IgM. In April 2021, International normalised ratio: high (High) 1.4. In April 2021, Magnetic resonance cholangiopancreatography: abnormal (abnormal) showed distal common bile duct dilation of 1.4cm consistent with prior cholecystectomy. In April 2021, Physical examination: abnormal (abnormal) jaundiced. In April 2021, Smooth muscle antibody: positive (Positive) strongly positive with a titre of 2560 and an anti-actin pattern. In April 2021, Ultrasound liver: abnormal (abnormal) showed distal common bile duct dilation of 1.4cm consistent with prior cholecystectomy. In April 2021, Viral test: negative (Negative) negative for hepatitis B, C, and E, Epstein-Barr virus, cytomegalovirus and HIV. The action taken with mRNA-1273 (Spikevax) (Intramuscular) was unknown. For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered AUTOIMMUNE HEPATITIS (Autoimmune Hepatitis) and JAUNDICE (jaundice) to be possibly related. Patient had no confounding risk factors for developing autoimmune liver disease such as other autoimmune conditions or recent pregnancy. Patient was on no regular medications or supplements. Treatment medication included steroids Company Comment: Although a temporal association exist and the fact that vaccines have been known to be associated with reactivation of autoimmune disorder, the reported event is strongly confounded by the patient's underlying autoimmune conditions medical history. Hence, causal relationship with Spikevax cannot be confirmed. Most recent FOLLOW-UP information incorporated above includes: On 10-Aug-2021: Follow up received by safety on 12-Aug-2021 included an Email with FTA received from SARA team and does not contain any new information.

Case ID	Narrative (Complete)
[redacted]	This case was received via [redacted] (Reference number: [redacted] on 10-Aug-2021 and was forwarded to Moderna on 10-Aug-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of AUTOIMMUNE HEPATITIS (Autoimmune hepatitis) in a 69-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 029A21A) for COVID-19 vaccination. No medical history was provided by the reporter. Concomitant products included BUPROPION HYDROCHLORIDE (WELLBUTRIN) for an unknown indication. On 04-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 01-Jul-2021, the patient experienced AUTOIMMUNE HEPATITIS (Autoimmune hepatitis) (seriousness criterion medically significant). At the time of the report, AUTOIMMUNE HEPATITIS (Autoimmune hepatitis) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 01-Jul-2021, Alanine aminotransferase: increased (High) Elevated ATL. On 01-Jul-2021, Aspartate aminotransferase: increased (High) Elevated AST. On 01-Jul-2021, Blood alkaline phosphatase: increased (High) Elevated alkaline phosphatase. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown) was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. No treatment medication information was mentioned by reporter. It was reported that the patient developed likely autoimmune hepatitis about 2 months after her second shot. Patient wanted this reported to the CDC in case it is a trend. Company comment: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.

Case ID	Narrative (Complete)
[redacted]	This case was initially received via European Medicines Agency (Reference number: [redacted] on 12-Aug-2021. The most recent information was received on 25-Aug-2021 and was forwarded to Moderna on 25-Aug-2021. This regulatory authority case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of MYOCARDIAL INFARCTION (Multiple heart attacks), VENTRICULAR FIBRILLATION (Ventricular fibrillation), CARDIAC ARREST (VF cardiac arrest/ recurrent VF cardiac arrest), ANURIA (Anuria), LIVER INJURY (Significant hepatic injury), CARDIOGENIC SHOCK (Shock physiology/ cardiogenic shock), ATRIAL FIBRILLATION (persistant atrial fibrillation with rapid ventricular rate/ Paroxysmal atrial fibrillation), ACUTE KIDNEY INJURY (Acute kidney injury), THROMBOCYTOPENIA (Thrombocytopenia), PERIPHERAL SWELLING (leg swelling), CARDIOMYOPATHY (probable tachycardic medicated cardiomyopathy), LEFT VENTRICULAR DYSFUNCTION (severe systolic impairment of left ventricular function/ persistent severe systolic impairment of left ventricular function with restolation of sinus rhythm), JOINT SWELLING (Ankles started to swell), DYSPNOEA (shortness of breath become very pronounced), CARDIAC FAILURE CONGESTIVE (decompensated congestive heart failure/ cardiac decompensation), TACHYCARDIA (probable tachycardic mediated cardiomyopathy), DYSPNOEA (Shortness of breath/ breathlessness), JOINT SWELLING (Ankles were more swollen) and ELECTROCARDIOGRAM QT PROLONGED (QT prolonged) in a 48-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 3001946 and 3001650) for COVID-19 immunisation. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included [redacted] positive. Concomitant products included EMTRICITABINE, RILPIVIRINE HYDROCHLORIDE, [redacted] for an unknown indication. On 29-Apr-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 24-May-2021, received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. On 29-Apr-2021, the patient experienced HYPERHIDROSIS (Sweats), LETHARGY (Lethargic), LETHARGY (LETHARGIC), NAUSEA (Nausea), FATIGUE (Extreme tiredness), VOMITING (Vomiting) and CHILLS (Chills). In May 2021, the patient experienced JOINT SWELLING (Ankles started to swell) (seriousness criterion hospitalization) and DYSPNOEA (Shortness of breath/ breathlessness) (seriousness criterion hospitalization). On 24-May-2021, the patient experienced PERIPHERAL SWELLING (leg swelling) (seriousness criterion hospitalization), DYSPNOEA (shortness of breath become very pronounced) (seriousness criteria hospitalization and medically significant) and JOINT SWELLING (Ankles were more swollen) (seriousness criterion hospitalization). On 30-May-2021, the patient experienced CARDIOGENIC SHOCK (Shock physiology/ cardiogenic shock) (seriousness criteria hospitalization and medically significant), ATRIAL FIBRILLATION (persistant atrial fibrillation with rapid ventricular rate/ Paroxysmal atrial fibrillation) (seriousness criteria hospitalization and medically significant), CARDIOMYOPATHY (probable tachycardic medicated cardiomyopathy) (seriousness criteria hospitalization and medically significant), LEFT VENTRICULAR DYSFUNCTION (severe systolic impairment of left ventricular function/ persistent severe systolic impairment of left ventricular function with restolation of sinus rhythm) (seriousness criteria hospitalization and medically significant), CARDIAC FAILURE CONGESTIVE (decompensated congestive heart failure/ cardiac decompensation) (seriousness criteria hospitalization and medically significant), TACHYCARDIA (probable tachycardic mediated cardiomyopathy) (seriousness criteria hospitalization and medically significant) and ELECTROCARDIOGRAM QT PROLONGED (QT prolonged) (seriousness criteria hospitalization and medically significant). On 31-May-2021, the patient experienced MYOCARDIAL INFARCTION (Multiple heart attacks) (seriousness criteria hospitalization, medically significant and life threatening) and VENTRICULAR FIBRILLATION (Ventricular fibrillation) (seriousness criteria hospitalization, medically significant and life threatening). 31-May-2021, the patient experienced CARDIAC ARREST (VF cardiac arrest/ recurrent VF cardiac arrest) (seriousness criteria hospitalization, medically significant and life threatening). In June 2021, the patient experienced ANURIA (Anuria) (seriousness criteria hospitalization and medically significant), LIVER INJURY (Significant hepatic injury) (seriousness criteria hospitalization and medically significant), ACUTE KIDNEY INJURY (Acute kidney injury) (seriousness criteria hospitalization and medically significant) and THROMBOCYTOPENIA (Thrombocytopenia) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDIAL INFARCTION (Multiple heart attacks), VENTRICULAR FIBRILLATION (Ventricular fibrillation), CARDIAC ARREST (VF cardiac arrest/ recurrent VF cardiac arrest), CARDIOGENIC SHOCK (Shock physiology/ cardiogenic shock), ATRIAL FIBRILLATION (persistant atrial fibrillation with rapid ventricular rate/ Paroxysmal atrial fibrillation), PERIPHERAL SWELLING (leg swelling), CARDIOMYOPATHY (probable tachycardic medicated cardiomyopathy), LEFT VENTRICULAR DYSFUNCTION (severe systolic impairment of left ventricular function/ persistent severe systolic impairment of left ventricular function with restolation of sinus rhythm), JOINT SWELLING (Ankles started to swell), DYSPNOEA (shortness of breath become very pronounced), CARDIAC FAILURE CONGESTIVE (decompensated congestive heart failure/ cardiac decompensation), TACHYCARDIA (probable tachycardic mediated cardiomyopathy), DYSPNOEA (Shortness of breath/ breathlessness), JOINT SWELLING (Ankles were more swollen) and ELECTROCARDIOGRAM QT PROLONGED (QT prolonged) was resolving, ANURIA (Anuria), LIVER INJURY (Significant hepatic injury), ACUTE KIDNEY INJURY (Acute kidney injury) and THROMBOCYTOPENIA (Thrombocytopenia) had resolved and HYPERHIDROSIS (Sweats), LETHARGY (Lethargic), LETHARGY (LETHARGIC), NAUSEA (Nausea), FATIGUE (Extreme tiredness), VOMITING (Vomiting) and CHILLS (Chills) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 30-May-2021, Electrocardiogram QT prolonged: abnormal (abnormal) Repeat echo confirmed persistent severe systolic impairment of left ventricular function. On 30-May-2021, Heart rate: high (High) Very high heart rate of 190. No treatment information was reported. Additional laboratory data included, in Jul-2021 patient underwent blood test, results not provided. On an unspecified date, the patient underwent echocardiogram and repeat echo confirmed persistent severe systolic impairment of left ventricular function. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Most recent FOLLOW-UP information incorporated above includes: On 25-Aug-2021: Updated patient's age, laboratory data and added additional events.

Case ID	Narrative (Complete)
[redacted]	This case was received via [redacted] (Reference number: [redacted] on 17-Aug-2021 and was forwarded to Moderna on 17-Aug-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of AUTOIMMUNE HEPATITIS (Autoimmune hepatitis) in a 51-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The patient's past medical history included GERD. Concurrent medical conditions included Blood pressure high and Hypothyroidism. Concomitant products included ATENOLOL, OLMESARTAN MEDOXOMIL (BENICAR), LEVOTHYROXINE SODIUM (SYNTHROID), LIOTHYRONINE SODIUM (T3), ROSUVASTATIN and PANTOPRAZOLE for an unknown indication. On 13-Apr-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 28-May-2021, the patient experienced AUTOIMMUNE HEPATITIS (Autoimmune hepatitis) (seriousness criterion medically significant). At the time of the report, AUTOIMMUNE HEPATITIS (Autoimmune hepatitis) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Blood cholesterol: elevated (High) Elevated. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Treatment information was not provided. Company Comment: Based on the current available information, although the use of the product and the start date of the events were not temporarily close, a causal relationship cannot be excluded. Medical history of hypothyroidism and polypharmacy, could be potentially confounding factors.
[redacted]	This case was received via [redacted] (Reference number: [redacted] on 17-Aug-2021 and was forwarded to Moderna on 17-Aug-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of CERVICAL VERTEBRAL FRACTURE (Cervical vertebral fracture), HEPATITIS ACUTE (Hepatitis acute) and OBSTRUCTIVE PANCREATITIS (Obstructive pancreatitis) in a 66-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 05-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 14-Apr-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 20-Mar-2021, the patient experienced CERVICAL VERTEBRAL FRACTURE (Cervical vertebral fracture) (seriousness criteria hospitalization and medically significant), HEPATITIS ACUTE (Hepatitis acute) (seriousness criteria hospitalization and medically significant) and OBSTRUCTIVE PANCREATITIS (Obstructive pancreatitis) (seriousness criteria hospitalization and medically significant). On 14-Apr-2021, the patient experienced INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (Inappropriate schedule of vaccine administered). The patient was hospitalized on 06-Apr-2021 due to CERVICAL VERTEBRAL FRACTURE, then on 23-May-2021 due to HEPATITIS ACUTE and OBSTRUCTIVE PANCREATITIS. On 14-Apr-2021, INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (Inappropriate schedule of vaccine administered) had resolved. At the time of the report, CERVICAL VERTEBRAL FRACTURE (Cervical vertebral fracture), HEPATITIS ACUTE (Hepatitis acute) and OBSTRUCTIVE PANCREATITIS (Obstructive pancreatitis) outcome was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medications were reported. The patient went to the emergency department on 20 Mar 2021,21 Mar 2021,22 Mar 2021,25 Mar 2021,26 Mar 2021,27 Mar 2021,01 Apr 2021 and on 04 Apr 2021.On 06 Apr 2021,the patient was hospitalized for cervical fracture. On 23 May 2021,the patient was presented to the emergency department and was subsequently hospitalized for acute gallstone pancreatitis and acute hepatitis. Company Comment : This is a case of inappropriate schedule of product administration with associated AEs. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Event terms, onset dates, outcomes and seriousness captured per SD from Regulatory Authority reporting.

Case ID	Narrative (Complete)
[redacted]	This regulatory authority case was reported by a pharmacist and describes the occurrence of HEPATITIS ACUTE (Acute hepatitis), HEPATIC CIRRHOSIS (Liver cirrhosis), HEPATIC NEOPLASM (Hepatic tumors), GALLBLADDER ENLARGEMENT (GB wall thickening), PNEUMOTHORAX (right pneumothorax), METASTASES TO LUNG (Multiple lung tumors), SPLENOMEGALY (Splenomegaly), NAUSEA (Nausea), VOMITING (Vomiting), ABDOMINAL PAIN UPPER (epigastric pain) and PYREXIA (fever) in a 66-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. Concurrent medical conditions included Splenomegaly, HBV viral load increased (HBV carrier under Baraclude 0.5 mg), Hypertension and Hemangioma (followed for 20+ year). Concomitant products included ENTECAVIR (BARACLUDE) for HBV coinfection. On 12-Jul-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) .5 milliliter. On 21-Jul-2021, the patient experienced HEPATIC CIRRHOSIS (Liver cirrhosis) (seriousness criteria hospitalization prolonged and medically significant), HEPATIC NEOPLASM (Hepatic tumors) (seriousness criteria hospitalization prolonged and medically significant), GALLBLADDER ENLARGEMENT (GB wall thickening) (seriousness criteria hospitalization prolonged and medically significant) and SPLENOMEGALY (Splenomegaly) (seriousness criterion hospitalization). On 27-Jul-2021, the patient experienced METASTASES TO LUNG (Multiple lung tumors) (seriousness criteria hospitalization and medically significant). On 29-Jul-2021, the patient experienced PNEUMOTHORAX (right pneumothorax) (seriousness criteria hospitalization and medically significant). On 30-Jul-2021, the patient experienced HEPATITIS ACUTE (Acute hepatitis) (seriousness criteria hospitalization prolonged and medically significant). On an unknown date, the patient experienced NAUSEA (Nausea) (seriousness criterion hospitalization), VOMITING (Vomiting) (seriousness criterion hospitalization), ABDOMINAL PAIN UPPER (epigastric pain) (seriousness criterion hospitalization) and PYREXIA (fever) (seriousness criterion hospitalization). The patient was hospitalized on 18-Jul-2021 due to NAUSEA and PYREXIA, then on 20-Jul-2021 due to GALLBLADDER ENLARGEMENT, HEPATIC CIRRHOSIS, HEPATIC NEOPLASM, HEPATITIS ACUTE, METASTASES TO LUNG, PNEUMOTHORAX and SPLENOMEGALY. The patient was treated with URSODEOXYCHOLIC ACID on 26-Jul-2021 for Adverse event, at a dose of 1 dosage form; CYSTEINE HYDROCHLORIDE, GLYCINE, GLYCYRRHIZIC ACID (STRONGER NEO-MINOPHAGEN C [CYSTEINE HYDROCHLORIDE;GLYCINE;GLYCYRRHIZIC ACID]) on 21-Jul-2021 for Adverse event, at a dose of 100 milliliter and TENOFOVIR on 21-Jul-2021 for Adverse event, at a dose of 300 milligram once a day. On 23-Jul-2021, ABDOMINAL PAIN UPPER (epigastric pain) had resolved. At the time of the report, HEPATITIS ACUTE (Acute hepatitis), HEPATIC CIRRHOSIS (Liver cirrhosis), HEPATIC NEOPLASM (Hepatic tumors), GALLBLADDER ENLARGEMENT (GB wall thickening), PNEUMOTHORAX (right pneumothorax), METASTASES TO LUNG (Multiple lung tumors), SPLENOMEGALY (Splenomegaly) and VOMITING (Vomiting) outcome was unknown, NAUSEA (Nausea) had resolved and PYREXIA (fever) was resolving. Not Provided DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 20-Jul-2021, Alanine aminotransferase increased: 3256 u/l (High) 3256 U/L. On 20-Jul-2021, Aspartate aminotransferase increased: 3201 (High) 3201 U/L. On 20-Jul-2021, Blood bilirubin: 9.9 (High) 9.9 mg/dl. On 21-Jul-2021, Ultrasound abdomen: abnormal (abnormal) Liver cirrhosis, Hepatic tumors, multiple, GB wall thickening, Splenomegaly, mild. On 22-Jul-2021, Alanine aminotransferase increased: 2078 u/l (High) 2078 U/L. On 22-Jul-2021, Alpha 1 foetoprotein increased: 160 (High) 160 ng/ml. On 22-Jul-2021, Aspartate aminotransferase increased: 1729 (High) 1729 U/L. On 22-Jul-2021, Blood bilirubin: 9.2 (High) 9.2 mg/dl. On 22-Jul-2021, Hepatitis B e antigen: abnormal (abnormal) 0.15 (Non-reactive) COI. On 22-Jul-2021, Hepatitis B surface antigen: abnormal (abnormal) HBs Ag 2535 (Reactive) COI. On 22-Jul-2021, Hepatitis C antibody positive: abnormal (abnormal) 0.054 (Non-reactive). On 24-Jul-2021, Alanine aminotransferase increased: 1167 u/l (High) 1167 U/L. On 24-Jul-2021, Aspartate aminotransferase increased: 538 (High) 538 U/L. On 24-Jul-2021, Blood bilirubin: 10.4 (High) 10.4 mg/dl. On 26-Jul-2021, Alanine aminotransferase increased: 669 u/l (High) 669 U/L. On 26-Jul-2021, Aspartate aminotransferase increased: 237 (High) 237 U/L. On 26-Jul-2021, Blood bilirubin: 11.9 (High) 11.9 mg/dl. On 27-Jul-2021, Computerised tomogram: abnormal (abnormal) CT Chest :Multiple lung tumours, larger at RML and RLL, in favor of metastasis. Left hepatic tumors. On 28-Jul-2021, Alanine aminotransferase increased: 342 u/l (High) 342 U/L. On 28-Jul-2021, Aspartate aminotransferase increased: 139 (High) 139 U/L. On 28-Jul-2021, Blood bilirubin: 16.7 mg/dl (High) 16.7 mg/dl. On 29-Jul-2021, Biopsy: unknown (Inconclusive) Unknown. On 02-Aug-2021, Alanine aminotransferase increased: 123 u/l (High) 123 U/L. On 02-Aug-2021, Aspartate aminotransferase increased: 138 u/l (High) 138 U/L. On 02-Aug-2021, Blood bilirubin: 19.6 mg/dl (High) 19.6 mg/dl. On 04-Aug-2021, Alanine aminotransferase increased: 144 (High) 144 U/L. On 04-Aug-2021, Aspartate aminotransferase increased: 274 u/l (High) 274 U/L. On 04-Aug-2021, Blood bilirubin: 21.1 mg/dl (High) 21.1 mg/dl. On 10-Aug-2021, Blood bilirubin: 17.2 mg/dl (High) 17.2 mg/dl. 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. Lab data includes on 20-Jul-2021 , r-GT 165 U/L. It was reported that on 30 Jul 2021 patient reported acute hepatitis with decompensation, resolving, suspect HBV reactivation, also stated that on 27-Jul-2021 CT Chest: Multiple lung tumors, larger at RML and RLL, in favor of metastasis and on 03-Aug-2021 informed the possibility of liver transplant. reference number [redacted]

Case ID	Narrative (Complete)
	Company Comment: Based on the current available information and temporal association between the use of the product and the start date of some events, a causal relationship cannot be excluded. However, based on the pathophysiology and biological implausibility of hepatic cirrosis, lung metastasis and hepatic neoplasm, and the reporter´s causality of pneumothorax these events are assessed as unlikely related to mRNA-1273. Patient´s history of Hepatitis B is a very strong confounder for the event hepatitis acute. Most recent FOLLOW-UP information incorporated above includes: On 19-Aug-2021: Translation document received on 31 Aug 2021. Additional information include new events(Liver cirrhosis, liver tumor, gall bladder wall thickening, lung neoplasm, splenomegaly, nausea, vomitting). Updated concomitant medications to treatment medications.

Case ID	Narrative (Complete)
[redacted]	This regulatory authority case was reported by a pharmacist and describes the occurrence of HEPATIC FAILURE (Hepatic failure) and TRANSAMINASES INCREASED (GOT: 406 and GPT: 184 (higher than normal)) in a 51-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 3003184) for COVID-19 vaccination. Concurrent medical conditions included Schizophrenia and Hypothyroidism. Concomitant products included LITHIUM and VALPROATE SODIUM for an unknown indication. On 13-Jul-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 22-Jul-2021, the patient experienced TRANSAMINASES INCREASED (GOT: 406 and GPT: 184 (higher than normal)) (seriousness criterion hospitalization). On an unknown date, the patient experienced HEPATIC FAILURE (Hepatic failure) (seriousness criterion hospitalization). At the time of the report, HEPATIC FAILURE (Hepatic failure) and TRANSAMINASES INCREASED (GOT: 406 and GPT: 184 (higher than normal)) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 16-Jul-2021, Blood creatine phosphokinase: 686 (abnormal) (CPK: 686, amyloid: 11, Albumin: 3.1) => we gave IV supplement for elevated CPK and poor intake in recent few days.. On 22-Jul-2021, Alanine aminotransferase: 184 (High) higher-than-normal. On 22-Jul-2021, Ammonia: 44 (High) higher-than-normal. On 22-Jul-2021, Aspartate aminotransferase increased: 406 (High) higher-than-normal. On 22-Jul-2021, Lymphocyte count: 16.4 (Low) lower-than-normal. On 22-Jul-2021, Neutrophil count: 77.3 (High) higher-than-normal. On 22-Jul-2021, Red cell distribution width increased: 16.2 (High) higher-than-normal. On 22-Jul-2021, Toxicity to various agents: inconclusive (Inconclusive) 0.37. On 22-Jul-2021, White blood cell count: 8800 (normal) 8800. 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 concomitant medication were provided. Reporter stated that IV supplement was given for elevated CPK and poor intake in recent few days. Additional lab data was provided as VPA : 27.5ug/ml. Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. However, more information is required for further assessment. The concomitant treatment with lithium and valproate sodium could be confounders for the case. Based on SD it is not clear if patient was diagnosed with Hepatic failure. Conservatively, the event was captured.
[redacted]	This case was received via European Medicines Agency (Reference number [redacted] on 30-Aug-2021 and was forwarded to Moderna on 30-Aug-2021. This regulatory authority case was reported by a physician and describes the occurrence of HEPATOCELLULAR INJURY (Hepatocellular damage) and PYREXIA (Fever) in a 55-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 3003187) for COVID-19 vaccination. No Medical History information was reported. On 22-Jun-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 28-Jun-2021, the patient experienced HEPATOCELLULAR INJURY (Hepatocellular damage) (seriousness criterion medically significant) and PYREXIA (Fever) (seriousness criterion medically significant). At the time of the report, HEPATOCELLULAR INJURY (Hepatocellular damage) was resolving and PYREXIA (Fever) had resolved. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Concomitant products were not provided. Treatment medications were not reported. Company comment: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Most recent FOLLOW-UP information incorporated above includes: On 30-Aug-2021: Translation received on 08Sep2021 contains no new information

Case ID	Narrative (Complete)
[redacted]	This case was received via [redacted] (Reference number: [redacted]) on 31-Aug-2021 and was forwarded to Moderna on 31-Aug-2021. This regulatory authority case was reported by an other health care professional (subsequently medically confirmed) and describes the occurrence of DEEP VEIN THROMBOSIS (Deep vein thrombosis) and AUTOIMMUNE HEPATITIS (Autoimmune hepatitis) in a 38-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. Concurrent medical conditions included Penicillin allergy. On 05-Feb-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 22-Mar-2021, the patient experienced DEEP VEIN THROMBOSIS (Deep vein thrombosis) (seriousness criteria medically significant and life threatening) and AUTOIMMUNE HEPATITIS (Autoimmune hepatitis) (seriousness criteria medically significant and life threatening). The patient was treated with APIXABAN (ELIQUIS) on 02-May-2021 for Adverse event, at a dose of 1 dosage form and PREDNISONE for Adverse event, at a dose of 40 mg. At the time of the report, DEEP VEIN THROMBOSIS (Deep vein thrombosis) and AUTOIMMUNE HEPATITIS (Autoimmune hepatitis) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 22-Mar-2021, Hepatic enzyme: high (High) High. On 02-May-2021, Ultrasound scan: abnormal (abnormal) shows second DVT left leg. On 10-May-2021, Alanine aminotransferase: 500+ (High) 500+. On 10-May-2021, Antinuclear antibody: positive (Positive) Positive. On 10-May-2021, Blood bilirubin: 5 (High) 5. On 12-Jul-2021, Blood bilirubin: 5 (High) 5. On 12-Jul-2021, Red blood cell sedimentation rate: 36 (High) 36. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Concomitant medication information was not provided.laboratory exams performed on 12 July 2021 Alanine Aminotransferase but the result was not provided and on 22-Jul-2021 the value was 1299. it was reported that patient diagnosed with Autoimmune hepatitis and possible lupus. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded

Case ID	Narrative (Complete)
[redacted]	This case was received via [redacted] (Reference number: [redacted] on 31-Aug-2021 and was forwarded to Moderna on 31-Aug-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of LIVER INJURY (Liver injury) in a 31-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 Fibromyalgia, Anxiety, Depression and GERD. Concurrent medical conditions included Penicillin allergy, Drug allergy, Drug allergy, Drug allergy and Iodine allergy. Concomitant products included VENLAFAXINE HYDROCHLORIDE (EFFEXOR) for an unknown indication. On 01-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 01-Apr-2021, the patient experienced LIVER INJURY (Liver injury) (seriousness criterion medically significant), ABDOMINAL PAIN UPPER (Abdominal pain upper), IRRITABILITY (Irritability), MENSTRUAL DISORDER (Menstrual disorder), MUSCULOSKELETAL CHEST PAIN (Musculoskeletal chest pain) and VOMITING (Vomiting). At the time of the report, LIVER INJURY (Liver injury), ABDOMINAL PAIN UPPER (Abdominal pain upper), IRRITABILITY (Irritability), MENSTRUAL DISORDER (Menstrual disorder), MUSCULOSKELETAL CHEST PAIN (Musculoskeletal chest pain) and VOMITING (Vomiting) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Blood test: abnormal (abnormal) -shows elevated levels that can be a sign of blood clots but no blood clots Pain, nausea, anxiety medications and fluids.. On an unknown date, Ultrasound abdomen: abnormal (abnormal) abnormal. On an unknown date, Ultrasound scan: abnormal (abnormal) showed liver damage. 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. The patient had severe arm pain, swelling and redness with tetanus (prior vaccination). Treatment information was not provided by the reporter. Pain, nausea, anxiety medications and fluids Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Event liver injury was automatically upgraded as a Serious event as per IME list and kept as serious as per medical judgement, despite it was reported as non-serious.

Case ID	Narrative (Complete)
[redacted]	This case was received via [redacted] (Reference number: [redacted]) on 31-Aug-2021 and was forwarded to Moderna on 31-Aug-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of AUTOIMMUNE HEPATITIS (Autoimmune hepatitis), HEPATOCELLULAR INJURY (Hepatocellular injury), PERIPORTAL OEDEMA (Periportal oedema), ABDOMINAL PAIN UPPER (Abdominal pain upper), CHROMATURIA (Chromaturia), FATIGUE (Fatigue), HAEMANGIOMA OF LIVER (Haemangioma of liver) and JAUNDICE (Jaundice) in a 43-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 041C21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Wrist pain. Concurrent medical conditions included Fruit allergy (Blueberry allergy), Seasonal allergy, Depression and Autoimmune hepatitis (Autoimmune hepatitis after Vaccine). Concomitant products included BUPROPION HYDROCHLORIDE (WELLBUTRIN), OXYMETAZOLINE HYDROCHLORIDE (CLARITIN ALLERGIC) and IBUPROFEN for an unknown indication. On 19-May-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Subcutaneous) 1 dosage form. On 19-May-2021, the patient experienced INCORRECT ROUTE OF PRODUCT ADMINISTRATION (administration subcutaneously). On 22-May-2021, the patient experienced AUTOIMMUNE HEPATITIS (Autoimmune hepatitis) (seriousness criteria hospitalization, medically significant and life threatening), HEPATOCELLULAR INJURY (Hepatocellular injury) (seriousness criteria hospitalization, medically significant and life threatening), PERIPORTAL OEDEMA (Periportal oedema) (seriousness criteria hospitalization, medically significant and life threatening), ABDOMINAL PAIN UPPER (Abdominal pain upper) (seriousness criteria hospitalization and life threatening), CHROMATURIA (Chromaturia) (seriousness criteria hospitalization and life threatening), FATIGUE (Fatigue) (seriousness criteria hospitalization and life threatening), HAEMANGIOMA OF LIVER (Haemangioma of liver) (seriousness criteria hospitalization and life threatening) and JAUNDICE (Jaundice) (seriousness criteria hospitalization and life threatening). On 19-May-2021, INCORRECT ROUTE OF PRODUCT ADMINISTRATION (administration subcutaneously) had resolved. At the time of the report, AUTOIMMUNE HEPATITIS (Autoimmune hepatitis), HEPATOCELLULAR INJURY (Hepatocellular injury), PERIPORTAL OEDEMA (Periportal oedema), ABDOMINAL PAIN UPPER (Abdominal pain upper), CHROMATURIA (Chromaturia), FATIGUE (Fatigue), HAEMANGIOMA OF LIVER (Haemangioma of liver) and JAUNDICE (Jaundice) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 22-May-2021, Biopsy liver: abnormal (abnormal) abnormal. On 22-May-2021, Hepatic enzyme: increased (High) Increased. On 22-May-2021, Magnetic resonance imaging: abnormal (abnormal) Magnetic resonance imaging hepatobiliary abnormal. On 06-Jun-2021, Magnetic resonance imaging: hemangioma (abnormal) Liver Hemangioma- perportal edema. On 12-Jun-2021, Biopsy liver: hepatitis (abnormal) Acute pan lobular hepatitis- hepatocellular injury variant of autoimmune hepatitis. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Subcutaneous) was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Subcutaneous), the reporter did not provide any causality assessments. No treatment information was provided. On 09-Jun-2021, CAT test was performed and results are unknown. On 22-May-2021, Computerized tomogram was unknown. Company Comment: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.

Case ID	Narrative (Complete)
[redacted]	This regulatory authority prospective pregnancy case was reported by a pharmacist and describes the occurrence of ACUTE HEPATITIS B (Suspect fulminant hepatitis), LACTIC ACIDOSIS (Severe lactic acidosis), SEPTIC SHOCK (Suspect septic shock), ACUTE HEPATIC FAILURE (deteriorated acute liver failure with decompensation), HYPERAESTHESIA (Local hyperalgesia), JAUNDICE (Yellowish skin), OCULAR ICTERUS (Icteric sclera), CHROMATURIA (Tea-colored urine), VAGINAL HAEMORRHAGE (Vaginal bleeding), PREMATURE LABOUR (Preterm uterine contraction), HYPOTENSION (Hypotension), HYPOGLYCAEMIA (Hypoglycemia) and TACHYPNOEA (Tachypnea) in a 38-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 Chronic hepatitis B. Concurrent medical conditions included Autoimmune thyroiditis (under regular medical control since 12-Apr-2021). Concomitant products included PREDNISOLONE from 16-Jul-2021 to an unknown date for an unknown indication. On 15-Jul-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. Last menstrual period and estimated date of delivery were not provided. On 15-Jul-2021, the patient experienced MATERNAL EXPOSURE DURING PREGNANCY (Pregnant). In July 2021, the patient experienced SEPTIC SHOCK (Suspect septic shock) (seriousness criteria hospitalization, medically significant and life threatening), HYPERAESTHESIA (Local hyperalgesia) (seriousness criteria hospitalization and life threatening) and VACCINATION SITE PAIN (Persistent inject site pain). On 20-Jul-2021, the patient experienced JAUNDICE (Yellowish skin) (seriousness criteria hospitalization and life threatening), OCULAR ICTERUS (Icteric sclera) (seriousness criteria hospitalization and life threatening) and CHROMATURIA (Tea-colored urine) (seriousness criteria hospitalization and life threatening). On 23-Jul-2021, the patient experienced ACUTE HEPATITIS B (Suspect fulminant hepatitis) (seriousness criteria hospitalization, medically significant and life threatening). On 26-Jul-2021, the patient experienced VAGINAL HAEMORRHAGE (Vaginal bleeding) (seriousness criteria hospitalization and life threatening) and PREMATURE LABOUR (Preterm uterine contraction) (seriousness criteria hospitalization and life threatening). On 27-Jul-2021, the patient experienced ACUTE HEPATIC FAILURE (deteriorated acute liver failure with decompensation) (seriousness criteria hospitalization prolonged, medically significant and life threatening), HYPOTENSION (Hypotension) (seriousness criteria hospitalization prolonged and life threatening), HYPOGLYCAEMIA (Hypoglycemia) (seriousness criteria hospitalization prolonged and life threatening) and TACHYPNOEA (Tachypnea) (seriousness criteria hospitalization prolonged and life threatening). On an unknown date, the patient experienced LACTIC ACIDOSIS (Severe lactic acidosis) (seriousness criteria hospitalization, medically significant and life threatening). The patient was hospitalized on 23-Jul-2021 due to ACUTE HEPATITIS B and SEPTIC SHOCK. The patient was treated with TENOFOVIR for Hepatitis fulminant, at an unspecified dose and frequency; ATOSIBAN for Tocolysis, at an unspecified dose and frequency and Surgery (Therapeutic plasma exchange for liver failure) for Acute hepatitis B. On 15-Jul-2021, MATERNAL EXPOSURE DURING PREGNANCY (Pregnant) had resolved. At the time of the report, ACUTE HEPATITIS B (Suspect fulminant hepatitis), LACTIC ACIDOSIS (Severe lactic acidosis), SEPTIC SHOCK (Suspect septic shock), ACUTE HEPATIC FAILURE (deteriorated acute liver failure with decompensation), HYPERAESTHESIA (Local hyperalgesia), JAUNDICE (Yellowish skin), OCULAR ICTERUS (Icteric sclera), CHROMATURIA (Tea-colored urine), VAGINAL HAEMORRHAGE (Vaginal bleeding), PREMATURE LABOUR (Preterm uterine contraction), HYPOTENSION (Hypotension), HYPOGLYCAEMIA (Hypoglycemia), TACHYPNOEA (Tachypnea) and VACCINATION SITE PAIN (Persistent inject site pain) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Amniocentesis: normal (normal) normal. On an unknown date, Liver function test: abnormal (abnormal) liver function with hepatocellular pattern. 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. The patient was pregnant with GA 19+5 weeks by IVF and also received amniocentesis/aCGH, which showed normal result. The patient post receiving their first dose of vaccine experienced sensation of persistent inject site pain and local hyperalgesia in the following days. Prednisolone was tapered to 5 mg daily on 16-Jul-2021. The patient reported that the pregnancy course was uneventful until 1 week before this admission, when yellowish skin and icteric sclera, tea-colored urine were noted since 20-Jul-2021. The patient had no fever, nausea or vomiting, abdominal pain, and chest discomfort. The patient came to Gastrointestinal clinic, where the lab data showed abnormal liver function with hepatocellular pattern. On 23-Jul-2021, the patient was then admitted to LMD for suspect fulminant hepatitis. The patient was prescribed Tenofovir and viral hepatitis serology, autoimmune hepatitis antibodies were checked. The Vaginal bleeding and preterm uterine contraction of the patient was noted since 26-Jul-2021. On 27-Jul-2021, along with the deteriorated acute liver failure with decompensation, the patient was transferred to NTUH for further management and the obstetrician was consulted and cash atosiban was administered for tocolysis. Meanwhile, the hypotension, hypoglycemia and the tachypnea of the patient was noted. The patient was admitted to ICU for further management due to acute liver failure with suspect septic shock and after admission, the CVVHDF was indicated for severe lactic acidosis. On respective dates 28-Jul-2021, 29-Jul-2021 and 31-Jul-2021, therapeutic plasma exchange for liver failure was started and the patient was given deep sedation. Most recent FOLLOW-UP information incorporated above includes: On 19-Aug-2021: Translated document with TCERT received on 06-SEP-2021 and contains no new information.

Case ID	Narrative (Complete)
[redacted]	This spontaneous case was reported by a consumer and describes the occurrence of LIVER INJURY (Liver issue) in a 46-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 031L20A and 042L20A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Morbid obesity, Blood pressure high, Asthma, Immunocompromised (Immunocompromised secondary) and Sciatica (Patient received cortisone shots for her back pain.). Concomitant products included LOSARTAN and METOPROLOL SUCCINATE [redacted] for an unknown indication, HYDROCHLOROTHIAZIDE. On 20-Jan-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 17-Feb-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 17-Feb-2021, the patient experienced FEELING OF BODY TEMPERATURE CHANGE (Feelings of hot then cold), PAIN IN EXTREMITY (Her arm hurt, but not as bad as with the first shot), PAIN (A little achy) and CHILLS (Chills). In March 2021, the patient experienced MENSTRUAL DISORDER (Periods have gotten really bad), HEAVY MENSTRUAL BLEEDING (Periods have gotten heavier/feel the blood flowing out/Periods have gotten longer/Clots (in the flow)) and ASTHENIA (Gets weak (from blood loss)). In August 2021, the patient experienced LIVER INJURY (Liver issue) (seriousness criterion medically significant). On 18-Feb-2021, PAIN (A little achy) and CHILLS (Chills) had resolved. At the time of the report, MENSTRUAL DISORDER (Periods have gotten really bad), FEELING OF BODY TEMPERATURE CHANGE (Feelings of hot then cold), HEAVY MENSTRUAL BLEEDING (Periods have gotten heavier/feel the blood flowing out/Periods have gotten longer/Clots (in the flow)), ASTHENIA (Gets weak (from blood loss)), LIVER INJURY (Liver issue) and PAIN IN EXTREMITY (Her arm hurt, but not as bad as with the first shot) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In August 2021, Liver function test: abnormal (abnormal) Liver issue/Patient had a liver panel drawn and one of the liver enzymes was elevated.. Patient took water pill (sounds like hydrochlorothiazide) and allergy pills as a concomitant product. She reiterated several times her periods had been completely normal, occurring on a 28 day cycle, until she received the vaccine. She had one child and had no fertility issues. This case was linked to [redacted] (Patient Link).
[redacted]	This case was received via United States FDA VAERS (Reference number: [redacted] on 07-Sep-2021 and was forwarded to Moderna on 07-Sep-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of ACUTE HEPATIC FAILURE (Acute hepatic failure), CEREBRAL VENOUS THROMBOSIS (Cerebral venous thrombosis), MESENTERIC VENOUS OCCLUSION (Mesenteric venous occlusion) and SUPERIOR MESENTERIC ARTERY SYNDROME (Superior mesenteric artery syndrome) in a 64-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The patient's past medical history included Breast cancer and Mastectomy NOS (Breast Ca s/p resection). On 08-Mar-2021, the patient received dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 10-Aug-2021, the patient experienced ACUTE HEPATIC FAILURE (Acute hepatic failure) (seriousness criteria death, hospitalization and medically significant), CEREBRAL VENOUS THROMBOSIS (Cerebral venous thrombosis) (seriousness criteria death, hospitalization and medically significant), MESENTERIC VENOUS OCCLUSION (Mesenteric venous occlusion) (seriousness criteria death and hospitalization) and SUPERIOR MESENTERIC ARTERY SYNDROME (Superior mesenteric artery syndrome) (seriousness criteria death, hospitalization and medically significant). The patient was treated with TPA for Superior mesenteric artery syndrome, at an unspecified dose and frequency. The patient died on 23-Aug-2021. The reported cause of death was Acute liver failure, Cerebral venous thrombosis and Superior mesenteric artery syndrome. It is unknown if an autopsy was performed. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Patient other medication was reported as HRT (hormonal replacement therapy) since 2016. It was reported that 4 months after completing immunization series patient was noted with SMA, SMV, and cerebral venous thrombus. Report from outside hospital show that the SMA had collateralization in August suggestive of a chronic occlusion s/p thrombectomy with TPA infusion the patient developed ALF and died on 23-Aug-2021. Patient treatment information was also reported as Anticoagulant therapy from 10-Aug-2021. Action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown) was Not applicable. Very limited information regarding this event/s has been provided at this time. Further information has been requested. Further information is not expected.

Case ID	Narrative (Complete)
[redacted]	This spontaneous case was reported by a consumer and describes the occurrence of MULTIPLE ORGAN DYSFUNCTION SYNDROME (Most of his organs shut down), ACUTE MYOCARDIAL INFARCTION (Non-ST-Elevation Myocardial Infarction), CORONARY ARTERY THROMBOSIS (Coronary Artery thrombosis), SEPSIS (Sepsis secondary to intra-abdominal infection), ACUTE KIDNEY INJURY (Acute kidney injury), HEPATOCELLULAR INJURY (Acute hepatocellular injury), INFLUENZA LIKE ILLNESS (flu-like symptoms), DEHYDRATION (dehydration), DIARRHOEA (Diarrhea), URTICARIA (Utricarial rash), EOSINOPHILIA (Eosinophilia) and RASH (Transient rash in lower extremities) in a 41-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 005C21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Pericarditis, Chest pain, Tobacco user, COVID-19 on 04-Aug-2021, Stent placement (Cardiac stents to mild proximal left anterior descending artery on the 1st septal perforator with 2.5*38 mm drug-eluting onyx stent proximal left anterior descending artery using 3*12 mm drug-eluting synergy stent) and Cardiac catheterization. Concurrent medical conditions included Coronary artery disease, Hypertension, ST segment elevation myocardial infarction (ST elevation myocardial infarction involving left anterior descending coronary artery), Hyperlipidemia, Chronic back pain, Allergy to antibiotic (Rash, urticarial) since 19-May-2021, Non-smoker, Drug allergy (Ceftriaxone), Left ventricular thrombosis since 08-Jun-2021, Pyrexia, Leukocytosis, Hypotension, Blood lactic acid increased, Hyponatraemia, Liver function test increased, Chronic heart failure and GERD. Concomitant products included GLYCERYL TRINITRATE (NITROSTAT) for Chest pain, LIDOCAINE (LIDODERM) for Chronic back pain, METOPROLOL SUCCINATE ([redacted] XL) for Heart failure, OMEPRAZOLE (PRILOSEC [OMEPRAZOLE]), PRASUGREL HYDROCHLORIDE (EFFIENT) and SPIRONOLACTONE for an unknown indication. On 15-Jun-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 15-Jun-2021, the patient experienced VACCINATION SITE PAIN (his arm hurt for several days). In June 2021, the patient experienced ACUTE KIDNEY INJURY (Acute kidney injury) (seriousness criteria hospitalization and medically significant), DIARRHOEA (Diarrhea) (seriousness criterion hospitalization), URTICARIA (Utricarial rash) (seriousness criterion hospitalization), EOSINOPHILIA (Eosinophilia) (seriousness criterion hospitalization) and RASH (Transient rash in lower extremities) (seriousness criterion hospitalization). On 18-Jun-2021, the patient experienced INFLUENZA LIKE ILLNESS (flu-like symptoms) (seriousness criterion hospitalization). On 21-Jun-2021, the patient experienced MULTIPLE ORGAN DYSFUNCTION SYNDROME (Most of his organs shut down) (seriousness criteria hospitalization and medically significant), ACUTE MYOCARDIAL INFARCTION (Non-ST-Elevation Myocardial Infarction) (seriousness criterion medically significant), CORONARY ARTERY THROMBOSIS (Coronary Artery thrombosis) (seriousness criterion medically significant), SEPSIS (Sepsis secondary to intra-abdominal infection) (seriousness criteria hospitalization and medically significant) and DEHYDRATION (dehydration) (seriousness criterion hospitalization). On an unknown date, the patient experienced HEPATOCELLULAR INJURY (Acute hepatocellular injury) (seriousness criteria hospitalization and medically significant) and OFF LABEL USE (Not safe for him to get the second shot right now). The patient was hospitalized from 21-Jun-2021 to 26-Jun-2021 due to ACUTE KIDNEY INJURY, DEHYDRATION, DIARRHOEA, EOSINOPHILIA, HEPATOCELLULAR INJURY, INFLUENZA LIKE ILLNESS, MULTIPLE ORGAN DYSFUNCTION SYNDROME, RASH, SEPSIS and URTICARIA. The patient was treated with ACETAMINOPHEN;HYDROCODONE (oral) for Chronic back pain, at a dose of 5 mg/325 mg, every 8 hours; APIXABAN (ELIQUIS) (oral) for Thrombus, at a dose of 5 mg twice a day; ACETYLSALICYLIC ACID (ECOTRIN) (oral) for Heart attack, at a dose of 81 mg once a day; ATORVASTATIN CALCIUM (LIPITOR) (oral) for Heart attack and Blood cholesterol increased, at a dose of 80 mg at bedtime; LISINOPRIL DIHYDRATE (PRINIVIL) (oral) for Heart attack, at a dose of 2.5 mg once a day; SPIRONOLACTONE (ALDACTONE [SPIRONOLACTONE]) (oral) for Adverse event, at a dose of 37.5 mg once a day; CEFTRIAXONE for Adverse event, at an unspecified dose and frequency; METRONIDAZOLE (FLAGYL [METRONIDAZOLE]) (intravenous) for Adverse event, at a dose of 500 mg every eight hours; FUROSEMIDE (LASIX [FUROSEMIDE]) (intravenous) for Adverse event, at a dose of 20 mg every twelve hours; ALBUMIN HUMAN (intravenous) for Adverse event, at a dose of 12.5 g every twelve hours; LEVOFLOXACIN (oral) for Adverse event, at a dose of 500 mg once a day; MAGNESIUM SULPHATE [MAGNESIUM SULFATE] (intravenous) for Adverse event, at a dose of 4 g as required; DIPHENHYDRAMINE HYDROCHLORIDE (BENADRYL [DIPHENHYDRAMINE HYDROCHLORIDE]) (oral) for Adverse event, at a dose of 25 mg every six hours; LACTOBACILLUS ACIDOPHILUS, LACTOBACILLUS CASEI, LACTOBACILLUS RHAMNOSUS (BIO K PLUS) (oral) for Adverse event, at a dose of 2 cap, daily; POTASSIUM CHLORIDE (oral) for Adverse event, at a dose of 20 mEq,; ACETAMINOPHEN (oral) for Adverse event, at a dose of 650 mg every four hours; BISACODYL (DULCOLAX [BISACODYL]) (rectal) for Adverse event, at a dose of 10 mg once a day; CALCIUM CHLORIDE, POTASSIUM CHLORIDE, SODIUM LACTATE (LACTATED RINGERS) (intravenous) for Adverse event, at a dose of 250 ml as required; METOCLOPRAMIDE (REGLAN [METOCLOPRAMIDE]) (intravenous) for Adverse event, at a dose of 10 mg every six hours; ONDANSETRON (ZOFRAN [ONDANSETRON]) (intravenous) for Adverse event, at a dose of 4 mg every six hours; POLYETHYLENE GLYCOL 3350 (oral) for Adverse event, at a dose of 17 g twice a day; ZOLPIDEM TARTRATE [redacted] (oral) for Adverse event, at a dose of 2.5 mg at bedtime and URSODIOL for Adverse event, at an unspecified dose and frequency. On 18-Jun-2021, VACCINATION SITE PAIN (his arm hurt for several days) outcome was unknown. At the time of the report, MULTIPLE ORGAN DYSFUNCTION SYNDROME (Most of his organs shut down), ACUTE MYOCARDIAL INFARCTION (Non-ST-Elevation Myocardial Infarction), CORONARY ARTERY THROMBOSIS (Coronary Artery thrombosis), SEPSIS (Sepsis secondary to intra-abdominal infection), ACUTE KIDNEY INJURY (Acute kidney injury), HEPATOCELLULAR INJURY (Acute hepatocellular injury), INFLUENZA LIKE ILLNESS (flu-like symptoms), DEHYDRATION (dehydration), DIARRHOEA (Diarrhea), URTICARIA (Utricarial rash), EOSINOPHILIA (Eosinophilia), RASH (Transient rash in lower extremities) and OFF LABEL USE (Not safe for him to get the second shot right now) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 08-Jun-2021, Blood pressure measurement: 98/58 (Low) 98/58. On 08-Jun-2021, Echocardiogram: lv apical thrombus (abnormal) LV apical thrombus. On 21-Jun-2021, Computerised tomogram abdomen: abnormal (abnormal) diffuse lymph nodes in the upper abdomen which may due inflammation.. On 21-Jun-2021, Liver function test: elevated (High) Elevated LFTs. On 22-Jun-2021, Magnetic resonance imaging: abnormal (abnormal) abnormal LFTs, gall bladder shows mild wall edema. On 23-Jun-2021, Echocardiogram: abnormal (abnormal) Congestive heart failure. On 23-Jun-2021, X-ray: normal (normal) Clear lungs. On an unknown date, Alanine aminotransferase: 109 (High) 109. On an unknown date, Anion gap: 18 (High) 18. On an unknown date, Bilirubin urine: 1 (normal) 1 +. On an unknown date, Blood albumin: 2.5 (Low) 2.5. On an unknown date, Blood alkaline phosphatase: 803 (High) 803 and 1400 (High) 1400. On an unknown date, Blood bicarbonate: 19.6 (Low) 19.6. On an unknown date, Blood bilirubin: 2.5 (normal) 2.5.

Case ID	Narrative (Complete)
	On an unknown date, Blood chloride: 93 (Low) 93. On an unknown date, Blood creatine: 3.18 (High) 3.18. On an unknown date, Blood glucose: 134 (normal) 134. On an unknown date, Blood lactic acid: 2.4 (High) High. On an unknown date, Blood potassium: 3.4 (normal) 3.4. On an unkno

Case ID	Narrative (Complete)
[redacted]	This case was received via European Medicines Agency (Reference number: [redacted] on 10-Sep-2021 and was forwarded to Moderna on 10-Sep-2021. This regulatory authority case was reported by a consumer and describes the occurrence of CEREBRAL HAEMORRHAGE [redacted] LIVER INJURY [redacted] CORONARY ARTERY OCCLUSION [redacted] ACUTE KIDNEY INJURY [redacted] and COAGULOPATHY [redacted] in a 38-year-old female patient who received mRNA-1273 (Spikevax) for Prophylactic vaccination. The patient's past medical history included Nicotine abuse. On 27-Jun-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 11-Jul-2021, the patient experienced CEREBRAL HAEMORRHAGE [redacted] (seriousness criteria hospitalization and medically significant), LIVER INJURY [redacted] (seriousness criteria hospitalization and medically significant), CORONARY ARTERY OCCLUSION [redacted] (seriousness criteria hospitalization and medically significant), ACUTE KIDNEY INJURY [redacted] (seriousness criteria hospitalization and medically significant) and COAGULOPATHY [redacted] (seriousness criterion hospitalization). At the time of the report, CEREBRAL HAEMORRHAGE [redacted] LIVER INJURY [redacted] CORONARY ARTERY OCCLUSION [redacted] ACUTE KIDNEY INJURY [redacted] and COAGULOPATHY [redacted] had not resolved. Laboratory data was mentioned as Intracranial pressure measurement status epilepticus Concomitant medication use information was not provided by reporter. Treatment information included done resuscitation for the events cerebral hemorrhage and coronary artery occlusion. Company Comment: This case concerns a 38-year-old, female patient who experienced the unexpected events of cerebral hemorrhage, liver injury, coronary artery occlusion, acute kidney injury and coagulopathy. The events occurred approximately 2 weeks after the second dose of Spikevax. The events are consistent with the current understanding of the mechanism of action of the vaccine. The re-challenge was unknown since no information about events after the first dose was disclosed. The reporter did not provide a causality assessment. The benefit-risk relationship of Spikevax in not affected by this report. Event seriousness assessed as per Regulatory Authority reporting and per IME list. Status epilepticus as mentioned in narrative not captured as an event as it was not captured as an event by the Authorities and is likely a symptom of the cerebral hemorrhage. Event of resuscitation as captured by Authority not captured as an event as it was a treatment / procedure for the other events and is captured as such. Most recent FOLLOW-UP information incorporated above includes: On 10-Sep-2021: Translated document received on 14-SEP-2021 as live follow up and contain include Relevant History nicotine was added.

Case ID	Narrative (Complete)
[redacted]	This spontaneous case was reported by a consumer and describes the occurrence of HEPATOTOXICITY (hepatotoxicity) and PRURITUS (itching) in a 30-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 004m204 and 025l20a) for COVID-19 vaccination. No Medical History information was reported. On 08-Jan-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) .5 milliliter. On 05-Feb-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to .5 milliliter. On 05-May-2021, the patient experienced HEPATOTOXICITY (hepatotoxicity) (seriousness criteria hospitalization and medically significant). On an unknown date, the patient experienced PRURITUS (itching) (seriousness criterion hospitalization). On 22-May-2021, HEPATOTOXICITY (hepatotoxicity) was resolving. At the time of the report, PRURITUS (itching) had not resolved. Concomitant medication not provided. Treatment drug included ANTIHISTAMINE ALLERGY RELIEF. Company Comment: This case concerns a 30-year-old female patient with unknown medical history, who experienced the unexpected serious events of hepatotoxicity and pruritis. The events occurred 90 days after receiving the second dose of mRNA-1273 vaccine. The rechallenge is not applicable. The reporter did not provide the causality assessment. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Further information has been requested.
[redacted]	This case was received via [redacted] (Reference number: [redacted]) on 14-Sep-2021 and was forwarded to Moderna on 14-Sep-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of ADVERSE REACTION (Adverse reaction), AUTOIMMUNE HEPATITIS (Autoimmune hepatitis), CONTUSION (Contusion/large bruise on my neck), FEELING ABNORMAL (Feeling abnormal/feeling even worse.), IMMUNE THROMBOCYTOPENIA (Immune thrombocytopenia), HEADACHE (Severe headache), FATIGUE (Exhaustion), LYMPHADENOPATHY (large swollen gland on my right arm pit) and PAIN (The swollen gland was painful to the touch) in a 37-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 018B21A) for COVID-19 vaccination. Concurrent medical conditions included Psoriasis and Drug allergy (SULFA). On 28-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 28-Mar-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 10-Mar-2021, the patient experienced HEADACHE (Severe headache) (seriousness criteria hospitalization prolonged and disability), FATIGUE (Exhaustion) (seriousness criteria hospitalization prolonged and disability), LYMPHADENOPATHY (large swollen gland on my right arm pit) (seriousness criteria hospitalization prolonged and disability) and PAIN (The swollen gland was painful to the touch) (seriousness criteria hospitalization prolonged and disability). On 28-Mar-2021, the patient experienced ADVERSE REACTION (Adverse reaction) (seriousness criteria hospitalization prolonged and disability), AUTOIMMUNE HEPATITIS (Autoimmune hepatitis) (seriousness criteria hospitalization prolonged, disability and medically significant), CONTUSION (Contusion/large bruise on my neck) (seriousness criteria hospitalization prolonged and disability), FEELING ABNORMAL (Feeling abnormal/feeling even worse.) (seriousness criteria hospitalization prolonged and disability) and IMMUNE THROMBOCYTOPENIA (Immune thrombocytopenia) (seriousness criteria hospitalization prolonged, disability and medically significant). The patient was treated with MYCOPHENOLATE MOFETIL (CELLCEPT [MYCOPHENOLATE MOFETIL]) for Immunosuppression, at a dose of UNK, qd. At the time of the report, ADVERSE REACTION (Adverse reaction), AUTOIMMUNE HEPATITIS (Autoimmune hepatitis), CONTUSION (Contusion/large bruise on my neck), FEELING ABNORMAL (Feeling abnormal/feeling even worse.) and IMMUNE THROMBOCYTOPENIA (Immune thrombocytopenia) had not resolved and HEADACHE (Severe headache), FATIGUE (Exhaustion), LYMPHADENOPATHY (large swollen gland on my right arm pit) and PAIN (The swollen gland was painful to the touch) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 28-Mar-2021, Biopsy liver: abnormal (abnormal) biopsy showed that I had autoimmune hepatitis. On 28-Mar-2021, Blood test: abnormal (abnormal) Abnormal. On 28-Mar-2021, Hepatic enzyme: increased (High) increased. On 28-Mar-2021, Platelet count: decreased (Low) decreased. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Treatment as reported: high doses of steroids and antirejection medication called Cellcept that to take every day No concomitant drugs were reported Company comment: This case concerns a 37-year-old female patient with relevant medical history of Psoriasis and Drug allergy (SULFA) who experienced the serious unexpected events of autoimmune hepatitis (AESI), immune thrombocytopenia (AESI), contusion and feeling abnormal after the second dose of mRNA-1273 and the unexpected events of headache, fatigue, lymphadenopathy and pain 10 days after the first dose of mRNA-1273. After the first dose was tested for COVID and Lyme disease and everything came back normal. After second dose the patient started feeling worse. Blood work and ultrasound were performed and showed very low platelets and increased liver enzymes. The patient was diagnosed with immune thrombocytopenia. Then the patient had a large bruise on her neck so after a blood work was admitted to hospital for 5 days. After a weekly blood work, her liver enzymes were elevated so a liver biopsy was performed and showed autoimmune hepatitis. It was reported that the doctor said it was a reaction to the vaccine. The benefit-risk relationship of mRNA-1273 is not affected by this report.

Case ID	Narrative (Complete)
	Most recent FOLLOW-UP information incorporated above includes: On 14-Sep-2021: Upon internal review on 06-Jan-2022, non-significant correction was performed in company comment

Case ID	Narrative (Complete)
[redacted]	This regulatory authority case was reported by a pharmacist and describes the occurrence of ACUTE HEPATITIS B (Acute hepatitis B), HEPATIC FAILURE (Hepatitis B with acute liver failure), SEPSIS (Sepsis), CELLULITIS (Right forearm cellulitis), BILIARY TRACT DISORDER (Delirium suspected biliary tract problem), HYPOKALAEMIA (Hypokalemia), ASTHENIA (generalized asthenia/weakness), ALTERED STATE OF CONSCIOUSNESS (altered state of consciousness), CHILLS (chills), PYREXIA (Fever), DELIRIUM (Delirium suspected biliary tract problem), DECUBITUS ULCER (r/o pressure sore), BILIARY TRACT INFECTION (biliary tract infection) and BANDAEMIA (bandemia) in a 71-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. Concurrent medical conditions included Hepatitis B (Hepatitis B with liver failure) and Hepatic encephalopathy (hepatic encephalopathy (grade 3 – 4), suspected to be induced by liver failure). On 07-Jul-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 07-Jul-2021, the patient experienced ACUTE HEPATITIS B (Acute hepatitis B) (seriousness criteria death, hospitalization and medically significant). On 14-Jul-2021, the patient experienced HEPATIC FAILURE (Hepatitis B with acute liver failure) (seriousness criteria death, hospitalization and medically significant), SEPSIS (Sepsis) (seriousness criteria death, hospitalization and medically significant), HYPOKALAEMIA (Hypokalemia) (seriousness criteria death, hospitalization and medically significant), ALTERED STATE OF CONSCIOUSNESS (altered state of consciousness) (seriousness criteria death, hospitalization and medically significant), CHILLS (chills) (seriousness criteria death and hospitalization), PYREXIA (Fever) (seriousness criteria death and hospitalization), DECUBITUS ULCER (r/o pressure sore) (seriousness criteria death and hospitalization), BILIARY TRACT INFECTION (biliary tract infection) (seriousness criteria death, hospitalization and medically significant) and BANDAEMIA (bandemia) (seriousness criteria death and medically significant). On 02-Aug-2021, the patient experienced CELLULITIS (Right forearm cellulitis) (seriousness criteria death, hospitalization and medically significant), BILIARY TRACT DISORDER (Delirium suspected biliary tract problem) (seriousness criteria death and hospitalization), ASTHENIA (generalized asthenia/weakness) (seriousness criteria death and hospitalization) and DELIRIUM (Delirium suspected biliary tract problem) (seriousness criteria death, hospitalization and medically significant). The patient was hospitalized from 14-Jul-2021 to 31-Jul-2021 due to ALTERED STATE OF CONSCIOUSNESS, BILIARY TRACT INFECTION, CELLULITIS, CHILLS, DECUBITUS ULCER, HYPOKALAEMIA, PYREXIA and SEPSIS. The patient died on 26-Aug-2021. The reported cause of death was hepatitis b with acute liver failure. It is unknown if an autopsy was performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 14-Jul-2021, Ammonia: 112 (Inconclusive) 112. On 14-Jul-2021, Blood pressure measurement: 134/93 (Inconclusive) 134/93 mmHg. On 14-Jul-2021, Body temperature: 39.1°C (Inconclusive) 39.1°C. On 14-Jul-2021, Heart rate: 107 (Inconclusive) 107 beats per minute. On 14-Jul-2021, Hypokalaemia: k 3.0 -> 3.1 (Inconclusive) K 3.0 -> 3.1. On 14-Jul-2021, Respiratory rate: 20 (Inconclusive) 20 breaths per minute. On 02-Aug-2021, Blood bilirubin: 5.9 => 8.7 (High) 5.9 => 8.7. On 02-Aug-2021, Blood pressure measurement: 146/103 (Inconclusive) 146/103 mmHg. On 02-Aug-2021, Body temperature: 37°C (Inconclusive) 37°C. On 02-Aug-2021, Heart rate: 65 (Inconclusive) 65 beats per minute. On 02-Aug-2021, Respiratory rate: 18 (Inconclusive) 18 breaths per minute. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. No concomitant medication reported. Treatment information not provided. Company Comment: This case concerns a 71-year-old, female patient with relevant medical history of hepatitis B with liver failure and Hepatic encephalopathy, who experienced the unexpected events of acute hepatitis Hepatic failure, cellulitis, biliary tract disorder, hypokalemia, asthenia, altered state of consciousness, chills, pyrexia, delirium, decubitus ulcer, biliary tract infection and bandaemia. The events occurred approximately between 1 and 8 days after the first dose of mRNA-1273 and had a fatal outcome 12 days after. The rechallenge was not applicable, as the events happened after the first dose. The medical history of T hepatitis B with liver failure and Hepatic encephalopathy remains a cofounder. he benefit-risk relationship of mRNA-1273 is not affected by this report.

Case ID	Narrative (Complete)
[redacted]	This case was received via European Medicines Agency (Reference number: [redacted] on 17-Sep-2021 and was forwarded to Moderna on 17-Sep-2021. This regulatory authority case was reported by a consumer and describes the occurrence of HEPATITIS ACUTE ([redacted] and DECREASED APPETITE ([redacted] in a 46-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 Vaccination. No Medical History information was reported. On 01-Jun-2021, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. In 2021, the patient experienced DECREASED APPETITE [redacted] (seriousness criterion hospitalization). On 17-Jun-2021, the patient experienced HEPATITIS ACUTE [redacted] (seriousness criteria hospitalization and medically significant). At the time of the report, HEPATITIS ACUTE [redacted] was resolving and DECREASED APPETITE [redacted] outcome was unknown. The action taken with mRNA-1273 (Spikevax) (Unknown) was unknown. The treatment history was not reported. The concomitant medication was not reported. Company Comment: This case concerns a 46-year-old, female patient with no relevant medical history, who experienced the unexpected events of Hepatitis acute and appetite loss. The event Hepatitis acute occurred approximately 17 days after the first dose of Spikevax and the event appetite loss occurred unknown days after the first dose of Spikevax. The rechallenge was unknown, since at the time of report no information about second dose is available. The benefit-risk relationship of Spikevax is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 17-Sep-2021: Translated document received on 23-Sep-2021 as live follow up: Dosage text translated
[redacted]	This literature-non-study case was reported in a literature article and describes the occurrence of AUTOIMMUNE HEPATITIS (Autoimmune hepatitis) in a 36-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. LITERATURE REFERENCE: Zhou T, Fronhoffs F, Dold L, Strassburg CP, Weismuller TJ. New-onset autoimmune hepatitis following mRNA COVID-19 vaccination in a 36-year-old woman with primary sclerosing cholangitis – should we be more vigilant?. J Hepatol. 2022;76(1):218–20 Concurrent medical conditions included Ulcerative colitis (was diagnosed at 33 years) since 2018, Primary sclerosing cholangitis (Due to recurrent episodes of purulent cholangitis and refractory strictures scheduled balloon dilatations had to be performed regularly every three months.) since 2018 and Pruritus. Concomitant products included URSODEOXYCHOLIC ACID for Ulcerative colitis and Primary sclerosing cholangitis. On 20-May-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 19-Jun-2021, received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. In 2021, the patient experienced AUTOIMMUNE HEPATITIS (Autoimmune hepatitis) (seriousness criteria hospitalization and medically significant) and MYALGIA (Minor muscle ache). The patient was hospitalized on 31-May-2021 due to AUTOIMMUNE HEPATITIS. The patient was treated with PREDNISONE on 10-Jun-2021 for Autoimmune hepatitis, at a dose of 50 mg and AZATHIOPRINE on 01-Jul-2021 for Autoimmune hepatitis, at an unspecified dose and frequency. At the time of the report, AUTOIMMUNE HEPATITIS (Autoimmune hepatitis) and MYALGIA (Minor muscle ache) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In 2021, Alanine aminotransferase: 588u/l (High) elevated (588U/l). In 2021, Antimitochondrial antibody: negative (Negative) negative. In 2021, Antineutrophil cytoplasmic antibody: negative (Negative) negative. In 2021, Antinuclear antibody: positive (Positive) 1:2560; homogeneous pattern was positive. In 2021, Aspartate aminotransferase: 581u/l (High) elevated (581U/l). In 2021, Blood alkaline phosphatase: slightly elevated (High) slightly elevated. In 2021, Blood bilirubin: normalization (normal) normalization and 1.4 mg/dl (High) rise (1.4 mg/dl). In 2021, Blood immunoglobulin G: elevated (High) elevated up to 24.75g/l (upper limit of normal: 16g/l) and normalization (14.6g/l) (normal) normalization (14.6g/l). In 2021, DNA antibody: positive (Positive) (186.8IU/l (ULN: 100 IU/l) were positive. In 2021, Gamma-glutamyltransferase: slightly elevated (High) slightly elevated. In 2021, Hepatic enzyme: rapidly decreasing (Low) rapidly decreasing. In 2021, Histology: dense lymphoplasmacellular portal infiltrate shows a dense lymphoplasmacellular portal infiltrate with involvement of the adjacent lobular parenchyma (interface hepatitis), which consists of lymphocytes, plasma cells and few eosinophils and abnormal showed a dense lymphoplasmacellular portal infiltrate with involvement of the adjacent lobular parenchyma (interface hepatitis) and discrete presence of rosette formation and apoptotic hepatocytes. Besides lymphocytes and plasma cells few eosinophils and small bile ducts with associated neutrophilic granulocytes (ductular reaction) were observed.. In 2021, International normalised ratio: 1.2 1.2 and rise (High) rise (1.2). In 2021, Serology test: negative (Negative) was negative for acute viral infections (hepatitis A, B, C, E, cytomegalovirus, Epstein-Barr-Virus, herpes virus). On an unknown date, Alanine aminotransferase: 193 u/l (High) 193 U/l and normalized (normal) normalized. On an unknown date, Aspartate aminotransferase: 117u/l (High) 117U/l and normalized (normal) normalized. On an unknown date, Blood alkaline phosphatase: 1077u/l (High) highly elevated (AP, 1077U/l).

Case ID	Narrative (Complete)
	On an unknown date, Blood immunoglobulin G: 16.9g/l 16.9g/l and 16.9g/l (High) 16.9g/l. On an unknown date, Cholangiogram: abnormal Diagnosis was made after exclusion of viral or metabolic hepatopathy due to a typical cholangiogram. On an unknown date, Endoscopy biliary tract: decreased (Low) decreased. On an unknown date, Gamma-glutamyltransferase: 757u/l (High) 757U/l and decreased (Low) decreased. On an unknown date, Histology: abnormal (abnormal) Liver histology showed a dense lymphoplasmacellular portal infiltrate wit. On an unknown date, Red blood cell sedimentation rate: showed multiple highgrade showed multiple highgrade intra- and extrahepatic strictures. On an unknown date, Serology test: negative (Negative) Serology was negative for acute viral infections (hepatitis A, B, C, E, cytomegalovirus, Epstein-Barr-Virus, herpes virus and negative (Negative) Negative. On an unknown date, Transaminases: elevated (High) elevated but less than AP/GGT. The action taken with mRNA-1273 (Spikevax) (Unknown) was unknown. For mRNA-1273 (Spikevax) (Unknown), the reporter considered AUTOIMMUNE HEPATITIS (Autoimmune hepatitis) and MYALGIA (Minor muscle ache) to be possibly related. Diagnosis was made after exclusion of viral or metabolic hepatopathy due to a typical cholangiogram and highly elevated alkaline phosphatase (AP, 1077U/l) and gammaglutamyltransferase (GGT, 757U/l), while aspartate aminotransferase (AST, 117U/l), alanine aminotransferase (ALT, 193 U/l) and Immunoglobulin G (IgG, 16.9g/l) were only slightly elevated. Following treatment with ursodeoxycholic acid (1000mg/d) and endoscopic biliary intervention AP and gGT initially decreased and ALT and AST normalized. However, after one year, the patient presented with cholangitis and pruritus and ERC showed multiple highgrade intra- and extrahepatic strictures. Except for minor muscle aches the patient was without further symptoms after first dose of vaccine. On 31-May-2021 she was hospitalized for a scheduled endoscopic balloon dilatation of the strictures. Since the SARS-CoV2-antibody-titer two weeks after the 1st vaccination was only weak, we decided to vaccinate a 2nd time on 10-Jun-2021 while the patient was still treated with 50mg prednisone. Nonetheless, we recorded a further decline of liver enzymes. The SARS-CoV2-IgGantibody- response two weeks after the 2nd vaccination was sufficient with >384 BAU/ml. Author concluded that the question arises whether we should be more vigilant, at least in female patients with preexisting predisposition to autoimmune diseases, and routinely check aminotransferases 2-4 weeks after COVID-19-vaccination. Company comment: This case concerns a 36 year-old, female with a history of Primary sclerosing cholangitis and ulcerative colitis, who experienced the unexpected event of AUTOIMMUNE HEPATITIS. The event occurred within 11 days after the first dose of mRNA-1273 Moderna vaccine. Patients laboratory test showed elevated results Alanine aminotransferase, Aspartate aminotransferase, Blood alkaline, Blood immunoglobulin G, Gamma-glutamyltransferase; Postive for Antinuclear antibody, DNA antibody; Negative for Antimitochondrial antibody, Antineutrophil cytoplasmic antibody, Serology test; and Abnormal Histology results. The event was considered related to the product per the reporter´s assessment. The medical history could be a potentially confounder. The benefit-risk relationship of mRNA-1273 Moderna vaccine in not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 21-Sep-2021: Follow up received by safety on 22-Sep-2021 has Email with FTA received from SARA team and does not contain any new information. On 31-Mar-2022: Follow up received by safety on 31-Mar-2022 has Email with FTA received and contains significant information: Literature information updated (volume, issue, page number and year), start date of second dose updated and report type updated from Literature-Study to Literature-Non-Study as per current convention.
[redacted]	This case was received via European Medicines Agency (Reference number: [redacted] on 22-Sep-2021 and was forwarded to Moderna on 22-Sep-2021. This regulatory authority case was reported by a physician and describes the occurrence of HEPATITIS ACUTE (Hepatitis acute) in a 13-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 3004234) for COVID-19 vaccination. No Medical History information was reported. On 30-Jul-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 19-Aug-2021, after starting mRNA-1273 (Spikevax), the patient experienced HEPATITIS ACUTE (Hepatitis acute) (seriousness criterion medically significant). At the time of the report, HEPATITIS ACUTE (Hepatitis acute) 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 reported. Rechallenge was done however outcome was unknown. Text for Relevant Medical History and Concurrent Conditions included RAS. Company comment: This case concerns a 13-year-old, female patient with no previous relevant medical history, who experienced the unexpected event of hepatitis acute. The event occurred 19 days after the first dose of mRNA-1273 (Moderna COVID-19 Vaccine). The rechallenge was unknown since only information about the first dose was disclosed. 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 22-Sep-2021: Translation received on 28-Sept-2021. Dosage text updated.

Case ID	Narrative (Complete)
[redacted]	This case was received via European Medicines Agency (Reference number [redacted] on 23-Sep-2021 and was forwarded to Moderna on 23-Sep-2021. This regulatory authority case was reported by a physician and describes the occurrence of OROPHARYNGEAL PAIN (Throat pain), HEPATOTOXICITY (Hepatotoxic effect), CHOLESTATIC LIVER INJURY (Cholestatic liver injury) and PYREXIA (Pyrexia) in a 25-year-old male patient who received mRNA-1273 (Spikevax) (batch no. UNKNOWN) for COVID-19 vaccination. No Medical History information was reported. On 15-Jun-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient received dose of mRNA-1273 (Spikevax) (unknown route) at an unspecified dose. On 03-Jul-2021, the patient experienced OROPHARYNGEAL PAIN (Throat pain) (seriousness criterion hospitalization), HEPATOTOXICITY (Hepatotoxic effect) (seriousness criteria hospitalization and medically significant), CHOLESTATIC LIVER INJURY (Cholestatic liver injury) (seriousness criteria hospitalization and medically significant) and PYREXIA (Pyrexia) (seriousness criterion hospitalization). At the time of the report, OROPHARYNGEAL PAIN (Throat pain), HEPATOTOXICITY (Hepatotoxic effect), CHOLESTATIC LIVER INJURY (Cholestatic liver injury) and PYREXIA (Pyrexia) had not resolved. The action taken with mRNA-1273 (Spikevax) (Unknown Route) and mRNA-1273 (Spikevax) (Intramuscular) was unknown. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Concomitant medications were not reported. Treatment medications were not reported. This case concerns a 25 year old male patient with no relevant medical history, who experienced the serious unexpected events of Oropharyngeal pain, Hepatotoxicity, Cholestatic liver injury and Pyrexia. The events occurred approximately 19 days after first dose of Spikevax. The rechallenge was not applicable since only information about the first dose was disclosed. The benefit-risk relationship of Spikevax is not affected by this report. Very limited information regarding these events has been provided at this time. Most recent FOLLOW-UP information incorporated above includes: On 05-Nov-2021: Follow up received contains Non significant information. Reporter is added.

Case ID	Narrative (Complete)
[redacted]	This case was received via [redacted] Reference number [redacted] on 16-Sep-2021 and was forwarded to Moderna on 24-Sep-2021. This case was reported by an internist. Since the proprietary name of the coronavirus vaccine was not specified, the vaccine is handled as a [redacted] product in this case report. On 16-APR-2020, the patient's husband was hospitalized for coronavirus infection (through 22-APR-2020). On 30-APR-2020, test results were as follows: PCR (+) and pneumonia (+). On 02-MAY-2020, the patient was hospitalized for coronavirus infection (for 9 days). On 06-JUL-2020, the GOT was 20, GPT 19, and gamma-GTP 23. On 12-APR-2021, mosapride citrate hydrate (3 tablets/day) was started. On an unknown date, a digestive enzyme preparation (3 g/day) was started. On 10-MAY-2021, gastrointestinal fiberscopy showed chronic gastritis; an H pylori test was (+). On 20-MAY-2021, the patient started to receive [redacted] 400 (vonoprazan fumarate/amoxicillin/clarithromycin). Mosapride citrate hydrate and the digestive enzyme preparation were prescribed to be used on an as needed basis. On 27-MAY-2021, [redacted] 400 was completed (last dosing, 27-MAY-2021). Mosapride citrate hydrate and the digestive enzyme preparation were continued. On 31-MAY-2021, the patient received preventive vaccination for coronavirus. On 16-JUN-2021, increased test values were noted at a regular medical checkup; the GOT was 80, GPT 150, and gamma-GTP 96 (abnormal hepatic function [suspected drug-induced liver injury]). Ultrasonography also showed fatty liver. On 21-JUN-2021, the patient received preventive vaccination for coronavirus (vaccination interval of 21 days). On 28-JUN-2021, the GOT was 150, GPT 283, gamma-GTP 43, gamma-globin 17.6, and platelet 23.5. On 29-JUN-2021, the patient visited the hospital. As a result of the examination on JUN-28, it was decided that the patient be referred to another hospital for detailed examination and receive inpatient treatment. On 30-JUN-2021, the patient was examined at the other hospital. On 01-JUL-2021, glycyrrhizin/glycine/cysteine 100 mg was started (continued through 05-JUL-2021). On 02-JUL-2021, mosapride citrate hydrate was discontinued. On 06-JUL-2021, liver biopsy was performed. Ursodeoxycholic acid 600 mg was started (continued through 12-JUL-2021). On 07-JUL-2021, glycyrrhizin/glycine/cysteine 100 mg was resumed (continued through 12-JUL-2021). On 16-JUL-2021, the patient was discharged from the other hospital. Ursodeoxycholic acid 600 mg was resumed. On 10-AUG-2021, at the time of blood sampling, a lymphocyte transformation test was performed for the 3 drugs included in [redacted] 400. The results were negative for all the drugs. In AUG-2021 (date unknown), the abnormal hepatic function (suspected drug-induced liver injury) was resolving. On 07-SEP-2021, the liver injury was gradually improving, and ursodeoxycholic acid was discontinued. The following were written in the medical information sheet obtained from the other hospital: name of injury/disease, suspected drug-induced liver injury; suspected drugs, [redacted] 400, coronavirus vaccine, mosapride citrate hydrate, digestive enzyme preparation, etc. A lymphocyte transformation test was performed for the 3 drugs included in [redacted] 400 at the time of blood sampling on 10-AUG; the results were negative for all the drugs. However, since the test has a positive rate of approximately 50%, it is not necessarily the case that the 3 drugs can be used safely on the grounds of the test results. Therefore, it is requested that use of other drugs be considered to the extent possible. Although causal involvement of the digestive enzyme preparation, mosapride citrate hydrate, etc cannot be ruled out, the patient did not wish a lymphocyte transformation test for the other suspect drugs. If possible, it is desirable to avoid prescription of these drugs as well. A follow-up blood test will be performed at the other hospital on 11-OCT-2021. Follow-up received on 16-SEP-2021 Comprehensively updated Company Comment: The event onset after the start of [redacted] 400 shows a temporal relationship. However, causal influence of co-administered medication is also conceivable.

Case ID	Narrative (Complete)
	Although the event developed after the start of mRNA-1273 (Moderna COVID-19 Vaccine), it is difficult to assess a causal relationship to mRNA-1273 (Moderna COVID-19 Vaccine) because of lack of detailed information. Assessment of causal relationship between the products and the event from the following perspectives: (1) Temporal relationship: Yes Reason: The onset timing is consistent with the dosing of [redacted] 400 and mRNA-1273 (Moderna COVID-19 Vaccine). (2) Relationship to concomitant medication: Yes Reason: The suspicion cannot be ruled out. (3) Relationship to comorbidities: No (4) Relationship to therapeutic procedures: No The patient previously experienced drug-induced liver injury with a different drug, and thus a drug-induced etiology is strongly suspected also this time. Although no evidence was yielded by the test results, the suspect drugs are considered as ones that should be avoided. Suspected drugs: [redacted] 400, coronavirus vaccine, mosapride citrate hydrate, digestive enzyme preparation, etc.
[redacted]	This case was received via European Medicines Agency (Reference number: [redacted]) on 24-Sep-2021 and was forwarded to Moderna on 24-Sep-2021. This regulatory authority case was reported by a physician and describes the occurrence of AUTOIMMUNE HEPATITIS (Autoimmune hepatitis) in a 78-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 3000493) for COVID-19 vaccination. The patient's past medical history included Neutropenia and Hysterectomy. Concurrent medical conditions included Osteoporosis, Ovarian adenocarcinoma, Vitiligo and Hypertriglyceridaemia. On 10-Mar-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) .5 milliliter. On 06-May-2021, the patient experienced AUTOIMMUNE HEPATITIS (Autoimmune hepatitis) (seriousness criterion medically significant). At the time of the report, AUTOIMMUNE HEPATITIS (Autoimmune hepatitis) had not resolved. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medications were reported. Treatment information was not provided. This case concerns a 78-year-old, female patient with no relevant medical history, who experienced the serious unexpected event of Autoimmune hepatitis. The event occurred around 57 days after dose of Spikevax. The rechallenge was unknown since only information about one dose was disclosed. The benefit-risk relationship of Spikevax is not affected by this report.

Case ID	Narrative (Complete)
[redacted]	This case was received via European Medicines Agency (Reference number: [redacted]) on 27-Sep-2021 and was forwarded to Moderna on 27-Sep-2021. This regulatory authority case was reported by a physician and describes the occurrence of HEPATITIS ACUTE (Hepatitis acute) in a 23-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The patient's past medical history included Ingrowing nail, Attempted suicide, Anxiodepressive syndrome, Road traffic accident, Psychiatric disorder NOS, [redacted] Adenoidectomy and Tonsillectomy. On 18-Aug-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 21-Aug-2021, the patient experienced HEPATITIS ACUTE (Hepatitis acute) (seriousness criteria hospitalization and medically significant). At the time of the report, HEPATITIS ACUTE (Hepatitis acute) was resolving. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Concomitant medications were not provided by the reporter. No treatment information was provided by the reporter. This case concerns a 23-year-old, male patient with no relevant medical history, who experienced the unexpected event of hepatitis acute. The event hepatitis acute occurred 4 days after the first dose of mRNA-1273 vaccine administration. The rechallenge was unknown as there's no information available about the second dose. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.
[redacted]	This case was received via United States FDA VAERS (Reference number: [redacted] on 28-Sep-2021 and was forwarded to Moderna on 28-Sep-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCARDITIS (Myocarditis), CARDIOGENIC SHOCK (Cardiogenic shock), ASCITES (Ascites), CARDIAC ARREST (Cardiac arrest), CARDIAC FAILURE (Cardiac failure), CONGESTIVE HEPATOPATHY (Congestive hepatopathy), HEPATIC FAILURE (Hepatic failure), PERICARDIAL EFFUSION (Pericardial effusion), PNEUMONIA (Pneumonia) and RENAL FAILURE (Renal failure) in a 26-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Suspected COVID-19 since 10-Sep-2021. On 13-Sep-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 15-Sep-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria death and medically significant), CARDIOGENIC SHOCK (Cardiogenic shock) (seriousness criteria death and medically significant), ASCITES (Ascites) (seriousness criterion medically significant), CARDIAC ARREST (Cardiac arrest) (seriousness criterion medically significant), CARDIAC FAILURE (Cardiac failure) (seriousness criterion medically significant), CONGESTIVE HEPATOPATHY (Congestive hepatopathy) (seriousness criterion medically significant), HEPATIC FAILURE (Hepatic failure) (seriousness criterion medically significant), PERICARDIAL EFFUSION (Pericardial effusion) (seriousness criterion medically significant), PNEUMONIA (Pneumonia) (seriousness criterion medically significant), RENAL FAILURE (Renal failure) (seriousness criterion medically significant), HYPERVENTILATION (Hyperventilation), CARDIOMEGALY (Cardiomegaly), HEPATOMEGALY (Hepatomegaly), METABOLIC ACIDOSIS (Metabolic acidosis), INFLAMMATION (Inflammation) and RENAL DISORDER (Renal disorder). 15-Sep-2021, the patient experienced COVID-19 (COVID-19). The patient died on 15-Sep-2021. The reported cause of death was Cardiogenic shock and Myocarditis. It is unknown if an autopsy was performed. At the time of death, ASCITES (Ascites), CARDIAC ARREST (Cardiac arrest), CARDIAC FAILURE (Cardiac failure), CONGESTIVE HEPATOPATHY (Congestive hepatopathy), HEPATIC FAILURE (Hepatic failure), PERICARDIAL EFFUSION (Pericardial effusion), PNEUMONIA (Pneumonia), RENAL FAILURE (Renal failure), HYPERVENTILATION (Hyperventilation), CARDIOMEGALY (Cardiomegaly), HEPATOMEGALY (Hepatomegaly), METABOLIC ACIDOSIS (Metabolic acidosis), INFLAMMATION (Inflammation), RENAL DISORDER (Renal disorder) and COVID-19 (COVID-19) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 14-Sep-2021, SARS-CoV-2 test: positive (Positive) SARS-CoV-2 detected. On 15-Sep-2021, Anion gap: 30 (High) Anion gap increased - 30. On 15-Sep-2021, Blood bicarbonate: 9 (Low) Blood bicarbonate decreased - 9. On 15-Sep-2021, Blood chloride: 96 (Low) Blood chloride decreased - 96. On 15-Sep-2021, Blood creatinine: 2.97 (High) Blood creatinine increased - Renal failure with a creatinine of 2.97. On 15-Sep-2021, Blood glucose: 144 (normal) Blood glucose normal - 144. On 15-Sep-2021, Blood lactic acid: 14.0 (High) Blood lactic acid increased - Lactate was 14.0. On 15-Sep-2021, Blood pH: 7.124 (Low) Blood pH decreased - significant metabolic acidosis with a pH of 7.124. On 15-Sep-2021, Blood potassium: 4 (normal) Blood potassium normal - 4. On 15-Sep-2021, Blood sodium: 135 (Low) Blood sodium decreased - 135. On 15-Sep-2021, Blood urea: 22 (High) Blood urea increased - BUN 22. On 15-Sep-2021, Computerised tomogram abdomen: abnormal (abnormal) CTA abdomen and pelvis: No evidence of bowel ischemia. The enlargement of the liver and of mild ascites suggest hepatic congestion. This could reflect either heart failure or liver failure. Heterogeneous appearance of the kidneys, suggesting possible pyelonephritis, but this appearance could also be the result of some other inflammatory process. On 15-Sep-2021, Computerised tomogram thorax: abnormal (abnormal) CTA chest: Small to moderate relatively hyperdense pericardial effusion, nonspecific. Mild cardiomegaly. Evidence of heart failure. These findings collectively would be compatible with inflammatory disease. Consider myocarditis or pericarditis. No evidence of pulmonary thromboembolism. Bilateral pneumonia. On 15-Sep-2021, Electrocardiogram ST segment: elevation (abnormal) EKG showing diffuse ST elevations concerning for myocarditis. On 15-Sep-2021, Fibrin D dimer: 1.25 (High) D-dimer was elevated at 1.25 without any obvious pulmonary embolism according to the CT. On 15-Sep-2021, Glomerular filtration rate: 26 (Low) Glomerular filtration rate decreased - Renal failure with a GFR of 26. In September 2021, Oxygen saturation: 96.8 (normal) O2 sat 96.8 percentage on room air. On 15-Sep-2021, PCO2: 15.4 (Low) PCO2 decreased to 15.4.

Case ID	Narrative (Complete)
	On 15-Sep-2021, SARS-CoV-2 test: positive (Positive) Positive. On 15-Sep-2021, Troponin: 113.793 (High) Troponin increased - Troponin was elevated at 113.793. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No relevant concomitant medications were reported. On 10-Sep-2021, Active COVID-19 infection was suspected based on symptom onset, tested positive on 14 Sep 2021 and was confirmed in Emergency Department, on 15-Sep-2021. Cardiologist did not feel that transfer to a higher level care center immediately for cardiac catheterization indicated. The patient was presented to the emergency department with diffuse ST elevations concerning for myocarditis. Upon presentation he was hyperventilating, not complaining of chest pain. Labs demonstrate a significant metabolic acidosis with a pH of 7.124, PCO2 of 15.4. O2 sat 96.8% on room air. The patient unfortunately went into cardiac arrest and was unable to be revived. Cause of death suspected to be myocarditis and cardiogenic shock in the setting of active COVID-19 infection. No treatment information was reported. Company Comment: This is a fatal case that concerns a 26-year-old male patient, with no reported medical history, who experienced the unexpected events of ascites, cardiac arrest, cardiac failure, cardiogenic shock, congestive hepatopathy, hepatic failure, hyperventilation, myocarditis, pericardial effusion, pneumonia, renal failure, cardiomegaly, hepatomegaly, metabolic acidosis, inflammation, renal disorder and unexpected serious and aesi covid-19 . The events occurred two days after receiving the second dose of spikevax. Fatal outcome occurred two days after second dose of spikevax. Cause of death was reported as myocarditis and cardiogenic shock. The rechallenge was not applicable as no additional dose is going to be administered. The benefit-risk relationship of spikevax is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 12-Oct-2021: Follow up information received does not contain any new information..

Case ID	Narrative (Complete)
[redacted]	This case was received via [redacted] (Reference number: [redacted]) on 28-Sep-2021 and was forwarded to Moderna on 28-Sep-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of COELIAC ARTERY STENOSIS (Coeliac artery stenosis), HEPATIC ARTERY THROMBOSIS (Hepatic artery thrombosis), HEPATIC PERFUSION DISORDER (Hepatic perfusion disorder) and LIVER INJURY (Liver injury) in a 44-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 043b21a) for COVID-19 vaccination. The patient's past medical history included Fatty liver and Hemangioma (Hemangioma on right abdominal wall). Concurrent medical conditions included Penicillin allergy, Chronic sinusitis and Vascular malformation. Concomitant products included CETIRIZINE and GUAIFENESIN (MUCINEX) for an unknown indication. On 15-May-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 18-May-2021, the patient experienced COELIAC ARTERY STENOSIS (Coeliac artery stenosis) (seriousness criteria hospitalization and medically significant), HEPATIC ARTERY THROMBOSIS (Hepatic artery thrombosis) (seriousness criteria hospitalization and medically significant), HEPATIC PERFUSION DISORDER (Hepatic perfusion disorder) (seriousness criteria hospitalization and medically significant) and LIVER INJURY (Liver injury) (seriousness criteria hospitalization and medically significant). At the time of the report, COELIAC ARTERY STENOSIS (Coeliac artery stenosis), HEPATIC ARTERY THROMBOSIS (Hepatic artery thrombosis), HEPATIC PERFUSION DISORDER (Hepatic perfusion disorder) and LIVER INJURY (Liver injury) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 17-Jun-2021, Angiogram: abnormal (abnormal) Arterial thrombosis and malperfusion of the liver. On 23-Jun-2021, International normalised ratio: 1.7 (High) International normalized ratio increased. On 23-Jun-2021, Transaminases: increased (High) A tripling of transaminases occurred but has normalized. On 01-Sep-2021, Angiogram: abnormal (abnormal) Partial resolution of clot on anticoagulation. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. The events were reported as acute common hepatic and celiac thrombosis, and liver injury. On 18-May-2021, the patient had an angiogram, with unknown results. On 18-May-2021, the patient had anticoagulant therapy. Company Comment : This case concerns a 44-year-old female patient, with relevant medical history of fatty liver and vascular malformation/hemangioma on the right abdominal wall, who developed the serious and unexpected events of coeliac artery stenosis, hepatic artery thrombosis, hepatic perfusion disorder, and liver injury, 2 days after receiving the second dose of Moderna COVID-19 vaccine. The rechallenge was unknown since it was not disclosed whether same/similar event(s) occurred after the first dose. Causality is confounded by the patient's history of fatty liver and vascular malformation/hemangioma on the right abdominal wall. The benefit-risk relationship of Moderna COVID-19 vaccine is not affected by this report.

Case ID	Narrative (Complete)
[redacted]	This case was initially received via [redacted] (Reference number: [redacted]) on 14-Sep-2021. The most recent information was received on 27-Sep-2021 and was forwarded to Moderna on 06-Oct-2021. This case was reported via a medical representative. The reporter was unknown. On 27-Sep-2021, follow-up information was received via a medical representative. The reporter was unknown. Acute hepatitis was assessed as serious by the MAH. On 07-Sep-2021, the patient received the 1st dose of this vaccine. On an unknown date, AST increased to 3,000 IU/L. Abnormal hepatic function was noted. On 13-Sep-2021, the patient visited a medical institution. Detailed examination was made. AST decreased to 1,000 IU/L. The patient was taking ursodeoxycholic acid. Abnormal hepatic function was resolving. On an unknown date, acute hepatitis and jaundice developed. On 22-Sep-2021, the patient visited the hospital. On an unknown date, the patient recovered from jaundice. The outcome of abnormal hepatic function was reported as resolving. The outcome of acute hepatitis was unknown. The outcome of jaundice was reported as resolved. Follow-up investigation will be impossible due to non-cooperation of the reporter. Follow-up received on 27-SEP-2021 Updated: Event Information, Narrative Company Comment: The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.

Case ID	Narrative (Complete)
[redacted]	This regulatory authority case was reported by a consumer and describes the occurrence of PYREXIA (Fever), HEPATIC FAILURE (Gradual failure of liver, kidney and lung), RENAL FAILURE (gradual failure of liver, kidney and lung), RESPIRATORY FAILURE (Gradual failure of liver, kidney and lung) and MYOCARDITIS (Myocarditis) in a 52-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. On 09-Jul-2021, the patient received dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 20-Aug-2021, the patient experienced PYREXIA (Fever) (seriousness criterion life threatening). On 23-Aug-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization, medically significant and life threatening). On 26-Aug-2021, the patient experienced HEPATIC FAILURE (Gradual failure of liver, kidney and lung) (seriousness criteria hospitalization, medically significant and life threatening), RENAL FAILURE (gradual failure of liver, kidney and lung) (seriousness criteria hospitalization, medically significant and life threatening) and RESPIRATORY FAILURE (Gradual failure of liver, kidney and lung) (seriousness criteria hospitalization, medically significant and life threatening). At the time of the report, PYREXIA (Fever) had not resolved and HEPATIC FAILURE (Gradual failure of liver, kidney and lung), RENAL FAILURE (gradual failure of liver, kidney and lung), RESPIRATORY FAILURE (Gradual failure of liver, kidney and lung) and MYOCARDITIS (Myocarditis) outcome was unknown. Not Provided The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. The patient was prescribed with medicine for fever and returned home after diagnosed with non-COVID 2019 symptoms. On 23-Aug-2021, symptoms did not improve, hence patient visited the emergency department of hospital and was initially diagnosed with myocarditis then was admitted to the hospital for emergency treatment. On 17-Sep-2021 patient had heart transplantation and the current condition remained not good and admitted to ICU for treatment. The patient's wife stated that she intended to apply for VICP, and was initially informed of the process. No concomitant medications provided. Company comment: This case concerns a 52-year-old male patient with no relevant medical history, who experienced the serious expected event of Myocarditis and serious unexpected events of Pyrexia, Respiratory failure, Hepatic failure and Renal failure. The event onset latency is 1 month 12 days (Pyrexia), 1 month 15 days (Myocarditis) and 1 month 18 days (Respiratory failure, Hepatic failure and Renal failure) after the first dose of Moderna COVID-19 Vaccine. The re-challenge was not applicable as the information regarding the second dose is not reported. The event pyrexia is unexpected as the event is retained as serious per the source document authority reporting. Critical illness in the ICU setting is associated with the increased risk of respiratory failure, hepatic failure and renal failure. 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 04-Oct-2021 and was forwarded to Moderna on 04-Oct-2021. This regulatory authority case was reported by a physician and describes the occurrence of HEPATITIS FULMINANT (Hepatitis fulminant) in a 30-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 214013) for COVID-19 immunisation. No Medical History information was reported. On 08-Aug-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) .5 milliliter. On 31-Aug-2021, the patient experienced HEPATITIS FULMINANT (Hepatitis fulminant) (seriousness criteria hospitalization, medically significant and life threatening). At the time of the report, HEPATITIS FULMINANT (Hepatitis fulminant) was resolving. mRNA-1273 (Spikevax) (Intramuscular) was withdrawn on an unknown date. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Concomitant information was not provided. Treatment information was not provided. Company Comment: This case concerns a 30 year old female patient with no relevant medical history,who experienced the serious unexpected event of Hepatitis fulminant.The event occurred 24 days after unknown dose of Spikevax.The rechallenge was not applicable.mRNA-1273 (Spikevax) was withdrawn on an unknown date. Very limited information regarding this event has been provided at this time. .The benefit-risk relationship of Spikevax is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 04-Oct-2021: Translation document received on 06-Oct-2021 and included no new information

Case ID	Narrative (Complete)
[redacted]	This case was received via [redacted] (Reference number: [redacted] on 05-Oct-2021 and was forwarded to Moderna on 05-Oct-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of ASCITES (Ascites), AUTOIMMUNE HEPATITIS (Autoimmune hepatitis), PORTAL VEIN THROMBOSIS (Portal vein thrombosis), VARICES OESOPHAGEAL (Varices oesophageal) and THROMBOSIS (blood clots) in a 64-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The patient's past medical history included Liver transplant on 16-May-2021 and Hypertension. Concurrent medical conditions included Autoimmune hepatitis since 15-Feb-2017. Concomitant products included AZATHIOPRINE SODIUM (IMURAN [AZATHIOPRINE SODIUM]), ATORVASTATIN, AZATHIOPRINE SODIUM (AZATHIOPRINE [AZATHIOPRINE SODIUM]), ONDANSETRON, METOPROLOL and MAGNESIUM OXIDE for an unknown indication. On 10-Feb-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 22-Mar-2021, the patient experienced ASCITES (Ascites) (seriousness criteria hospitalization and medically significant), AUTOIMMUNE HEPATITIS (Autoimmune hepatitis) (seriousness criteria hospitalization and medically significant), PORTAL VEIN THROMBOSIS (Portal vein thrombosis) (seriousness criteria hospitalization and medically significant) and VARICES OESOPHAGEAL (Varices oesophageal) (seriousness criterion hospitalization). 22-Mar-2021, the patient experienced THROMBOSIS (blood clots) (seriousness criteria hospitalization and medically significant). At the time of the report, ASCITES (Ascites), AUTOIMMUNE HEPATITIS (Autoimmune hepatitis), PORTAL VEIN THROMBOSIS (Portal vein thrombosis) and VARICES OESOPHAGEAL (Varices oesophageal) had resolved and THROMBOSIS (blood clots) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 22-Mar-2021, Hepatic enzyme: elevated (High) elevated. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. On 22-Mar-2021, the patient had complications of transplant surgery and condition aggravated. Pt. underwent a liver transplant with complications May 16, 2021. We understand with his autoimmune hepatitis a liver transplant was a reality at some point. We believe the vaccine exasperated his condition, we also understand his liver disease could cause blood clots, but he had no issues with blood clots, we also believe the severe blood clots could have been exasperated due to the vaccine. Company Comment: This case concerns a 64-year-old male patient with past medical history of hypertension and concurrent history of Autoimmune hepatitis who experienced the unexpected events of ascites, autoimmune hepatitis, portal vein thrombosis, esophageal varices and thrombosis. The events occurred 1 month 12 days after the second dose of mRNA-1273 (Moderna COVID-19 Vaccine). The rechallenge was not applicable as the event occurred after the second dose. Causality for the reported events were not provided by the reporter. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report. Event assessed as serious per Regulatory authority as events were assessed as serious due to hospitalization and surgical intervention. Causality I confounded by the subject's underlying autoimmune hepatitis. Liver injuries and thrombosis are adverse events of special interest.

Case ID	Narrative (Complete)
[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 a physician and describes the occurrence of LIVER INJURY (Hepatic damage) in a 74-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 214011) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 30-Jul-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 2 dosage form. On 02-Aug-2021, the patient experienced LIVER INJURY (Hepatic damage) (seriousness criterion medically significant) and REACTOGENICITY EVENT (Reactogenicity event). At the time of the report, LIVER INJURY (Hepatic damage) and REACTOGENICITY EVENT (Reactogenicity event) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 04-Aug-2021, Transaminases: positive (High) Transaminases increased. The action taken with mRNA-1273 (Spikevax) (Intramuscular) was unknown. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No relevant concomitant medications were reported. Treatment medication was not provided by the reporter. Company Comment: This case concerns a 74 year-old, female subject without significant clinical history who experienced the unexpected events of LIVER INJURY and REACTOGENICITY EVENT. The events occurred three days after the second dose of [Spikevax] The rechallenge was unknown (there isn't enough information if positive dechallenge occurs or not before 2nd dose). The events were considered related to the study drug per the reporter's assessment The benefit-risk relationship of the vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 07-Oct-2021: Translation received on 11-Oct-2021 in which lab test name updated.
[redacted]	This case was received via European Medicines Agency (Reference number: [redacted]) on 12-Oct-2021 and was forwarded to Moderna on 12-Oct-2021. This regulatory authority case was reported by a pharmacist and describes the occurrence of HEPATITIS ACUTE (Acute Hepatitis) in a 70-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 214029, 3002330 and 3001532) for COVID-19 vaccination. No Medical History information was reported. On 15-Apr-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 14-May-2021, received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. On 16-Sep-2021, received third dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. On 20-Sep-2021, the patient experienced HEPATITIS ACUTE (Acute Hepatitis) (seriousness criteria hospitalization, medically significant and life threatening). At the time of the report, HEPATITIS ACUTE (Acute Hepatitis) was resolving. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. The concomitant medications were not reported. The treatment information was not provided. Company Comment: This case concerns a 70 year-old male patient with no medical history provided, who experienced the unexpected event of Hepatitis acute(seriousness criteria hospitalization, medically significant and life threatening). This event occurred 4 days after the third dose of Spikevax. At the time of the report the event was resolving. The benefit-risk relationship of Spikevax is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 12-Oct-2021: Translation received on 14 Oct 2021 and event verbatim was updated from native to English language.

Case ID	Narrative (Complete)
[redacted]	This case was received via [redacted] (Reference number: [redacted]) on 12-Oct-2021 and was forwarded to Moderna on 12-Oct-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of HEPATIC FAILURE (Hepatic failure) in an 80-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 037A21B) for COVID-19 vaccination. The patient's past medical history included Cardiac arrest, Diverticulosis, TIA, Cardiac ablation (Ablation) and Defibrillator/pacemaker insertion (defibrillator). Concurrent medical conditions included Drug allergy (Ampicillin), Sulfonamide allergy (Sulfa drugs), Hypertension and Hypercholesterolemia. On 25-Mar-2021, the patient received dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 05-Aug-2021, the patient experienced HEPATIC FAILURE (Hepatic failure) (seriousness criteria hospitalization and medically significant). At the time of the report, HEPATIC FAILURE (Hepatic failure) outcome was unknown. 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. On 05-AUG-2021, SARS-CoV-2 test was done and results not provided No concomitant and treatment information were reported by the reporter It was reported that the Patient sent to ER by doctor for liver failure. Company comment: This case concerns an 80 year-old, female patient with a history of cardiac arrest, who experienced the serious (due to hospitalization) unexpected AESI event of Hepatic failure. The event occurred approximately 4 months and 12 days after the Moderna COVID-19 vaccine, dose number not provided. The rechallenge was not applicable since dose number was not provided. The medical history of cardiac arrest 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 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 OCULAR ICTERUS (and white of eye yellow), CHROMATURIA (Urine orange in color), DRUG-INDUCED LIVER INJURY (Drug-induced hepatitis), SKIN DISCOLOURATION (dark skin), DISTURBANCE IN ATTENTION (Difficulty concentrating), DECREASED APPETITE (Partial loss of appetite) and FATIGUE (Fatigue) in a 77-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 300153c) for COVID-19 immunisation. Concurrent medical conditions included Type 2 diabetes mellitus and Blood pressure high. Concomitant products included AMOXICILLIN, CLAVULANIC ACID (AUGMENTIN [AMOXICILLIN;CLAVULANIC ACID]) for an unknown indication. On 12-Apr-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 12-Apr-2021, the patient experienced OCULAR ICTERUS (and white of eye yellow) (seriousness criterion hospitalization), CHROMATURIA (Urine orange in color) (seriousness criterion hospitalization), DRUG-INDUCED LIVER INJURY (Drug-induced hepatitis) (seriousness criteria hospitalization and medically significant), SKIN DISCOLOURATION (dark skin) (seriousness criterion hospitalization), DISTURBANCE IN ATTENTION (Difficulty concentrating) (seriousness criterion hospitalization), DECREASED APPETITE (Partial loss of appetite) (seriousness criterion hospitalization) and FATIGUE (Fatigue) (seriousness criterion hospitalization). At the time of the report, OCULAR ICTERUS (and white of eye yellow), CHROMATURIA (Urine orange in color), DRUG-INDUCED LIVER INJURY (Drug-induced hepatitis), SKIN DISCOLOURATION (dark skin), DISTURBANCE IN ATTENTION (Difficulty concentrating), DECREASED APPETITE (Partial loss of appetite) and FATIGUE (Fatigue) had not resolved. Treatment information was not provided. Patient was advised to take rest and to have non-fatty food. He was hospitalized for one week and lab investigation such as liver, bladder and pancreas CT scan and ultrasound found normal .Had poor bloodwork, dark urine, skin and white of eye yellow. Most recent FOLLOW-UP information incorporated above includes: On 15-Oct-2021: Translation document received on 18-OCT-2021, relevant medical history, dosage text, event verbatim, reporter's comment are translated and updated.

Case ID	Narrative (Complete)
[redacted]	This case was received via European Medicines Agency (Reference number: [redacted] on 18-Oct-2021 and was forwarded to Moderna on 18-Oct-2021. This regulatory authority case was reported by a consumer and describes the occurrence of ACUTE HEPATIC FAILURE (Acute liver failure) in a 39-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. No Medical History information was reported. On 26-Jun-2021, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 26-Jun-2021, the patient experienced ACUTE HEPATIC FAILURE (Acute liver failure) (seriousness criteria hospitalization, medically significant and life threatening). At the time of the report, ACUTE HEPATIC FAILURE (Acute liver failure) had not resolved. The action taken with mRNA-1273 (Spikevax) (Unknown) was unknown. Patient initial was [redacted] The patient medical history mentioned as nicotine abuse until 2019, bronchial asthma since 6 years old. Patient allergy mention as penicillin, house dust mites, blood counts are enclosed. The patient was autoinflammatory syndrome, DDx macrophage activation syndrome with post Covid vaccination. The patient had malaise symptoms on 26-Jun-2021. On this day, the 2nd COVID vaccination occurred. On 27-Jun-2021, the patient experienced fever up to 39.5° C and recovered on 28-Jun-2021. Laboratory data was mentioned as Blood test revealed elevated,Bilirubin max 33.8 mg/dL-28.7%, GOT up to 2,658 U/L, CPT up to 2,848 U/L. on 01-Sep-2021 Liver values slightly increased. No concomitant medications reported. The patient had Plasmapheresis with 12 FFP each, therapy with tofacitinib and prednisolone. Patient treatment mention as paracetamol 2-3 units 500 mg. Company Comment - This case concerns a 39 year-old male patient with medical history of asthma, who experienced serious unexpected AESI of Acute hepatic failure. The event occurred the same day after second dose of mRNA-1273. The re-challenge is not applicable since the event occurred after second dose and the outcome is not recovered. Patient´s treatment medication (paracetamol) remains a confounder. The benefit-risk relationship of Spikevax is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 18-Oct-2021: Translation received on 19-Oct-2021 included patient initial, medical history, allergy, laboratory data added, treatment information added in narrative, updated translated event verbatim and sender's comment On 25-Oct-2021: Follow-up contain no new information

Case ID	Narrative (Complete)
[redacted]	This case was received via European Medicines Agency (Reference number: [redacted] on 18-Oct-2021 and was forwarded to Moderna on 18-Oct-2021. This regulatory authority case was reported by a pharmacist and describes the occurrence of AUTOIMMUNE HEPATITIS (Autoimmune hepatitis) in a 61-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. Concurrent medical conditions included Post surgical hypothyroidism and Carcinoma epidermoid since 2012. On 19-Jul-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) .5 milliliter. On 17-Aug-2021, the patient experienced AUTOIMMUNE HEPATITIS (Autoimmune hepatitis) (seriousness criteria hospitalization and medically significant). At the time of the report, AUTOIMMUNE HEPATITIS (Autoimmune hepatitis) was resolving. mRNA-1273 (Spikevax) (Intramuscular) was withdrawn on 19-Jul-2021. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medication was given. No treatment medication was given. Company Comment: This case concerns a 61-year-old, female patient with no relevant medical history, who experienced the unexpected event of autoimmune hepatitis. The event autoimmune hepatitis occurred 29 days after the unknown dose number of mRNA-1273 vaccine administration. The rechallenge was not applicable since the only information disclosed was with this unknown dose number. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 18-Oct-2021: Translation document received on 19-Oct-2021 and included no new information.
[redacted]	This case was initially received via [redacted] (Reference number: [redacted] on 14-Oct-2021. The most recent information was received on 22-Feb-2022 and was forwarded to Moderna on 01-Mar-2022. This case, initially reported to the [redacted] by a (physician), was received via the [redacted] (Ref, [redacted]). On an unknown date, the patient received the 1st dose of this vaccination. On an unknown date, body temperature before vaccination: 36.5 degrees Celsius. On 28-Aug-2021, the patient received the 2nd dose of this vaccination. On 01-Sep-2021, hepatic function disorder developed. The patient had a symptom of queasy. On 17-Sep-2021, the patient visited a previous physician. AST and ALT increased to 1,159 IU/L and 1,167 IU/L, respectively. The patient was diagnosed with acute hepatic failure due to decreased hepatic failure with T-Bil 11.4 mg/dL and PT 23.8%. The patient was hospitalized on the same day. On 20-Sep-2021, disorientation was noted. On 21-Sep-2021, the patient was transferred to our hospital for treatment including liver transplantation. The patient was negative for various viral markers and antinuclear antibodies, and the cause of acute hepatic failure was unknown. Although plasma exchange therapy was performed, but hepatic reserve was not improved. On 03-Oct-2021, brain death liver transplantation was performed. On 05-Oct-2021, the patient is being hospitalized. The symptoms did not resolve. The outcome of hepatic function disorder, queasy, acute hepatic failure, disorientation was reported as ongoing and unchanged. Follow-up investigation was tried, but it was not possible because of non-cooperation of the reporter. Follow-up received on 22-FEB-2022 Updated: Lab Data, Narrative Company Comment: The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.

Case ID	Narrative (Complete)
[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 AGEUSIA (Ageusia), ANOSMIA (Anosmia), AUTOIMMUNE HEPATITIS (Autoimmune hepatitis) and MALAISE (Malaise) in a 46-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 047C21A) for COVID-19 vaccination. Concurrent medical conditions included Hypertension, Pre-diabetes, Anxiety depression and Hyperlipidemia. Concomitant products included LISINOPRIL, HCTZ, ESCITALOPRAM and ATORVASTATIN for an unknown indication. On 22-Jul-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 29-Jul-2021, the patient experienced AGEUSIA (Ageusia) (seriousness criteria hospitalization and life threatening), ANOSMIA (Anosmia) (seriousness criteria hospitalization and life threatening), AUTOIMMUNE HEPATITIS (Autoimmune hepatitis) (seriousness criteria hospitalization, medically significant and life threatening) and MALAISE (Malaise) (seriousness criteria hospitalization and life threatening). At the time of the report, AGEUSIA (Ageusia), ANOSMIA (Anosmia), AUTOIMMUNE HEPATITIS (Autoimmune hepatitis) and MALAISE (Malaise) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 29-Jul-2021, Alanine aminotransferase: increased (High) 1248. On 29-Jul-2021, Aspartate aminotransferase: increased (High) 1065. On 29-Jul-2021, Blood alkaline phosphatase: increased (High) 203. On 29-Jul-2021, Blood bilirubin: increased (High) 2.8. On 29-Jul-2021, Liver function test: increased (High) Increased. On 30-Aug-2021, Biopsy liver: abnormal (abnormal) autoimmune hepatitis. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. No Treatment medication was reported. Company Comment: This case concerns a 46 year old female patient with relevant medical history of Hypertension, Pre-diabetes, Anxiety depression and Hyperlipidemia,who experienced the serious unexpected events of Ageusia, Anosmia, Autoimmune hepatitis and Malaise.The events occurred 7 days after second dose of Spikevax .The rechallenge was not applicable.The patient's medical history of Hypertension, Pre-diabetes, Anxiety depression and Hyperlipidemia along with concomitant medications remains as confounders.The benefit-risk relationship of Spikevax is not affected by this report.

Case ID	Narrative (Complete)
[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 AUTOIMMUNE HEPATITIS (Autoimmune hepatitis), SJOGREN'S SYNDROME (Sjogren's syndrome), FATIGUE (Fatigue) and ARTHRALGIA (Arthralgia) in a 42-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. Concurrent medical conditions included Type 1 diabetes mellitus, Colitis microscopic, Allergy to antibiotic (Allergic to Cepholosporins), Drug allergy (Allergic to myacins), Penicillin allergy and Sulfonamide allergy (Allergic to sulpha). Concomitant products included CETIRIZINE HYDROCHLORIDE (ZYRTEC [CETIRIZINE HYDROCHLORIDE]), BISMUTH SUBSALICYLATE (PEPTO-BISMOL) and INSULIN for an unknown indication. On 01-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 01-May-2021, the patient experienced AUTOIMMUNE HEPATITIS (Autoimmune hepatitis) (seriousness criteria hospitalization, disability and medically significant), SJOGREN'S SYNDROME (Sjogren's syndrome) (seriousness criteria hospitalization, disability and medically significant), FATIGUE (Fatigue) (seriousness criteria hospitalization and disability) and ARTHRALGIA (Arthralgia) (seriousness criteria hospitalization and disability). At the time of the report, AUTOIMMUNE HEPATITIS (Autoimmune hepatitis), SJOGREN'S SYNDROME (Sjogren's syndrome), FATIGUE (Fatigue) and ARTHRALGIA (Arthralgia) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 01-May-2021, Alanine aminotransferase: increased (High) increased. On 01-May-2021, Aspartate aminotransferase: increased (High) increased. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. LAB Data included Antinuclear antibody, Biopsy liver, Blood immunoglobulin G, Ultrasound liver on 1-MAY-2021 with Unknown Results. The patient had extreme fatigue and joint pain starting April/May, had elevated AST/ALT levels in June, confirmed diagnosis of Autoimmune Hepatitis in July and confirmed diagnosis of Sjogrens in September. Company Comment: This case concerns a 42-year-old female subject, with medical history of type I diabetes mellitus and colitis microscopic, who experienced the unexpected and serious events of Autoimmune hepatitis, Sjogren´s syndrome, Fatigue, and Arthralgia. The events of Fatigue and Arthralgia are unexpected as they are retained as serious per the source document Authority reporting. The events occurred approximately 1 month and 1 day after an unknown dose of Moderna COVID-19 Vaccine. The rechallenge is not applicable, as it cannot be assessed. The medical history of type I diabetes mellitus and colitis microscopic, remain confounders. The benefit-risk relationship of Moderna COVID-19 Vaccine is not affected by this report. Source document reports same date for both 1 and both 2. Onset dates captured as per structured field in Regulatory Authority reporting.

Case ID	Narrative (Complete)
[redacted]	This case was received via United States FDA VAERS (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 ACUTE MYOCARDIAL INFARCTION (Acute myocardial infarction), COVID-19 PNEUMONIA (COVID-19 pneumonia), HEPATIC FAILURE (Hepatic failure), HYPOXIA (Hypoxia), PNEUMOTHORAX (Pneumothorax), RESPIRATORY FAILURE (Respiratory failure), SEIZURE LIKE PHENOMENA (Seizure like phenomena), SHOCK (Shock), VENTRICULAR TACHYCARDIA (Ventricular tachycardia) and VOMITING (Vomiting) in a 68-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The patient's past medical history included COPD, Hypertension and Leukemia. On 19-Mar-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 05-Oct-2021, the patient experienced ACUTE MYOCARDIAL INFARCTION (Acute myocardial infarction) (seriousness criteria death, hospitalization and medically significant), COVID-19 PNEUMONIA (COVID-19 pneumonia) (seriousness criteria death, hospitalization and medically significant), HEPATIC FAILURE (Hepatic failure) (seriousness criteria death, hospitalization and medically significant), HYPOXIA (Hypoxia) (seriousness criteria death, hospitalization and medically significant), PNEUMOTHORAX (Pneumothorax) (seriousness criteria death, hospitalization and medically significant), RESPIRATORY FAILURE (Respiratory failure) (seriousness criteria death, hospitalization and medically significant), SEIZURE LIKE PHENOMENA (Seizure like phenomena) (seriousness criteria death, hospitalization and medically significant), SHOCK (Shock) (seriousness criteria death, hospitalization and medically significant), VENTRICULAR TACHYCARDIA (Ventricular tachycardia) (seriousness criteria death, hospitalization and medically significant) and VOMITING (Vomiting) (seriousness criteria death and hospitalization). The patient was treated with DEXAMETHASONE at an unspecified dose and frequency; REMDESIVIR for COVID-19 pneumonia, at an unspecified dose and frequency; NOREPINEPHRINE BITARTRATE (LEVOPHED BITARTRAT) at an unspecified dose and frequency and PROPOFOL at an unspecified dose and frequency. The patient died on 05-Oct-2021. The cause of death was not reported. It is unknown if an autopsy was performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 05-Oct-2021, Electrocardiogram: st segment elevation (abnormal) ST segment elevation. On 05-Oct-2021, Oxygen saturation: 80 (Low) 80. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. The patients has gone through procedures like Cardioversion, Endotracheal intubation, Haemofiltration, Mechanical ventilation, Resuscitation on 5th oct 2021. Also it has been described that the patient has been Transfer from clinic where patient was attempting to receive monoclonal antibody infusion when found to be hypoxic with SPO2 in low 80s. Upon arrival to our hospital vomited and underwent seizure like activity and lost pulse. CPR initiated with v tach. Defibrillated, intubated, started on amiodarone drip. Developed shock and started on levophed and propofol drips. STAT EKG showed ST elevation, code STEMI was called. Ejection fraction 15%. Started on remdesevir for covid pneumonia but stopped due to liver failure. Given dexamethasone. Developed right sided pneumothorax and developed renal failure requiring CRRT. Increasing respiratory failure with max vent settings and flolan. Family decided to transition to comfort care.

Case ID	Narrative (Complete)
[redacted]	This regulatory authority case was reported by a physician and describes the occurrence of LIVER INJURY (Liver injury) in a 49-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) (batch no. 3003188) for COVID-19 vaccination. No Medical History information was reported. On 07-Jul-2021, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (unknown route) 1 dosage form. On 09-Jul-2021, after starting mRNA-1273 (COVID-19 Vaccine Moderna), the patient experienced LIVER INJURY (Liver injury) (seriousness criteria hospitalization and medically significant). At the time of the report, LIVER INJURY (Liver injury) outcome was unknown. For mRNA-1273 (COVID-19 Vaccine Moderna) (Unknown), the reporter considered LIVER INJURY (Liver injury) to be possibly related. Patient has medical history like gluten intolerance and as of 09-Jul-2021, the patient presented with: pronounced abdominal cramps, back pain, clinically and laboratory-confirmed hepatitis with elevated transaminases, itching, dark urine, light-colored stools. On Jul-2021, the reporter states that the problem has not yet resolved, but that but that it was not severe. No concomitant medication was reported. No treatment medication was reported. Company Comment This case refers to a 49-year-old male patient with no relevant medical history who experienced the unexpected event of Liver Injury approximately 2 days after the first dose of Moderna COVID-19 Vaccine. Rechallenge was assessed as not applicable. The event was considered related to the vaccine per the reporter's assessment. The benefit-risk relationship of Moderna COVID-19 Vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 20-Oct-2021: Translation received on 21-Oct-2021 with translated case narrative and sender's comments include patient event info.
[redacted]	This case was received via European Medicines Agency (Reference number [redacted], on 22-Oct-2021 and was forwarded to Moderna on 22-Oct-2021. This regulatory authority case was reported by a physician and describes the occurrence of HEPATITIS ACUTE ([redacted]) in a 66-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3001939 Moderna/Lonza) for COVID-19 vaccination. No Medical History information was reported. On 10-May-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 14-May-2021, the patient experienced HEPATITIS ACUTE ([redacted] (seriousness criterion medically significant). At the time of the report, HEPATITIS ACUTE [redacted] was resolving. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Concomitant and treatment medications were not reported. Company comment This case concerns a 66-year-old, male patient with no relevant medical history, who experienced the unexpected event of hepatitis acute. The event hepatitis acute occurred 4 days after the first dose of mRNA-1273 vaccine administration. The rechallenge was not applicable, as the event occurred after the first dose and no mention of other dose. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. The RA SD captured the reaction/event as reported by primary source as hepatitis aguda alcohólica and it was coded as hepatitis acute instead of acute alcoholic hepatitis. Also, the RA SD captured the onset latency and onset from the last dose as 5 days instead of 4 days, RA SD coding was captured and maintained.

Case ID	Narrative (Complete)
[redacted]	This case was received via United States FDA VAERS (Reference number: [redacted] on 26-Oct-2021 and was forwarded to Moderna on 26-Oct-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of ACUTE HEPATIC FAILURE (Acute hepatic failure) in a 31-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 048F21A) for COVID-19 vaccination. Concurrent medical conditions included Drug allergy (Clindamycin), Penicillin allergy, Type 1 diabetes mellitus, Endometriosis and Hypothyroidism. Concomitant products included INSULIN DETEMIR (LEVEMIR) for an unknown indication. On 30-Sep-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 04-Oct-2021, the patient experienced ACUTE HEPATIC FAILURE (Acute hepatic failure) (seriousness criteria death, hospitalization and medically significant). The patient died on 08-Oct-2021. The reported cause of death was Acute hepatic failure. It is unknown if an autopsy was performed. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No treatment medications provided by the reporter. This case concerns a 31-year-old, female patient with medical history of type 2 diabetes mellitus, who experienced the unexpected serious adverse event of special interest of acute hepatic failure. The event occurred approximately 4 days after the first dose of Spikevax (Moderna COVID-19 vaccine) and had a fatal outcome, with death occurring 4 days after the event on set. It is not known if an autopsy was performed to the patient. The rechallenge was not applicable since the event occurred after the first dose and the patient died. The medical history diabetes mellitus could remain as a confounding factor. The benefit-risk relationship of Spikevax (Moderna COVID-19 vaccine) is not affected by this report.
[redacted]	This case was initially received via European Medicines Agency (Reference number: [redacted] on 27-Oct-2021. The most recent information was received on 12-Nov-2021 and was forwarded to Moderna on 12-Nov-2021. This regulatory authority case was reported by a physician and describes the occurrence of HEPATITIS FULMINANT (Acute fulminant hepatitis) in a 53-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The patient's past medical history included COVID-19 in November 2020. On 10-Aug-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 12-Oct-2021, the patient experienced HEPATITIS FULMINANT (Acute fulminant hepatitis) (seriousness criteria hospitalization, medically significant and life threatening). At the time of the report, HEPATITIS FULMINANT (Acute fulminant hepatitis) was resolving. mRNA-1273 (Spikevax) (Intramuscular) was withdrawn on an unknown date. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medications were reported. Treatment information was not provided. Company Comment : This case concerns a 53-year old, female subject with a medical history of COVID-19 infection, who experienced the serious unexpected AESI of Acute fulminant hepatitis. The event, with seriousness criteria of Hospitalization and Life threatening, occurred 2 months 2 days after a dose of mRNA 1273 VACCINE, dose number unknown. At the time of the report, outcome of the events was Recovering/ Resolving. The benefit-risk relationship of mRNA 1273 VACCINE is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 12-Nov-2021: Significant Follow up received includes information on medical history. On 12-Nov-2021: Translation doc received on 15-Nov-2021 includes, No New information.

Case ID	Narrative (Complete)
[redacted]	This case was received via European Medicines Agency (Reference number: [redacted] on 28-Oct-2021 and was forwarded to Moderna on 28-Oct-2021. This regulatory authority case was reported by a physician and describes the occurrence of HEPATITIS ACUTE (Fever and cough. Hospitalized for acute hepatitis on Sep 2019. Rapid onset of acute kidney failure until dialysis treatment. Signs of hyperacute inflammatory syndrome. CID), PYREXIA (Fever and cough. Hospitalized for acute hepatitis on Sep 2019. Rapid onset of acute kidney failure until dialysis treatment. Signs of hyperacute inflammatory syndrome. CID), DISSEMINATED INTRAVASCULAR COAGULATION (Fever and cough. Hospitalized for acute hepatitis on Sep 2019. Rapid onset of acute kidney failure until dialysis treatment. Signs of hyperacute inflammatory syndrome. CID), COUGH (Fever and cough. Hospitalized for acute hepatitis on Sep 2019. Rapid onset of acute kidney failure until dialysis treatment. Signs of hyperacute inflammatory syndrome. CID), ACUTE KIDNEY INJURY (Fever and cough. Hospitalized for acute hepatitis on Sep 2019. Rapid onset of acute kidney failure until dialysis treatment. Signs of hyperacute inflammatory syndrome. CID) and SYSTEMIC INFLAMMATORY RESPONSE SYNDROME (Fever and cough. Hospitalized for acute hepatitis on Sep 2019. Rapid onset of acute kidney failure until dialysis treatment. Signs of hyperacute inflammatory syndrome. CID) in a 69-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 214019) for COVID-19 vaccination. No medical history was reported. Concomitant products included CLARITHROMYCIN for an unknown indication. On 08-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 10-Sep-2021, the patient experienced HEPATITIS ACUTE (Fever and cough. Hospitalized for acute hepatitis on Sep 2019. Rapid onset of acute kidney failure until dialysis treatment. Signs of hyperacute inflammatory syndrome. CID) (seriousness criteria death and medically significant), PYREXIA (Fever and cough. Hospitalized for acute hepatitis on Sep 2019. Rapid onset of acute kidney failure until dialysis treatment. Signs of hyperacute inflammatory syndrome. CID) (seriousness criterion death), DISSEMINATED INTRAVASCULAR COAGULATION (Fever and cough. Hospitalized for acute hepatitis on Sep 2019. Rapid onset of acute kidney failure until dialysis treatment. Signs of hyperacute inflammatory syndrome. CID) (seriousness criteria death and medically significant), COUGH (Fever and cough. Hospitalized for acute hepatitis on Sep 2019. Rapid onset of acute kidney failure until dialysis treatment. Signs of hyperacute inflammatory syndrome. CID) (seriousness criterion death), ACUTE KIDNEY INJURY (Fever and cough. Hospitalized for acute hepatitis on Sep 2019. Rapid onset of acute kidney failure until dialysis treatment. Signs of hyperacute inflammatory syndrome. CID) (seriousness criteria death and medically significant) and SYSTEMIC INFLAMMATORY RESPONSE SYNDROME (Fever and cough. Hospitalized for acute hepatitis on Sep 2019. Rapid onset of acute kidney failure until dialysis treatment. Signs of hyperacute inflammatory syndrome. CID) (seriousness criteria death and medically significant). The patient died on 27-Sep-2021. The reported cause of death was fever and cough. hospitalized for acute hepatitis on sep 2019. rapid onset of acute kidney failure until dialysis treatment. signs of hyperacute inflammatory syndrome. cid, fever and cough. hospitalized for acute hepatitis on sep 2019. rapid onset of acute kidney failure until dialysis treatment. signs of hyperacute inflammatory syndrome. cid, fever and cough. hospitalized for acute hepatitis on sep 2019. rapid onset of acute kidney failure until dialysis treatment. signs of hyperacute inflammatory syndrome. cid, fever and cough. hospitalized for acute hepatitis on sep 2019. rapid onset of acute kidney failure until dialysis treatment. signs of hyperacute inflammatory syndrome. cid and fever and cough. hospitalized for acute hepatitis on sep 2019. rapid onset of acute kidney failure until dialysis treatment. signs of hyperacute inflammatory syndrome. cid. It is unknown if an autopsy was performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 27-Sep-2021, Blood bilirubin:. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. No treatment information mentioned. The patient received the 1st dose of the Spikevax (ex Moderna) vaccine on 04-Aug-2021 at 1:28 pm lot 3004730. Received the 2nd dose on 08-Sep-2021 at 09:45 am lot 214019. Company Comment This case concerns a 69-year-old male patient with no relevant medical history reported, who experienced the unexpected, serious (fatal) events of hepatitis acute, pyrexia, disseminated intravascular coagulation, cough, acute kidney injury and systemic inflammatory response syndrome. The events occurred 2 days after the second dose of mRNA-1273. The rechallenge was not applicable since information about the first dose was not disclosed. The benefit-risk relationship of mRNA-1273 is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 28-Oct-2021: Signficant Translation received on 29-Oct-2021 for initial SD: Time of vaccination, dose details updated. On 29-Oct-2021: Significant followup received: newevent added. On 19-Nov-2021: Follow-up information included no new information.

Case ID	Narrative (Complete)
[redacted]	This case was received via European Medicines Agency (Reference number: [redacted] on 01-Nov-2021 and was forwarded to Moderna on 01-Nov-2021. This regulatory authority case was reported by a physician and describes the occurrence of AUTOIMMUNE HEPATITIS (Autoimmune hepatitis) in a 73-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 3001653) for SARS-CoV-2 vaccination. Concurrent medical conditions included Hypertension arterial, Sleep apnea syndrome and Dyslipidaemia. Concomitant products included BECLOMETASONE DIPROPIONATE, FORMOTEROL FUMARATE (INNOVAIR) and CANDESARTAN CILEXETIL, HYDROCHLOROTHIAZIDE (CANDESARTAN HYDROCHLOROTHIAZIDE ACTAVIS) for an unknown indication. On 05-Apr-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 15-May-2021, the patient experienced AUTOIMMUNE HEPATITIS (Autoimmune hepatitis) (seriousness criteria hospitalization and medically significant). At the time of the report, AUTOIMMUNE HEPATITIS (Autoimmune hepatitis) had 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. This report is linked to [redacted] Company Comment: This case concerns a 73-year-old female patient with no relevant medical history who experienced serious unexpected event of Autoimmune hepatitis. The event occurred approximately one and a half month after the dose of Moderna COVID-19 vaccine. The rechallenge was not applicable since no information about the dose number was disclosed. Very limited information regarding clinical course of the event has been provided at this time. The benefit-risk relationship of Moderna COVID-19 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 01-Nov-2021: Translated document received on 03NOV2021 Contains No new information.
[redacted]	This case was received via [redacted] (Reference number: [redacted] on 02-Nov-2021 and was forwarded to Moderna on 02-Nov-2021. This case was presented at [redacted] Since the proprietary name of the suspect drug was not specified, the drug is handled as a [redacted] product in this case report. A male patient in his 50s was admitted to the hospital for surgery, and pyrexia did not developed in the postoperative course. Since he was a healthcare provider, he was considered among the priority groups for the novel coronavirus vaccination (proprietary name unknown), he received the first dose, and was to be discharged from the hospital after completion of the second dose. After he received the second vaccination, blood tests were conducted before discharge, showing deviation of hepatic enzymes and increased blood total bilirubin; thus, the discharge was postponed. Another blood tests on Day 2 of vaccination showed persisting deviation of hepatic enzymes, and the patient visited the gastroenterology department. The DDW-J 2004 scale for drug-induced liver disorder was 5 or higher, and the patient was diagnosed with suspected drug-induced liver disorder due to vaccination. On Day 3 of vaccination, he was discharged from the hospital, and on Day 14, his hepatic enzymes were normalized. Follow-up investigation will be made.

Case ID	Narrative (Complete)
[redacted]	This literature-non-study case was reported in a literature article and describes the occurrence of AUTOIMMUNE HEPATITIS (autoimmune hepatitis) in a 56-year-old female patient who received mRNA-1273 (COVID 19 Vaccine Moderna) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. LITERATURE REFERENCE: Tan CK, Wong YJ, Wang LM, Ang TL, Kumar R. Autoimmune hepatitis following COVID-19 vaccination: True causality or mere association?. J Hepatol. 2021;75:1239-60 Concomitant products included ROSUVASTATIN for an unknown indication. On 14-Apr-2021, the patient received first dose of mRNA-1273 (COVID 19 Vaccine Moderna) (unknown route) 1 dosage form. On 15-Apr-2021, the patient experienced INFLUENZA LIKE ILLNESS (flu-like symptoms) and MALAISE (malaise). On an unknown date, the patient experienced AUTOIMMUNE HEPATITIS (autoimmune hepatitis) (seriousness criterion medically significant) and INTENTIONAL DOSE OMISSION (she later decided against receiving the recommended second dose). The patient was treated with BUDESONIDE for Autoimmune hepatitis, at an unspecified dose and frequency. At the time of the report, AUTOIMMUNE HEPATITIS (autoimmune hepatitis) was resolving, INFLUENZA LIKE ILLNESS (flu-like symptoms) and MALAISE (malaise) outcome was unknown and INTENTIONAL DOSE OMISSION (she later decided against receiving the recommended second dose) had resolved. Possible DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In 2019, Liver function test: normal (normal) normal. On an unknown date, Alanine aminotransferase: 1,701 u/l 1,701 U/L. On an unknown date, Antinuclear antibody: positive (Positive) Positive. On an unknown date, Aspartate aminotransferase: 1,124 u/l 1,124 U/L. On an unknown date, Biopsy liver: liver biopsy demonstrated portal inflammation with Liver biopsy demonstrated portal inflammation with interface hepatitis, accompanied by conspicuous lobular inflammation with the presence of plasma cell aggregates, rosette formation and apoptotic hepatocytes. The histological features are in-keeping with an AIH-type pattern. Eosinophils were also identified, raising the possibility of drug association. Early young fibrosis is noted in the portal regions and would be compatible with recent subacute injury.. On an unknown date, Blood albumin: 46 g/l 46 g/L. On an unknown date, Blood alkaline phosphatase: 298 u/l 298 U/L. On an unknown date, Blood bilirubin: 102 lmol/l 102 lmol/L. On an unknown date, Blood immunoglobulin G: 32.6 g/l serum IgG level was raised (32.6 G/L).. On an unknown date, Cytomegalovirus test: negative (Negative) Negative. On an unknown date, Eosinophil count: present Eosinophils were also identified, raising the possibility of drug association. On an unknown date, Epstein-Barr virus test: negative (Negative) Negative. On an unknown date, Hepatitis A virus test: negative (Negative) Negative. On an unknown date, Hepatitis B virus test: negative (Negative) Negative. On an unknown date, Hepatitis C virus test: negative (Negative) Negative. On an unknown date, Hepatitis E virus test: negative (Negative) Negative. On an unknown date, Herpes simplex test: negative (Negative) Negative. On an unknown date, Histology: aih-type pattern The histological features are inkeeping with an AIH-type pattern. Early young fibrosis is noted in the portal regions and would be compatible with recent subacute injury.. On an unknown date, International normalised ratio: 1.0 1.0. On an unknown date, Laboratory test: the initial laboratory studies showed that she had The initial laboratory studies showed that she had hepatocellular injury. On an unknown date, Physical examination: physical examination was normal except for scleral physical examination was normal except for scleral icterus.. On an unknown date, Ultrasound abdomen: unremarkable unremarkable. The action taken with mRNA-1273 (COVID 19 Vaccine Moderna) (Unknown) was unknown. For mRNA-1273 (COVID 19 Vaccine Moderna) (Unknown), the reporter considered AUTOIMMUNE HEPATITIS (autoimmune hepatitis), INFLUENZA LIKE ILLNESS (flu-like symptoms) and MALAISE (malaise) to be possibly related and INTENTIONAL DOSE OMISSION (she later decided against receiving the recommended second dose) to be not applicable. Six weeks after vaccination, she presented with a 1-week history of jaundice, feeling unwell and persistent anorexia. Apart from her regular medication (rosuvastatin 10 mg daily) started 9 years ago, she was not on any other prescription or traditional medication/supplements. cross-sectional abdominal imaging was unremarkable. anti-smooth muscle antibody was positive. The pre-treatment revised original AIH score was 16. Patient is still undergoing steroid therapy. Company Comment: This case concerns a 56-year-old female with no details on medical history, who experienced the unexpected serious event/AESI of Autoimmune hepatitis after mRNA- 1273 Moderna vaccine (Moderna COVID-19 Vaccine). Additionally. The onset of the event occurred approximately 6 weeks after the first dose of mRNA- 1273 vaccine. Clinical manifestations included jaundice, malaise and persistent anorexia. The rechallenge is not applicable since only information about the one dose was disclosed. The benefit-risk relationship of mRNA- 1273 vaccine / Moderna COVID-19 Vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 03-Nov-2021: Follow up received by safety 03-Nov-2021 included an Email with FTA received from SARA team and lab data, product details and events were updated.

Case ID	Narrative (Complete)
[redacted]	This case was received via [redacted] (Reference number: [redacted] on 02-Nov-2021 and was forwarded to Moderna on 02-Nov-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of AUTOIMMUNE HEPATITIS (Autoimmune hepatitis) in a 36-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The patient's past medical history included Anxiety, Refractive errors NOS, Body mass index increased, Seborrheic dermatitis, Atopic dermatitis, Seizure, Major depression, Sinusitis, Maxillary sinus cyst, Fatty liver and Orthopedic procedure (Adjustment of Orthopedic Devices). Concurrent medical conditions included Gastroesophageal reflux disease, Stress, Pain in ankle, Dyslipidemia, Prediabetes and Sleep apnea. Concomitant products included CLONAZEPAM for Anxiety, DICLOFENAC SODIUM for Pain in ankle and Swelling. On 30-Apr-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 19-May-2021, the patient experienced AUTOIMMUNE HEPATITIS (Autoimmune hepatitis). At the time of the report, AUTOIMMUNE HEPATITIS (Autoimmune hepatitis) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 22-Feb-2019, Alanine aminotransferase: 77 (normal) 77. On 22-Feb-2019, Aspartate aminotransferase: 29 (normal) 29. On 19-May-2021, Alanine aminotransferase: 524 (High) increased. On 19-May-2021, Aspartate aminotransferase: 306 (High) increased. On 19-May-2021, Hepatic enzyme: increased (High) increased. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. On 22-Feb-2019, baseline AST 29 and ALT was 77. Always previously the AST was in the 20s for year prior. And the ALT was between 50-77 in years prior. Looks like patient developed an autoimmune hepatitis after the COVID 19 Moderna shot was administered. The liver enzymes went from 50's to 500 approximately two weeks after the shot. AST was 306, and ALT was 524. The baseline ALT was 77 and AST was 29. Treatment medications were not reported. Company Comment - This case concerns a 36-year-old male patient with a history of Body mass index increased and Fatty liver, who experienced the unexpected event of Autoimmune hepatitis (AESI). The event occurred nineteen days after the second dose of the Moderna COVID-19 vaccine. The rechallenge was not applicable as no information about additional dosing was disclosed. The history of Body mass index increased and Fatty liver remain confounders. The benefit-risk relationship of Moderna COVID-19 vaccine is not affected by this report.

Case ID	Narrative (Complete)
[redacted]	This case was received via United States FDA VAERS (Reference number: [redacted] on 02-Nov-2021 and was forwarded to Moderna on 02-Nov-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of ASTHENIA (Asthenia), ATELECTASIS (Atelectasis), BACK PAIN (Back pain), CHEST PAIN (Chest pain), CONDITION AGGRAVATED (Condition aggravated), CYANOSIS (Cyanosis), DISSEMINATED INTRAVASCULAR COAGULATION (Disseminated intravascular coagulation), DYSPNOEA (Dyspnoea), DYSSTASIA (Dysstasia), ENTEROCOCCAL BACTERAEMIA (Enterococcal bacteraemia), FLUID INTAKE REDUCED (Fluid intake reduced), HEPATIC FAILURE (Hepatic failure), HYPERVENTILATION (Hyperventilation), ILLNESS (Illness), IMPAIRED SELF-CARE (Impaired self-care), LUNG INFILTRATION (Lung infiltration), VACCINATION COMPLICATION (Malaise), OROPHARYNGEAL PAIN (Oropharyngeal pain), PAIN (Pain), PAINFUL RESPIRATION (Painful respiration), PNEUMONIA (Pneumonia), PSEUDOMONAL BACTERAEMIA (Pseudomonal bacteraemia), PYREXIA (Pyrexia), RENAL FAILURE (Renal failure), RESPIRATORY ARREST (Respiratory arrest), RESPIRATORY FAILURE (Respiratory failure), RESPIRATORY TRACT CONGESTION (Respiratory tract congestion), THROMBOTIC THROMBOCYTOPENIC PURPURA (Thrombotic thrombocytopenic purpura), INFLUENZA (tested positive for flu) and COVID-19 (COVID-19) in a 55-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 003C21A) for COVID-19 vaccination. The patient's past medical history included Overweight. Concurrent medical conditions included Depression and Rheumatoid arthritis. Concomitant products included BUPROPION and HYDROXYCHLOROQUINE for an unknown indication. On 24-Apr-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 08-Sep-2021, the patient experienced ASTHENIA (Asthenia) (seriousness criteria death, hospitalization, disability and life threatening), ATELECTASIS (Atelectasis) (seriousness criteria death, hospitalization, disability and life threatening), BACK PAIN (Back pain) (seriousness criteria death, hospitalization, disability and life threatening), CHEST PAIN (Chest pain) (seriousness criteria death, hospitalization, disability and life threatening), CONDITION AGGRAVATED (Condition aggravated) (seriousness criteria death, hospitalization, disability and life threatening), CYANOSIS (Cyanosis) (seriousness criteria death, hospitalization, disability and life threatening), DISSEMINATED INTRAVASCULAR COAGULATION (Disseminated intravascular coagulation) (seriousness criteria death, hospitalization, disability, medically significant and life threatening), DYSPNOEA (Dyspnoea) (seriousness criteria death, hospitalization, disability and life threatening), DYSSTASIA (Dysstasia) (seriousness criteria death, hospitalization, disability and life threatening), ENTEROCOCCAL BACTERAEMIA (Enterococcal bacteraemia) (seriousness criteria death, hospitalization, disability, medically significant and life threatening), FLUID INTAKE REDUCED (Fluid intake reduced) (seriousness criteria death, hospitalization, disability and life threatening), HEPATIC FAILURE (Hepatic failure) (seriousness criteria death, hospitalization, disability, medically significant and life threatening), HYPERVENTILATION (Hyperventilation) (seriousness criteria death, hospitalization, disability and life threatening), IMPAIRED SELF-CARE (Impaired self-care) (seriousness criteria death, hospitalization, disability and life threatening), LUNG INFILTRATION (Lung infiltration) (seriousness criteria death, hospitalization, disability and life threatening), VACCINATION COMPLICATION (Malaise) (seriousness criteria death, hospitalization, disability and life threatening), OROPHARYNGEAL PAIN (Oropharyngeal pain) (seriousness criteria death, hospitalization, disability and life threatening), PAIN (Pain) (seriousness criteria death, hospitalization, disability and life threatening), PAINFUL RESPIRATION (Painful respiration) (seriousness criteria death, hospitalization, disability and life threatening), PNEUMONIA (Pneumonia) (seriousness criteria death, hospitalization, disability, medically significant and life threatening), PSEUDOMONAL BACTERAEMIA (Pseudomonal bacteraemia) (seriousness criteria death, hospitalization, disability, medically significant and life threatening), PYREXIA (Pyrexia) (seriousness criteria death, hospitalization, disability and life threatening), RENAL FAILURE (Renal failure) (seriousness criteria death, hospitalization, disability, medically significant and life threatening), RESPIRATORY ARREST (Respiratory arrest) (seriousness criteria death, hospitalization, disability, medically significant and life threatening), RESPIRATORY FAILURE (Respiratory failure) (seriousness criteria death, hospitalization, disability, medically significant and life threatening), RESPIRATORY TRACT CONGESTION (Respiratory tract congestion) (seriousness criteria death, hospitalization, disability and life threatening) and THROMBOTIC THROMBOCYTOPENIC PURPURA (Thrombotic thrombocytopenic purpura) (seriousness criteria death, hospitalization, disability, medically significant and life threatening). On 09-Sep-2021, the patient experienced ILLNESS (Illness) (seriousness criteria death, hospitalization, disability and life threatening). On 13-Sep-2021, the patient experienced COVID-19 (COVID-19) (seriousness criteria death, hospitalization, disability and life threatening). On an unknown date, the patient experienced INFLUENZA (tested positive for flu) (seriousness criteria death and hospitalization). The patient was hospitalized on 13-Sep-2021 due to ASTHENIA, ATELECTASIS, BACK PAIN, CHEST PAIN, CONDITION AGGRAVATED, COVID-19, CYANOSIS, DISSEMINATED INTRAVASCULAR COAGULATION, DYSPNOEA, DYSSTASIA, ENTEROCOCCAL BACTERAEMIA, FLUID INTAKE REDUCED, HEPATIC FAILURE, HYPERVENTILATION, ILLNESS, IMPAIRED SELF-CARE, INFLUENZA, LUNG INFILTRATION, OROPHARYNGEAL PAIN, PAIN, PAINFUL RESPIRATION, PNEUMONIA, PSEUDOMONAL BACTERAEMIA, PYREXIA, RENAL FAILURE, RESPIRATORY ARREST, RESPIRATORY FAILURE, RESPIRATORY TRACT CONGESTION, THROMBOTIC THROMBOCYTOPENIC PURPURA and VACCINATION COMPLICATION. The patient was treated with GUAIFENESIN (MUCINEX) for Adverse event, at an unspecified dose and frequency; VITAMIN C [ASCORBIC ACID] for Adverse event, at an unspecified dose and frequency and HEPARIN for Adverse event, at an unspecified dose and frequency. The patient died on 09-Oct-2021. The reported cause of death was abrupt discontinuation of hydroxychloroquine for rheumatoid arthritis and antibody dependent enhancement of influenza due to covid vaccine.. It is unknown if an autopsy was performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 08-Sep-2021, Blood culture: positive (Positive) positive for streptoccocus pneumonia. On 08-Sep-2021, Influenza virus test positive: positive (Positive) Positive. On 08-Sep-2021, Oxygen saturation decreased: decreased (Low) decreased. On 08-Sep-2021, SARS-CoV-2 antibody test: positive (Positive) Positive IgG antibodies. On 08-Sep-2021, SARS-CoV-2 test: negative (Negative) negative and positive (Positive) positive IgG antibodies. On 08-Sep-2021, Sputum culture positive: positive (Positive) positive for streptoccocus pneumonia.. On 13-Sep-2021, Angiogram: abnormal (abnormal) No CT angiographic evidence of pulmonary embolus is seen. There are bilateral lower lung subsegmental atelectasis. Mild bilateral pulmonary infiltrates are seen.. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Patient stopped taking hydroxychloroquine and started taking a supplement from another country called RT King and reported improvement in arthritis symptoms.No concomitant product was provided. Patient was treated with maximal critical care management including broad spectrum antibiotics, ventilation, continuous renal replacement therapy, blood/platelet transfusions, chest tube, OG tube feedings, and anticoagulation initially that was later discontinued. Patient had minimal responsiveness to pain only after sedatio

Case ID	Narrative (Complete)
[redacted]	This spontaneous case was reported by a consumer and describes the occurrence of LIVER INJURY (liver damage) in a 66-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 939904) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 29-Oct-2021, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. In 2021, the patient experienced LIVER INJURY (liver damage) (seriousness criterion medically significant). 2021, the patient experienced LYMPHOPENIA (lymphopenia). On 30-Oct-2021, the patient experienced VACCINATION COMPLICATION (laid me really flat), ILLNESS (She felt really sick), PYREXIA (fever), NAUSEA (nausea) and HEADACHE (headache). 30-Oct-2021, the patient experienced CHILLS (chills). The patient was treated with NAPROXEN SODIUM (ALEVE) at a dose of 1 dosage form and DIPHENHYDRAMINE, PARACETAMOL (EXTRA STRENGTH TYLENOL PM) at a dose of 2 extra strength Tylenol. At the time of the report, LIVER INJURY (liver damage), VACCINATION COMPLICATION (laid me really flat), LYMPHOPENIA (lymphopenia), ILLNESS (She felt really sick), CHILLS (chills), PYREXIA (fever), NAUSEA (nausea) and HEADACHE (headache) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 01-Nov-2021, Blood test: elevated alt and ast which is indicative of liver (High) ALT increased she had blood work which showed an elevated ALT and AST which is indicative of liver damage.. On 01-Nov-2021, Lymphocyte count: low (Low) She also had some lymphopenia as her lymphocyte count was low.. On 04-Nov-2021, Blood test: counts were improving (normal) counts were improving. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Patient after receiving the booster dose it laid really flat. patient felt really sick with chills, fever, nausea, and headache and took 2 extra strength Tylenol, then took an additional 2 extra strength Tylenol 6 hours later. patient also took an Aleve the following morning.On Monday 1NOV2021 patient had blood work which showed an elevated ALT and AST which is indicative of liver damage. patient also had some lymphopenia as the lymphocyte count was low. The primary care doctor of patient advised her to stop taking her statins, NSAIDS, and Vitamins. patient had additional blood work on 4NOV2021 which showed these counts were improving Company's comment: This is a spontaneous case concerning a 66-year-old, female patient with no relevant medical history, who experienced the unexpected serious events of liver injury. The events occurred approximately 1 day after the third dose of using mRNA-1273 . The rechallenge was unknown since no information about the first dose was disclosed. The benefit-risk relationship of using mRNA-1273 is not affected by this report. This case was linked to [redacted] (Patient Link).
[redacted]	This case was received via European Medicines Agency (Reference number: [redacted]) on 09-Nov-2021 and was forwarded to Moderna on 09-Nov-2021. This regulatory authority case was reported by a consumer and describes the occurrence of AUTOIMMUNE HEPATITIS (Autoimmune hepatitis) in a 52-year-old male patient who received mRNA-1273 (Spikevax) for Prophylactic vaccination. No Medical History information was reported. On 27-Jun-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 31-Jul-2021, the patient experienced AUTOIMMUNE HEPATITIS (Autoimmune hepatitis) (seriousness criteria hospitalization and medically significant). At the time of the report, AUTOIMMUNE HEPATITIS (Autoimmune hepatitis) had resolved with sequelae. Patient was experienced severe jaundice four weeks after the second vaccination. No concomitant and treatment information were reported by the reporter. Company Comment - This case concerns a 52-year-old, male patient with no relevant medical history, who experienced the unexpected event of Autoimmune Hepatitis. The event occurred approximately 1 month 5 days after the second dose of mRNA-1273 (Moderna covid-19 vaccine); and presented as severe jaundice. The rechallenge was not applicable as event occurred after second dose. 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 09-Nov-2021: Translation received on 10-Nov-2021 contain event information updated.

Case ID	Narrative (Complete)
[redacted]	This case was received via [redacted] (Reference number: [redacted]) on 09-Nov-2021 and was forwarded to Moderna on 09-Nov-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of ABDOMINAL SYMPTOM (Abdominal symptom), BLOOD PRESSURE INCREASED (Blood pressure increased), DIARRHOEA (Diarrhoea), HEPATIC ENZYME ABNORMAL (Hepatic enzyme abnormal), INFLUENZA LIKE ILLNESS (Influenza like illness), LIVER INJURY (Liver injury), MUSCULOSKELETAL DISCOMFORT (Musculoskeletal discomfort), PAROSMIA (Parosmia) and TASTE DISORDER (Taste disorder) in a 40-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The patient's past medical history included Homocysteinaemia. Concurrent medical conditions included Drug allergy (sulfa drug allergy), Latex allergy, Drug allergy (Amoxicillin drug allergy), Vegetable allergy (Celery allergy), Fibromyalgia, Endometriosis and Migraine hemiplegic. Concomitant products included TOPIRAMATE (TOPAMAX), DULOXETINE HYDROCHLORIDE (CYMBALTA), CEFIXIME (FLEXERIL [CEFIXIME]), ASPIRIN [ACETYLSALICYLIC ACID] and FAMOTIDINE (PEPCID [FAMOTIDINE]) for an unknown indication. On 01-Mar-2021, the patient received dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 01-Mar-2021, the patient experienced ABDOMINAL SYMPTOM (Abdominal symptom) (seriousness criterion disability), BLOOD PRESSURE INCREASED (Blood pressure increased) (seriousness criterion disability), DIARRHOEA (Diarrhoea) (seriousness criterion disability), HEPATIC ENZYME ABNORMAL (Hepatic enzyme abnormal) (seriousness criterion disability), INFLUENZA LIKE ILLNESS (Influenza like illness) (seriousness criterion disability), LIVER INJURY (Liver injury) (seriousness criteria disability and medically significant), MUSCULOSKELETAL DISCOMFORT (Musculoskeletal discomfort) (seriousness criterion disability), PAROSMIA (Parosmia) (seriousness criterion disability) and TASTE DISORDER (Taste disorder) (seriousness criterion disability). At the time of the report, ABDOMINAL SYMPTOM (Abdominal symptom), BLOOD PRESSURE INCREASED (Blood pressure increased), DIARRHOEA (Diarrhoea), HEPATIC ENZYME ABNORMAL (Hepatic enzyme abnormal), INFLUENZA LIKE ILLNESS (Influenza like illness), LIVER INJURY (Liver injury), MUSCULOSKELETAL DISCOMFORT (Musculoskeletal discomfort), PAROSMIA (Parosmia) and TASTE DISORDER (Taste disorder) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Hepatic enzyme abnormal: 1600 (High) liver enzymes were over 1600.. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No treatment medication was reported Patient had chronic crick in the neck, ultrasound of the abdomen, Blood test and full blood panel done. Company Comment - This case concerns a 40-year-old, female patient with previous medical history of Hyperhomocysteinaemia, who experienced the unexpected serious events of Abdominal symptom, Blood pressure increased, Diarrhoea, Hepatic enzyme abnormal, Influenza like illness, Musculoskeletal discomfort, Parosmia, Taste disorder and the unexpected serious AESI event of liver injury. Ultrasound abdomen and blood test are also reported in the case. The events occurred on the same day after the dose of mRNA-1273. The rechallenge was not applicable as the outcome of the events is not recovered and no dose number was reported. Concomitant medication TOPIRAMATE and DULOXETINE HYDROCHLORIDE could be potentially confounder for liver injury. Concomitant medication DULOXETINE HYDROCHLORIDE, CEFIXIME and FAMOTIDINE could be potentially confounder for diarrhea. Concomitant medication CEFIXIME could be potentially confounder for abdominal symptom. Abdominal symptom, diarrhoea, Hepatic enzyme abnormal and liver injury could be in connection to each other. Patient´s medical history of Hyperhomocysteinaemia could be confounder. The benefit-risk relationship of mRNA-1273 is not affected by this report. Events terms and seriousness assessed as per Regulatory Authority reporting.

Case ID	Narrative (Complete)
[redacted]	This literature-non-study case was reported in a literature article and describes the occurrence of AUTOIMMUNE HEPATITIS (Autoimmune hepatitis) in a 52-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. LITERATURE REFERENCE: Goulas A, Kafiri G,Kranidiot H,Manolakopoulos S,et al. A typical autoimmune hepatitis (AIH) case following Covid-19 mRNA vaccination. More than a coincidence?. Liver Int. 2021 No Medical History information was reported. On 11-May-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On an unknown date, the patient experienced AUTOIMMUNE HEPATITIS (Autoimmune hepatitis) (seriousness criterion medically significant). The patient was treated with PREDNISOLONE for Malaise, Jaundice and Autoimmune hepatitis, at a dose of 50 mg once a day and AZATHIOPRINE for Malaise, Jaundice and Autoimmune hepatitis, at a dose of 50 mg once a day. At the time of the report, AUTOIMMUNE HEPATITIS (Autoimmune hepatitis) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Alanine aminotransferase (0-55): 936 u/l ALT: 936 U/L (0- 55 U/L). On an unknown date, Antinuclear antibody: positive (Positive) Antinuclear antibodies (1/320) and anti-smooth muscle antibody (ASMA) were positive.. On an unknown date, Aspartate aminotransferase (5-34): 350 u/l AST: 350 U/L (5-34 U/L),\. On an unknown date, Bilirubin conjugated (0-0.5): 5,5mg/dl D.Bil: 5,5mg/dL (0-0,5 mg/dL). On an unknown date, Blood alkaline phosphatase (40-150): 169 u/l ALP: 169 U/L (40-150 U/L). On an unknown date, Blood bilirubin (0.2-1.2): 9,06mg/dl T.Bil: 9,06mg/dL (0,2-1,2 mg/dL). On an unknown date, Blood immunoglobulin G (700-1600): elevated (High) IgG levels were elevated at 2396mg/dL (700-1600mg/dL). On an unknown date, Blood test: normal liver blood tests during previous periodica normal liver blood tests during previous periodical checkup. On an unknown date, C-reactive protein (<0.1-Unknown): 1,25mg/dl CRP: 1,25mg/dL (<1.0 mg/dL). On an unknown date, Cytomegalovirus test: negative (Negative) Serology for hepatitis A, B, C, E virus, CMV and EBV were negative.. On an unknown date, Epstein-Barr virus antibody: negative (Negative) Serology for hepatitis A, B, C, E virus, CMV and EBV were negative.. On an unknown date, Gamma-glutamyltransferase (9-36): 810 u/l 810 U/L (9-36 U/L). On an unknown date, Hepatitis A antibody: negative (Negative) Serology for hepatitis A, B, C, E virus, CMV and EBV were negative.. On an unknown date, Hepatitis B antibody: negative (Negative) Serology for hepatitis A, B, C, E virus, CMV and EBV were negative.. On an unknown date, Hepatitis C antibody: negative (Negative) Serology for hepatitis A, B, C, E virus, CMV and EBV were negative.. On an unknown date, Hepatitis E antibody: negative (Negative) Serology for hepatitis A, B, C, E virus, CMV and EBV were negative.. On an unknown date, Histology: liver histology (9 portal tracks) showed moderate Liver histology (9 portal tracks) showed moderate to severe inflammatory infiltration consisting of lymphocytes, plasmatocytes, histiocytes, few eosinophiles and neutrophiles with the presence of mild periportal hepatitis. Mild lobular inflammation, apoptotic bodies, hepatocytes with feathery degeneration of the cytoplasm and rosette formation were observed (Image. On an unknown date, Magnetic resonance cholangiopancreatography: normal (normal) MRCP was normal. and Abdominal ultrasound and MRCP were normal.. On an unknown date, Red blood cell sedimentation rate: 25 mm/h ESR: 25 mm/h. On an unknown date, Smooth muscle antibody: Antinuclear antibodies (1/320) and anti-smooth muscle antibody (ASMA) were positive.. On an unknown date, Ultrasound abdomen: normal (normal) Abdominal ultrasound was normal.. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown) was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter considered AUTOIMMUNE HEPATITIS (Autoimmune hepatitis) to be possibly related. No relevant concomitant medications were reported. No treatment information was provided. Patient with no medication history or alcohol abuse and normal liver blood tests during previous periodical checkup presented histologically confirmed AIH after 1st dose of the Moderna vaccine This is a literature case concerning a 52 years old, female patient with no clinical history who experienced the unexpected event of Autoimmune hepatitis. The event occurred following first dose of mRNA-1273 vaccine. Two weeks after receiving first dose the patient presented with malaise, jaundice and abnormal liver blood tests. Antinuclear antibodies (1/320) and anti-smooth muscle antibody (ASMA) were positive. Liver histology (9 portal tracks) showed moderate to severe inflammatory infiltration consisting of lymphocytes, plasmatocytes, histiocytes, few eosinophiles and neutrophiles with the presence of mild periportal hepatitis. The rechallenge was not applicable since only information about the second dose was disclosed. The patient started prednisolone per os daily followed by azathioprine, with gradual improvement of the symptoms and the laboratory tests. The benefit-risk relationship of Moderna Covid 19 vaccine is not affected by this report.. The patient started prednisolone 50mg per os daily followed by azathioprine 50mg daily, with gradual improvement of the symptoms and the laboratory tests. The patient did not have any known background of autoimmunity. The clinical and laboratory data were compatible with typical AIH while the simplified AIH score proved a definite AIH case. Most recent FOLLOW-UP information incorporated above includes: On 11-Nov-2021: Follow up received by safety 11-Nov-2021 included an Email with FTA received from SARA team contain significant information in which lab data , Treatment Medications and Drug start date were added.

Case ID	Narrative (Complete)
[redacted]	This case was initially received via European Medicines Agency (Reference number: [redacted] on 09-Nov-2021. The most recent information was received on 19-Nov-2021 and was forwarded to Moderna on 19-Nov-2021. This regulatory authority case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of AUTOIMMUNE HEPATITIS (Autoimmune hepatitis) in a 64-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 214011) for COVID-19 vaccination. The patient's past medical history included Thyroidectomy (Treated by Levothyrox 162.5) in 1994. Concomitant products included LEVOTHYROXINE SODIUM (LEVOTHYROX) for an unknown indication. On 06-Aug-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 05-Oct-2021, after starting mRNA-1273 (Spikevax), the patient experienced AUTOIMMUNE HEPATITIS (Autoimmune hepatitis) (seriousness criterion medically significant). At the time of the report, AUTOIMMUNE HEPATITIS (Autoimmune hepatitis) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 08-Oct-2021, SARS-CoV-2 test: negative (Negative) Negative. No treatment information was provided by the reporter. Company Comment : This is a regulatory authority case concerning a 64-year-old male patient with no relevant medical history, who experienced serious, unexpected event of Autoimmune hepatitis. The event occurred approximately 2 months after the first dose of mRNA-1273 vaccine. No information about second dose was disclosed. Rechallenge is not applicable. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 09-Nov-2021: Translated document received on 11-Nov-2021, included Medical history translated. On 16-Nov-2021: Follow up received contains no new information. On 19-Nov-2021: Follow up received contains updated event autoimmune hepatitis.

Case ID	Narrative (Complete)
[redacted]	This literature-non-study case was reported in a literature article and describes the occurrence of AUTOIMMUNE HEPATITIS (acute severe autoimmune hepatitis) in a 65-year-old female patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for COVID-19 vaccination. LITERATURE REFERENCE: Garrido I, Lopes S, Simoes MS, Liberal R, Lopes J, Carneiro F et al.. Autoimmune hepatitis after COVID-19 vaccine - more than a coincidence. J Autoimmun. 2021;125:102741 The patient's past medical history included Polycythemia vera (JAK2 V617F positive polycythemia vera under pegylated interferon since 2019). Concomitant products included ACETYLSALICYLIC ACID, SERTRALINE and ESOMEPRAZOLE for an unknown indication. 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, after starting mRNA-1273 (Moderna CoviD-19 Vaccine), the patient experienced AUTOIMMUNE HEPATITIS (acute severe autoimmune hepatitis) (seriousness criterion hospitalization). The patient was treated with PREDNISOLONE for Autoimmune hepatitis, at a dose of 60 milligram once a day. At the time of the report, AUTOIMMUNE HEPATITIS (acute severe autoimmune hepatitis) outcome was unknown. Possible DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Alanine aminotransferase: 24u/l 24U/L and 1092u/l 1092U/L - Two weeks after first dose. On an unknown date, Alpha-1 anti-trypsin: normal (normal) normal. On an unknown date, Antibody test: negative (Negative) antineutrophil cytoplasmic antibodies were negative. On an unknown date, Antimitochondrial antibody: negative (Negative) Negative. On an unknown date, Antineutrophil cytoplasmic antibody: negative (Negative) Negative. On an unknown date, Antinuclear antibody: positive (Positive) 1:100, speckled pattern. On an unknown date, Aspartate aminotransferase: 28u/l 28U/L and 1056u/l 1056U/L - Two weeks after first dose. On an unknown date, Autoantibody test: negative (Negative) Negative. On an unknown date, Biopsy liver: abnormal (abnormal) A percutaneous liver biopsy was performed, revealing a marked expansion of the portal tracts due to dense inflammatory infiltrate, with aggregates of plasma cells; severe interface hepatitis and multiple confluent foci of lobular necrosis were also observed.. On an unknown date, Blood alkaline phosphatase: 108u/l 108U/L and 24u/l 24U/L - Two weeks after first dose. On an unknown date, Blood bilirubin: 0.72 mg/dl 0.72 mg/dL and 1.14 mg/dl 1.14 mg/dL - Two weeks after first dose. On an unknown date, Blood immunoglobulin A: normal (normal) normal. On an unknown date, Blood immunoglobulin G: normal (normal) Normal after two weeks from vaccination and elevated (High) Elevated after five weeks from vaccination. On an unknown date, Blood immunoglobulin M: normal (normal) Normal. On an unknown date, Blood iron: normal (normal) Normal. On an unknown date, Ceruloplasmin: normal (normal) Normal. On an unknown date, Full blood count: normal (normal) Normal. On an unknown date, Gamma-glutamyltransferase: 24u/l 24U/L and 329u/l 329U/L - Two weeks after first dose. On an unknown date, International normalised ratio: normal (normal) Normal. On an unknown date, Investigation: negative (Negative) anti-soluble liver antigen was negative. On an unknown date, Polymerase chain reaction: negative (Negative) Polymerase chain reaction for hepatitis B, C and E viruses were negative.. On an unknown date, Serology test: negative (Negative) serology for hepatitis A virus, human immunodeficiency virus, cytomegalovirus, Epstein-Barr virus and herpes simplex virus type 1 and 2 were all negative.. On an unknown date, Smooth muscle antibody: negative (Negative) Negative. On an unknown date, Thyroid function test: normal (normal) Normal. On an unknown date, Ultrasound abdomen: normal (normal) hepatomegaly without cirrhotic morphology, and no biliary dilation or thrombosis.. The action taken with mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown) was unknown. For mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown), the reporter considered AUTOIMMUNE HEPATITIS (acute severe autoimmune hepatitis) to be possibly related. Patient reported that five weeks after vaccination, patient was presented with jaundice and choluria. The patient was admitted for clinical management. Patient symptoms include mild abdominal pain, jaundice and choluria. Treatment with prednisolone was started with a quick improvement of liver function tests and normalization of IgG levels. One month after initial diagnosis, the patient remains well on a tapering course of corticosteroids. Most recent FOLLOW-UP information incorporated above includes: On 11-Nov-2021: Upon review performed on 10-Feb-2021, Symptoms Abdominal pain, Jaundice and Choluria was removed and only the diagnosis 'acute severe autoimmune hepatitis' coded to LLT 'Autoimmune hepatitis' would be retained.

Case ID	Narrative (Complete)
[redacted]	This case was received via European Medicines Agency (Reference number: [redacted] on 10-Nov-2021 and was forwarded to Moderna on 10-Nov-2021. This regulatory authority case was reported by a consumer and describes the occurrence of AUTOIMMUNE HEPATITIS (Autoimmune hepatitis with fatal outcome) in a 77-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3004217) for Prophylactic vaccination. No Medical History information was reported. On 30-Jul-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 04-Aug-2021, the patient experienced AUTOIMMUNE HEPATITIS (Autoimmune hepatitis with fatal outcome) (seriousness criteria death and medically significant). The reported cause of death was autoimmune hepatitis with fatal outcome. It is unknown if an autopsy was performed. Patient medical history mention as depression, dementia, arterial hypertension, hyperlipoproteinemia. On 09-AUG-2021 onset of jaundice and on 14-AUG-2021 hospitalization with initial diagnosis of hepatitis. Patient had Initially very high transaminases and very high bilirubin. Patient was start of therapy with prednisolone and azathioprine. Patient had developed of transient cytopenia, reduction of the azathioprine dose. Reporter comment mention as 05-Nov-2021 The deceased's autopsy took place on 09-Nov-2021 by the forensic medicine department. No relevant concomitant and treatment medications were reported. Company Comment - This is a fatal case that concerns a 77-year-old male patient, with no relevant medical history reported, who experienced the unexpected fatal event of AUTOIMMUNE HEPATITIS. The event occurred five days after the first dose of mRNA-1273, with death occurring tow months later. The rechallenge was not applicable as no additional dose is going to be administered. The benefit-risk relationship of mRNA-1273 is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 10-Nov-2021: Translation document received on 15-Nov-2021 included verbatim added, medical history, event information, general information added in the inarrative. On 12-Nov-2021: Non-Significant Follow up On 12-Nov-2021: Translation document received on 15-Nov-2021 included reporter comment added.

Case ID	Narrative (Complete)
[redacted]	This literature-non-study case was reported in a literature article and describes the occurrence of IMMUNE-MEDIATED HEPATITIS (Immune-mediated hepatitis) in a 47-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. LITERATURE REFERENCE: Tun GSZ, Gleeson D, Dube A, Al-Joudeh A. Immune-mediated hepatitis with the moderna vaccine, no longer a coincidence but confirmed. J Hepatol. 2021 Concurrent medical conditions included Alcohol use (reported minimal alcohol intake). On 26-Apr-2021, the patient received first dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 06-Jul-2021, received second dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 29-Apr-2021, after starting mRNA-1273 (Moderna CoviD-19 Vaccine), the patient experienced IMMUNE-MEDIATED HEPATITIS (Immune-mediated hepatitis) (seriousness criterion medically significant). On 06-Jul-2021, the patient experienced INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (Inappropriate schedule of vaccine administered). The patient was treated with PREDNISOLONE on 21-Jul-2021 for Autoimmune hepatitis, at a dose of 40 milligram once a day. At the time of the report, IMMUNE-MEDIATED HEPATITIS (Immune-mediated hepatitis) was resolving and INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (Inappropriate schedule of vaccine administered) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In 2017, Liver function test: normal (normal) Liver function tests (LFTs) last checked 4 years previously were normal. On 30-Apr-2021, Alanine aminotransferase (10-49): 1048 u/l (High) ALT 1048 U/L. On 30-Apr-2021, Blood albumin (35-50): 41 g/l (normal) albumin 41 g/L. On 30-Apr-2021, Blood alkaline phosphatase (30-130): 229 u/l (High) ALP 229 U/L. On 30-Apr-2021, Blood bilirubin (0-20): 190 µmol/l (High) showed serum bilirubin 190 µmol/L. On 30-Apr-2021, Full blood count: normal (normal) normal. On 30-Apr-2021, International normalised ratio: normal (normal) normal. On 30-Apr-2021, Renal function test: normal (normal) normal. On 25-Jun-2021, Alanine aminotransferase (10-49): 332 u/l (High) ALT falling to 332 U/L. On 25-Jun-2021, Blood bilirubin (0-20): 69 µmol/l (High) bilirubin falling on 25th June to 69 µmol/L. On 20-Jul-2021, Alanine aminotransferase (10-49): 1084 u/l (High) ALT 1084 U/L. On 20-Jul-2021, Blood bilirubin (0-20): 355 µmol/l (High) bilirubin 355 µmol/L. On 20-Jul-2021, Prothrombin time: 18.4 seconds raised PT 18.4 seconds.. On an unknown date, Antinuclear antibody: positive (Positive) serum was positive for Anti-Nuclear Antibody. On an unknown date, Biopsy liver: abnormal (abnormal) Review of the liver biopsy showed acute active hepatitis: widespread areas of bridging necrosis, marked interface hepatitis, lymphoplasmatic inflammation including eosinophils, ballooned hepatocytes, multi-nucleated giant cells, and emperipolesis. There was minimal fibrosis, Ishak stage 1. The pattern of injury on histology was consistent with acute hepatitis, with features of autoimmune hepatitis or possible drug-induced liver injury (DILI), triggering an autoimmune-like hepatitis.. On an unknown date, Blood immunoglobulin G (6-16): 25.1 g/l (High) Serum IgG was raised at 25.1 g/L. On an unknown date, Blood immunoglobulin M (0.5-2): 2.2 g/l (High) 2.2 g/L. On an unknown date, Blood test: improve Prednisolone 40 mg/ day was continued and blood tests continue to improve. On an unknown date, Computerised tomogram abdomen: no significant findings showed no significant findings. On an unknown date, Computerised tomogram pelvis: no significant findings showed no significant findings. On an unknown date, Computerised tomogram thorax: no significant findings showed no significant findings. On an unknown date, Cytomegalovirus test: negative (Negative) Negative. On an unknown date, Epstein-Barr virus test: negative (Negative) Negative. On an unknown date, Hepatitis A virus test: negative (Negative) Negative. On an unknown date, Hepatitis B virus test: negative (Negative) Negative. On an unknown date, Hepatitis C virus test: negative (Negative) Negative. On an unknown date, Hepatitis E virus test: negative (Negative) Negative. On an unknown date, Liver function test: improved Prednisolone 40 mg/ day was continued and LFTs improved. On an unknown date, Magnetic resonance imaging: no significant findings MRI pancreas performed to exclude malignancy, showed no significant findings. On an unknown date, Physical examination: abnormal (abnormal) On examination, patient was alert, deeply jaundiced, with hepatomegaly but no ascites. On an unknown date, Prothrombin time: normalised (normal) On follow-up, PT normalised within 2 weeks.. On an unknown date, Ultrasound abdomen: abnormal (abnormal) Repeat abdominal ultrasound showed a mildly fatty liver, patent portal and hepatic vein flow, with no ascites.. On an unknown date, Ultrasound scan: no significant findings showed no significant findings. For mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown), the reporter considered IMMUNE-MEDIATED HEPATITIS (Immune-mediated hepatitis) and INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (Inappropriate schedule of vaccine administered) to be possibly related. Patient noted malaise and jaundice three days after receiving the 1st Moderna vaccine dose. Patient denied paracetamol use. Patient's jaundice faded and Liver function tests improved. The patient received his 2nd Moderna vaccine dose despite reporting the jaundice to the vaccination centre and the jaundice returned a few days after. After liver biopsy on the 21st July 2021 he was commenced onto Prednisolone Prednisolone was continued and LFTs improved. Patient was discharged on Prednisolone and on follow-up, blood tests continue to improve

Case ID	Narrative (Complete)
	Author concluded that long-term follow up of identified individuals will be essential in determining the prognosis of this immune-mediated liver injury. Company Comment: This literature-non-study case concerns a 47-year-old male patient, with no relevant medical history, who experienced the unexpected events of Immune-mediated hepatitis and Inappropriate schedule of product administration. The event Immune-mediated hepatitis occurred approximately 3 days after receiving the first dose of mRNA-1273 Vaccine. Several lab and imaging tests were done and showed increased results for liver function tests, while Ultrasound, CT scan (Thorax and Abdomen) and MRI. (Pancreas) had no significant findings. A few days after receiving the second dose of the mRNA 1273 vaccine, the patients' jaundice returned. LFT's were again increased and liver biopsy showed acute active hepatitis with features of autoimmune hepatitis or possible drug-induced liver injury. Patient was treated with Prednisolone with subsequent improvement of LFTs. At the time of the report the outcome of the events was unknown. The rechallenge is positive since the event recurred upon readministration of the vaccine. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 11-Nov-2021: Upon review performed on 10-Feb-2022, laboratory tests, dose 1 and dose 2 information, event outcome, addition event were updated

Case ID	Narrative (Complete)
[redacted]	This case was received via [redacted] (Reference number: [redacted]) on 16-Nov-2021 and was forwarded to Moderna on 16-Nov-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of AUTOIMMUNE HEPATITIS (Autoimmune hepatitis), BLOOD TEST (Blood test) and LIVER FUNCTION TEST (Liver function test) in a 64-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. Concurrent medical conditions included Drug allergy (bacitracin), Drug allergy (Neosporin), Drug allergy (morphine) and Asthma. On 06-Mar-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 13-Apr-2021, the patient experienced AUTOIMMUNE HEPATITIS (Autoimmune hepatitis) (seriousness criteria hospitalization and medically significant), BLOOD TEST (Blood test) (seriousness criterion hospitalization) and LIVER FUNCTION TEST (Liver function test) (seriousness criterion hospitalization). At the time of the report, AUTOIMMUNE HEPATITIS (Autoimmune hepatitis), BLOOD TEST (Blood test) and LIVER FUNCTION TEST (Liver function test) had resolved. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Concomitant medications included Aleeve. Treatment information was not provided. Patient was diagnosed with Autoimmune hepatitis. Patient had normal enzyme numbers after getting treated with Prednisone. Patient still have lab work once a month to monitor numbers. Company's comment: This regulatory authority case concerns a 64-year-old male patient with no relevant medical history who experienced serious unexpected events of autoimmune hepatitis. The event occurred approximately one month and a week after the second dose of the Moderna COVID-19 vaccine . The patient was treated with prednisone and at the time of the report, the event was considered resolved. Rechallenge was not applicable as the events occurred after the second dose so no rechallenge was done and thus, recurrence was not applicable. The benefit-risk relationship of product is not affected by this report

Case ID	Narrative (Complete)
[redacted]	This case was received via United States FDA VAERS (Reference number: [redacted]) on 16-Nov-2021 and was forwarded to Moderna on 16-Nov-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of CARDIAC FAILURE (Cardiac failure), DEATH (Death), HEPATIC FAILURE (Hepatic failure), LOSS OF CONSCIOUSNESS (Loss of consciousness), RENAL FAILURE (Renal failure), SYNCOPE (Syncope), ARTHROPATHY (Arthropathy), FALL (Fall), GAIT DISTURBANCE (Gait disturbance), HEAD INJURY (Head injury), WALKING AID USER (Walking aid user) and WHEELCHAIR USER (Wheelchair user) in a 63-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 012M20A and 029A21A) for COVID-19 vaccination. No Medical History information was reported. On 08-Mar-2021, the patient received dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 08-Mar-2021, received dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to I dosage form. On 09-Mar-2021, the patient experienced CARDIAC FAILURE (Cardiac failure) (seriousness criteria death, hospitalization and medically significant), DEATH (Death) (seriousness criteria death, hospitalization and medically significant), HEPATIC FAILURE (Hepatic failure) (seriousness criteria death, hospitalization and medically significant), LOSS OF CONSCIOUSNESS (Loss of consciousness) (seriousness criteria death, hospitalization and medically significant), RENAL FAILURE (Renal failure) (seriousness criteria death, hospitalization and medically significant), SYNCOPE (Syncope) (seriousness criteria death, hospitalization and medically significant), ARTHROPATHY (Arthropathy) (seriousness criteria death and hospitalization), FALL (Fall) (seriousness criteria death and hospitalization), GAIT DISTURBANCE (Gait disturbance) (seriousness criteria death and hospitalization), HEAD INJURY (Head injury) (seriousness criteria death and hospitalization), WALKING AID USER (Walking aid user) (seriousness criteria death and hospitalization) and WHEELCHAIR USER (Wheelchair user) (seriousness criteria death and hospitalization). The patient died on I4-May-202I. The reported cause of death was Arthropathy, Cardiac failure, Fall, Gait disturbance, Head injury, Hepatic failure, Loss of consciousness, Renal failure, Syncope, Walking aid user and Wheelchair user. 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 product use was not provided. Treatment information was not provided. It was stated that patient took first shot on 08-Feb-2021 and a day later he started to lose control of his nerves. He was constantly shaking. Patient could not hold a glass with water without it flying out of his hand accidentally and he needed someone behind him to walk anywhere because he would faint. The second shot was on 08-Mar-2021. The symptoms got worse. This case concerns a death of a 63-year-old, male patient with no relevant medical history, who experienced the unexpected events of cardiac failure, hepatic failure, loss of consciousness, renal failure, syncope, arthropathy, fall, gait disturbance, head injury, walking aid user and wheelchair user, which all required hospitalization and were reported with death as seriousness criteria. The events occurred approximately I day after the a dose of mRNA-I273. It was reported that two doses were administered on same day which seems unlikely. As reported a day after receiving first dose of mRNA-1273 the patient started to lose control of his nerves. He was constantly shaking and he needed someone behind him to walk anywhere because he would faint. After second dose the symptoms got worse. Patient was not able to walk without a walker, which quickly led him to a wheelchair. There was one day that the patient felt too confident and tried to sit at the counter barstool. The patient's legs gave out, or he fainted and landed on the ground and hit his head so hard, he was unconscious. Patient did not leave the hospital and his kidneys failed, then his liver and then his heart. He died 37 days after vaccination. The rechallenge was not applicable. The benefit-risk relationship of mRNA-I273 is not affected by this report. Event seriousness assessed as per Regulatory Authority reporting.

Case ID	Narrative (Complete)
[redacted]	This case was received via [redacted] (Reference number: [redacted]) on 16-Nov-2021 and was forwarded to Moderna on 16-Nov-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of AMMONIA INCREASED (Ammonia increased), ANTI-THYROID ANTIBODY INCREASED (Anti-thyroid antibody increased), AUTOIMMUNE THYROIDITIS (Autoimmune thyroiditis), AXILLARY PAIN (Axillary pain), BLOOD GLUCOSE INCREASED (Blood glucose increased), BLOOD IRON (Blood iron), BLOOD LACTIC ACID (Blood lactic acid), BLOOD THYROID STIMULATING HORMONE INCREASED (Blood thyroid stimulating hormone increased), CHEST X-RAY (Chest X-ray), COLONOSCOPY NORMAL (Colonoscopy normal), CONFUSIONAL STATE (Confusional state), DIABETES MELLITUS (Diabetes mellitus), FATIGUE (Fatigue), FULL BLOOD COUNT (Full blood count), GLYCOSYLATED HAEMOGLOBIN INCREASED (Glycosylated haemoglobin increased), HEPATITIS ACUTE (Hepatitis acute), HYPERAMMONAEMIA (Hyperammonaemia), HYPERSOMNIA (Hypersomnia), LETHARGY (Lethargy), LIVER FUNCTION TEST INCREASED (Liver function test increased), METABOLIC FUNCTION TEST (Metabolic function test), OESOPHAGOGASTRODUODENOSCOPY NORMAL (Oesophagogastroduodenoscopy normal), POSITRON EMISSION TOMOGRAM NORMAL (Positron emission tomogram normal), PROCALCITONIN (Procalcitonin), SARS-COV-2 TEST (SARS-CoV-2 test), SERUM FERRITIN (Serum ferritin), VIRAL TEST NEGATIVE (Viral test negative) and VITAMIN B12 (Vitamin B12) in a 67-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 050E21A and 939901) for COVID-19 vaccination. The patient's past medical history included GERD. Concurrent medical conditions included Drug allergy (sulfa), Hypertension, Squamous cell carcinoma of lung, COPD and Lumbar disc disease. On 17-Sep-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 26-Sep-2021, the patient experienced AMMONIA INCREASED (Ammonia increased) (seriousness criteria disability and life threatening), ANTI-THYROID ANTIBODY INCREASED (Anti-thyroid antibody increased) (seriousness criteria disability and life threatening), AUTOIMMUNE THYROIDITIS (Autoimmune thyroiditis) (seriousness criteria disability, medically significant and life threatening), AXILLARY PAIN (Axillary pain) (seriousness criteria disability and life threatening), BLOOD GLUCOSE INCREASED (Blood glucose increased) (seriousness criteria disability and life threatening), BLOOD IRON (Blood iron) (seriousness criteria disability and life threatening), BLOOD LACTIC ACID (Blood lactic acid) (seriousness criteria disability and life threatening), BLOOD THYROID STIMULATING HORMONE INCREASED (Blood thyroid stimulating hormone increased) (seriousness criteria disability and life threatening), CHEST X-RAY (Chest X-ray) (seriousness criteria disability and life threatening), COLONOSCOPY NORMAL (Colonoscopy normal) (seriousness criteria disability and life threatening), CONFUSIONAL STATE (Confusional state) (seriousness criteria disability and life threatening), DIABETES MELLITUS (Diabetes mellitus) (seriousness criteria disability, medically significant and life threatening), FATIGUE (Fatigue) (seriousness criteria disability and life threatening), FULL BLOOD COUNT (Full blood count) (seriousness criteria disability and life threatening), GLYCOSYLATED HAEMOGLOBIN INCREASED (Glycosylated haemoglobin increased) (seriousness criteria disability and life threatening), HEPATITIS ACUTE (Hepatitis acute) (seriousness criteria disability, medically significant and life threatening), HYPERAMMONAEMIA (Hyperammonaemia) (seriousness criteria disability and life threatening), HYPERSOMNIA (Hypersomnia) (seriousness criteria disability and life threatening), LETHARGY (Lethargy) (seriousness criteria disability and life threatening), LIVER FUNCTION TEST INCREASED (Liver function test increased) (seriousness criteria disability and life threatening), METABOLIC FUNCTION TEST (Metabolic function test) (seriousness criteria disability and life threatening), OESOPHAGOGASTRODUODENOSCOPY NORMAL (Oesophagogastroduodenoscopy normal) (seriousness criteria disability and life threatening), POSITRON EMISSION TOMOGRAM NORMAL (Positron emission tomogram normal) (seriousness criteria disability and life threatening), PROCALCITONIN (Procalcitonin) (seriousness criteria disability and life threatening), SARS-COV-2 TEST (SARS-CoV-2 test) (seriousness criteria disability and life threatening), SERUM FERRITIN (Serum ferritin) (seriousness criteria disability and life threatening), VIRAL TEST NEGATIVE (Viral test negative) (seriousness criteria disability and life threatening) and VITAMIN B12 (Vitamin B12) (seriousness criteria disability and life threatening). At the time of the report, AMMONIA INCREASED (Ammonia increased), ANTI-THYROID ANTIBODY INCREASED (Anti-thyroid antibody increased), AUTOIMMUNE THYROIDITIS (Autoimmune thyroiditis), AXILLARY PAIN (Axillary pain), BLOOD GLUCOSE INCREASED (Blood glucose increased), BLOOD IRON (Blood iron), BLOOD LACTIC ACID (Blood lactic acid), BLOOD THYROID STIMULATING HORMONE INCREASED (Blood thyroid stimulating hormone increased), CHEST X-RAY (Chest X-ray), COLONOSCOPY NORMAL (Colonoscopy normal), CONFUSIONAL STATE (Confusional state), DIABETES MELLITUS (Diabetes mellitus), FATIGUE (Fatigue), FULL BLOOD COUNT (Full blood count), GLYCOSYLATED HAEMOGLOBIN INCREASED (Glycosylated haemoglobin increased), HEPATITIS ACUTE (Hepatitis acute), HYPERAMMONAEMIA (Hyperammonaemia), HYPERSOMNIA (Hypersomnia), LETHARGY (Lethargy), LIVER FUNCTION TEST INCREASED (Liver function test increased), METABOLIC FUNCTION TEST (Metabolic function test), OESOPHAGOGASTRODUODENOSCOPY NORMAL (Oesophagogastroduodenoscopy normal), POSITRON EMISSION TOMOGRAM NORMAL (Positron emission tomogram normal), PROCALCITONIN (Procalcitonin), SARS-COV-2 TEST (SARS-CoV-2 test), SERUM FERRITIN (Serum ferritin), VIRAL TEST NEGATIVE (Viral test negative) and VITAMIN B12 (Vitamin B12) had not resolved. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Patient was on concomitant medication vitamin D, [redacted] metoprolol, Neurontin. On around about 24-Sept patient was started having fatigue , lethargic, increased sleeping, confusion, bilateral axillary pain. Patient presented to clinic on 26-sept-21 and had following: cbc, cmp, tsh, vitamin b12, ferritin, iron, covid pcr, procalcitonin, lactic acid, ammonia level 1; portable cxr. Test was returned revealing very high ammonia level of 140, elevated TSH of 19, elevated liver function test and elevated blood glucose. Additional labs ordered including workup for elevated LFT's, TSH and BG. Patient was referred for liver u/s and also for gastroenterology consult. Additional workup was revealed new onset diabetes with blood glucose getting as high as 700, A1c greater than11, Acute hepatitis (viral panel negative), anti TPO Ab of 269 (very high). Patient was started on lactulose, insulin, synthroid. Patient was also referred to oncology, had PET scan which was negative. Patient also underwent EGD and colonoscopy which was benign. Patient referred to rheumatology and endocrinology. Patient had numerous follow ups in clinic to trend labs and clinical status. Dx following vaccination: new onset diabetes mellitus, autoimmune thyroiditis, acute hepatitis, hyperammonemia. The case concerns a 67-year-old-female patient with previous relevant medical history of Squamous cell carcinoma of lung, who experienced the unexpected serious events of diabetes mellitus, autoimmune thyroiditis, acute hepatitis, hyperammonaemia and axillary pain. The events started approximately 9 days after the second dose of mRNA-1273 Vaccine. Lab tests have been reported supporting these events. The medical history of

Case ID	Narrative (Complete)
	lung cancer remains a confounder for the event axillary pain. The rechallenge was unknown since there's no information about the first dose. The benefit-risk relationsh

Case ID	Narrative (Complete)
[redacted]	This case was received via United States FDA VAERS (Reference number: [redacted] on 16-Nov-2021 and was forwarded to Moderna on 16-Nov-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of DEATH (Death), HEPATIC FAILURE (Hepatic failure), RENAL FAILURE (Renal failure), DEAFNESS (Deafness), DIZZINESS (Dizziness), VERTIGO (Vertigo) and LABORATORY TEST (Laboratory test) in a 73-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for an unknown indication. The patient's past medical history included Diabetes. On 03-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) I dosage form. On 05-Mar-2021, the patient experienced DEATH (Death) (seriousness criteria death and disability), HEPATIC FAILURE (Hepatic failure) (seriousness criteria death and disability), RENAL FAILURE (Renal failure) (seriousness criteria death and disability), DEAFNESS (Deafness) (seriousness criteria death and disability), DIZZINESS (Dizziness) (seriousness criteria death and disability), VERTIGO (Vertigo) (seriousness criteria death and disability) and LABORATORY TEST (Laboratory test) (seriousness criteria death and disability). The patient died on 27-Oct-2021. The reported cause of death was Deafness, Dizziness, Hepatic failure, Renal failure, Vertigo and Laboratory test. It is unknown if an autopsy was performed. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Concomitant medications included diabetes medication. No treatment medications were reported. Batch number of the suspect product was unknown. Action taken with the suspect product was not applicable. Multiple tests were done from 04-Apr-2021 to 10-Oct-2021. Patient had vertigo, dizziness, hearing loss progressing to kidney and liver failure and death. Company Comment: This case concerns a 73-year-old male patient with relevant medical history of Diabetes, who experienced the following serious unexpected events: Hepatic failure, Renal failure, Dizziness, Vertigo and Deafness. The outcome of all reported events was reported as fatal, and Death was also stated as separate event as per source document. In addition, Laboratory test was also reported as an event. The events occurred two days after the patient had received the first dose of the mRNA-1273 vaccine. Very limited information regarding the reported events was disclosed at the moment and details regarding tests which were performed were not provide. The patient died nearly 8 months after the administration of the vaccine. Although all events were reported with fatal outcome, the exact cause of death was not specified and it remained unknown whether the autopsy was performed. The re-challenge is not applicable having in mind that the patient died. The patient's elderly age and underlying Diabetes remain confounders for the reported events. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.

Case ID	Narrative (Complete)
[redacted]	This spontaneous case was reported by a consumer and describes the occurrence of IMMUNE-MEDIATED HEPATIC DISORDER (Immune system started attacking liver) in a 66-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 042L20A) for COVID-19 vaccination. Concurrent medical conditions included Liver cirrhosis since 2010. On 22-Jan-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On an unknown date, the patient experienced IMMUNE-MEDIATED HEPATIC DISORDER (Immune system started attacking liver) (seriousness criterion medically significant). The patient was treated with BUDESONIDE for Immune-mediated hepatic disorder, at a dose of 3 mg. At the time of the report, IMMUNE-MEDIATED HEPATIC DISORDER (Immune system started attacking liver) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 17-Feb-2021, Alanine aminotransferase: 62 (abnormal) 62. On 17-Feb-2021, Aspartate aminotransferase: 63 (abnormal) 63. On 17-Feb-2021, Blood alkaline phosphatase: 273 (abnormal) 273. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown) was unknown. No concomitant medications are provided. 01-Nov-2021: AST was 35, Immunoglobulin was at 1800. Dr said: Patient's immune system started attacking his liver. Company's comment: This case concerns a 66-year-old, male patient with a history of liver cirrhosis, who experienced the unexpected serious AESI event of Immune-mediated hepatic disorder. The event occurred at an unknown time after the first dose of mRNA-1273 vaccine. The rechallenge was not applicable since the events were ongoing. The medical history of cirrhosis remains as a confounder. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Case was assessed as serious due to important medical event and medical judgement. This case was linked to [redacted] (Patient Link).
[redacted]	This case was received via European Medicines Agency (Reference number: [redacted] on 17-Nov-2021 and was forwarded to Moderna on 17-Nov-2021. This regulatory authority case was reported by a physician and describes the occurrence of CHOLELITHIASIS (Cholelithiasis), HEPATOCELLULAR INJURY (Hepatocellular damage) and CHOLECYSTITIS ACUTE (Acute cholecystitis) in an 85-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 305789) for Revaccination with different COVID-19 vaccine. Previously administered products included for Product used for unknown indication: Janssen vaccine (Dose 1: Janssen vaccine, 31-May-2021, Right arm, Intramuscular injection and Batch No.: 21C11-02) on 31-May-2021. Past adverse reactions to the above products included No adverse event with Janssen vaccine. Concomitant products included COVID-19 VACCINE NRVV AD26 (JNJ 78436735) (COVID-19 VACCINE JANSSEN) from 31-May-2021 to 31-May-2021 for COVID-19 vaccination. On 15-Sep-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 19-Sep-2021, the patient experienced CHOLELITHIASIS (Cholelithiasis) (seriousness criterion hospitalization), HEPATOCELLULAR INJURY (Hepatocellular damage) (seriousness criteria hospitalization and medically significant) and CHOLECYSTITIS ACUTE (Acute cholecystitis) (seriousness criteria hospitalization and medically significant). At the time of the report, CHOLELITHIASIS (Cholelithiasis), HEPATOCELLULAR INJURY (Hepatocellular damage) and CHOLECYSTITIS ACUTE (Acute cholecystitis) had not resolved. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No treatment medication was given. Company Comment: This case concerns a 85-year-old, female patient with relevant medical history vaccination with Janssen COVID-19 vaccine , who experienced the unexpected serious events of Cholelithiasis, Hepatocellular injury (AESI) and Cholecystitis acute. The events occurred approximately 4 days after the a dose of mRNA-1273 Vaccine which resulted in Hospitalization. The rechallenge was not applicable since the first dose was from another manufacturer. The patient's medical history of vaccination with Janssen COVID-19 vaccine remain as confounder for the occurrence of the events. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 17-Nov-2021: Translation document received on 18 Nov 2021 include historical vaccine added.

Case ID	Narrative (Complete)
[redacted]	This case was received via European Medicines Agency (Reference number: [redacted] on 19-Nov-2021 and was forwarded to Moderna on 19-Nov-2021. This regulatory authority case was reported by a physician and describes the occurrence of HEPATOCELLULAR INJURY (Hepatocellular damage) in a 56-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3002919) for COVID-19 vaccination. No Medical History information was reported. On 11-Jun-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 02-Jul-2021, the patient experienced HEPATOCELLULAR INJURY (Hepatocellular damage) (seriousness criterion medically significant). At the time of the report, HEPATOCELLULAR INJURY (Hepatocellular damage) 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. No concomitant medication details was reported. No treatment medication details was reported. Company comment: This is a regulatory case concerning a 52- year-old male patient, with no relevant medical history reported, who experienced the serious unexpected event of HEPATOCELLULAR INJURY 21 days after receiving the first dose 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 19-Nov-2021: Translation received on 19-NOV-2021 contains no new information
[redacted]	This case was initially received via European Medicines Agency (Reference number: [redacted] on 19-Nov-2021. The most recent information was received 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 AUTOIMMUNE HEPATITIS (above all autoimmune hepatitis) in a 77-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3004217) for COVID-19 vaccination. The patient's past medical history included Dementia, Lipid metabolism disorder NOS and Hypertonus. On 30-Jul-2021, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 04-Aug-2021, the patient experienced AUTOIMMUNE HEPATITIS (above all autoimmune hepatitis) (seriousness criteria death and hospitalization). The patient died on 11-Oct-2021. The reported cause of death was Autoimmune hepatitis. It is unknown if an autopsy was performed. The action taken with mRNA-1273 (Spikevax) (Unknown) was unknown. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. Concomitant medications were not reported. It was reported that on 04-Aug-2021, patient had onset of symptoms with icterus and reduction in general state of health, on 17-Aug-2021, patient was hospitalized and diagnosis of (autoimmune) hepatitis was made. Patient had Treatment with Prednisolone and Azathioprine. Over the course slow improvement in liver values but clinical deterioration with fatal outcome on 11-Oct-2021. Company comment -This is a regulatory case concerning a 77 year- old male patient, with relevant medical history of Lipid metabolism disorders who experienced the serious unexpected event of autoimmune hepatitis with fatal outcome 4 days after receiving a dose of mRNA-1273 (seriousness criteria death, hospitalization). Patient was vaccinated on 30-Jul-2021 and it was reported the patient had onset of symptoms with icterus and reduction in general state of health, on 17-Aug-2021, patient was hospitalized and the diagnosis of autoimmune hepatitis was made; Patient had Treatment with Prednisolone and Azathioprine. Over the course slow improvement in liver values and died on 11-Oct-2021. The benefit-risk relationship of mRNA-1273 is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 19-Nov-2021: Translated document received on 19-Nov-2021 and included verbatim of the event was updated as per translation and Clinical course of events and treatment information was added in l narrative. On 04-Jan-2022: Due to incorrect follow-up receipt date, this case is amended to reflect the actual follow-up receipt date/Date FU Rcvd by Safety. This case was submitted on-time based on the actual follow-up receipt date. The actual follow-up receipt date/ Date FU Rcvd by Safety for this case is 04-Jan-2022 On 05-Jan-2022: Significant follow up information received on 05-Jan-2022, product indication was updated. history updated. Narrative updated.

Case ID	Narrative (Complete)
[redacted]	This case was initially received via European Medicines Agency (Reference number: [redacted] on 19-Nov-2021. The most recent information was received on 25-Jan-2022 and was forwarded to Moderna on 25-Jan-2022. This regulatory authority case was reported by a physician and describes the occurrence of HEPATITIS (Acute hepatitis from likely immune-mediated hyatrogenic toxic damage in dd with autoimmune hepatitis) and AUTOIMMUNE HEPATITIS (Acute hepatitis from likely immune-mediated hyatrogenic toxic damage in dd with autoimmune hepatitis) in a 60-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 3002543) for COVID-19 vaccination. Concurrent medical conditions included Hashimoto's thyroiditis. Concomitant products included LEVOTHYROXINE SODIUM and LEVOTHYROXINE SODIUM for an unknown indication. On 25-May-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) .5 ml. On 17-Jun-2021, the patient experienced HEPATITIS (Acute hepatitis from likely immune-mediated hyatrogenic toxic damage in dd with autoimmune hepatitis) (seriousness criterion hospitalization) and AUTOIMMUNE HEPATITIS (Acute hepatitis from likely immune-mediated hyatrogenic toxic damage in dd with autoimmune hepatitis) (seriousness criterion hospitalization). At the time of the report, HEPATITIS (Acute hepatitis from likely immune-mediated hyatrogenic toxic damage in dd with autoimmune hepatitis) and AUTOIMMUNE HEPATITIS (Acute hepatitis from likely immune-mediated hyatrogenic toxic damage in dd with autoimmune hepatitis) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 22-Jun-2021, Alanine aminotransferase: 1655 (abnormal) 1655 k[iU] (kilo-international unit). On 22-Jun-2021, Transaminases: 650 (abnormal) 650 INTERNATIONAL UNIT(S)-(UNDER 100). The action taken with mRNA-1273 (Spikevax) (Intramuscular) was unknown. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Treatment details was not reported by the reporter. Patient reported in event verbatim Acute hepatitis due to probable immunemediated iatrogenic and toxic damage in dd with autoimmune hepatitis. Company Comment: This Regulatory authority case concerns a 60 year-old, female patient, with medical history of Hashimoto's thyroiditis, who experienced the unexpected, serious (Hospitalization) event of Hepatitis and AESI of Autoimmune hepatitis. The events occurred approximately 23 days after receiving an unknown dose number of mRNA-1273 vaccine. The medical history of Hashimoto's thyroiditis could be considered as a risk factor. By the time of the report, the patient was recovered. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 19-Nov-2021: Translation received on 22-NOV-2021. Event verbatim updated. On 10-Jan-2022: Follow up contains no new information. On 25-Jan-2022: Significant follow-up received and Outcome of event updated

Case ID	Narrative (Complete)
[redacted]	This case was received via European Medicines Agency (Reference number: [redacted]) on 23-Nov-2021 and was forwarded to Moderna on 23-Nov-2021. This regulatory authority case was reported by a physician and describes the occurrence of CHOLESTASIS (Cholestatic liver impairment), HEPATOTOXICITY (Toxic liver impairment), PRURITUS (Skin itching universally, but mostly in the palms) and FATIGUE (Increasing tiredness) in a 96-year-old female patient who received mRNA-1273 (COVID 19 Vaccine Moderna) for COVID-19 immunisation. The patient's past medical history included Nephrectomy (Right sided nephrectomy). On 08-Feb-2021, the patient received first dose of mRNA-1273 (COVID 19 Vaccine Moderna) (Intramuscular) 1 dosage form. In February 2021, the patient experienced CHOLESTASIS (Cholestatic liver impairment) (seriousness criterion medically significant), HEPATOTOXICITY (Toxic liver impairment) (seriousness criterion medically significant) and PRURITUS (Skin itching universally, but mostly in the palms) (seriousness criterion medically significant). In 2021, the patient experienced FATIGUE (Increasing tiredness) (seriousness criterion medically significant). At the time of the report, CHOLESTASIS (Cholestatic liver impairment), HEPATOTOXICITY (Toxic liver impairment) and PRURITUS (Skin itching universally, but mostly in the palms) had not resolved and FATIGUE (Increasing tiredness) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In December 2020, Blood test: normal (normal) Liver values normal. In February 2021, Alanine aminotransferase: 185 (abnormal) 185 Unit not specified. In February 2021, Blood alkaline phosphatase: 1470 (abnormal) 1470 Unit not specified. In 2021, Alanine aminotransferase: 68 (abnormal) Light increase, 68 Unit not specified. In 2021, Antimitochondrial antibody: negative (Negative) Negative. In 2021, Antinuclear antibody: negative (Negative) Negative. In 2021, Blood alkaline phosphatase: 465 (abnormal) 465 Unit not specified. In 2021, Blood bilirubin: normal (normal) Normal. In 2021, Blood test: abnormal (abnormal) Liver values: with cholestatic impaction. In 2021, Immunoglobulins: normal (normal) Nothing abnormal. In 2021, International normalised ratio: normal (normal) Normal. In 2021, Serology test: negative (Negative) Negative hepatitis serology. In 2021, Smooth muscle antibody: positive (Positive) Medium strong positive SMA. In 2021, Ultrasound biliary tract: abnormal (abnormal) In liver hilus: slim ductus choledochus and abnormal (abnormal) Concrements. No bile duct dilatation. In 2021, Ultrasound liver: abnormal (abnormal) Liver with lightly rounded edges, no focal changes. In 2021, Ultrasound pancreas: normal (normal) Normal conditions. In 2021, Ultrasound scan: abnormal (abnormal) Sequelae from right sided nephrectomy. mRNA-1273 (COVID 19 Vaccine Moderna) (Intramuscular) dosing remained unchanged. For mRNA-1273 (COVID 19 Vaccine Moderna) (Intramuscular), the reporter did not provide any causality assessments. Concomitant medications were not reported by the reporter. Treatment details was not reported by the reporter. Company comment: This case concerns a 96 year old female with relevant medical history of Nephrectomy R kidney , who experienced Serious (medically significant) , Unexpected , AESI of Hepatotoxicity and Serious (Medically Significant) , unexpected events of cholestasis , pruritus which occurred on Feb , 2021 with the vaccination of the 1st dose of mRNA-1273 vaccine (Moderna Covid 19 Vaccine) , it is not clear if events happened before or after vaccination during Feb. 2021 . In 2021 patient experienced Serious , Unexpected event of Fatigue . Series of laboratoratories and diagnostics were performed l which supports the diagnosis of cholestasis and cholestatic impaction., negative for hepatitis serology. The Re-challenge for this case is not applicable since the event outcomes were unresolved and unknown. The benefit -risk relationship of mRNA -1273 (Moderna Covid 19 Vaccine) is not affected by this report.

Case ID	Narrative (Complete)
[redacted]	This spontaneous case was reported by a consumer and describes the occurrence of LIVER INJURY (Acute liver injury), NAUSEA (Nausea), VOMITING (Emesis), BACK PAIN (Back pain), CHEST PAIN (Chest pain), DIZZINESS (Dizziness), DIPLOPIA (Diplopia) and MYOCARDITIS (Myopericarditis/Myocarditis) in an adult female patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) (batch no. 3002187) for COVID-19 vaccination. No Medical History information was reported. On 22-May-2021, the patient received first dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On an unknown date, the patient experienced LIVER INJURY (Acute liver injury) (seriousness criteria hospitalization and medically significant), NAUSEA (Nausea) (seriousness criterion hospitalization), VOMITING (Emesis) (seriousness criterion hospitalization), BACK PAIN (Back pain) (seriousness criterion hospitalization), CHEST PAIN (Chest pain) (seriousness criterion hospitalization), DIZZINESS (Dizziness) (seriousness criterion hospitalization), DIPLOPIA (Diplopia) (seriousness criterion hospitalization) and MYOCARDITIS (Myopericarditis/Myocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, LIVER INJURY (Acute liver injury), NAUSEA (Nausea), VOMITING (Emesis), BACK PAIN (Back pain), CHEST PAIN (Chest pain), DIZZINESS (Dizziness), DIPLOPIA (Diplopia) and MYOCARDITIS (Myopericarditis/Myocarditis) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, SARS-CoV-2 test: negative (Negative) Negative. The action taken with mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown) was unknown. Concomitant product use was not provided by the reporter. Treatment information was not provided. Patient age group was reported to be 18 to 49 years. The report was received from the [redacted] program with [redacted] ID [redacted] Company comment- This case concerns an adult female patient with no relevant medical history, who experienced the unexpected events of liver injury, nausea, vomiting, back pain, chest pain, dizziness, diplopia, and expected event of myocarditis, which required hospitalization. The events occurred after the first dose of mRNA-1273. The rechallenge was not applicable as outcome of events was unknown and no information regarding second dose was provided. The benefit-risk relationship of mRNA-1273 is not affected by this report.

Case ID	Narrative (Complete)
[redacted]	This regulatory authority case was reported by an other health care professional and describes the occurrence of HEPATIC FAILURE (Liver failure) and ABDOMINAL PAIN (Abdominal pain) in a 65-year-old male patient who received mRNA-1273 (COVID 19 Vaccine Moderna) for COVID-19 vaccination. No Medical History information was reported. On 22-Oct-2021, the patient received dose of mRNA-1273 (COVID 19 Vaccine Moderna) (unknown route) 1 dosage form. On 06-Nov-2021, the patient experienced HEPATIC FAILURE (Liver failure) (seriousness criteria death and medically significant) and ABDOMINAL PAIN (Abdominal pain) (seriousness criteria death and medically significant). The reported cause of death was Hepatic failure and Abdominal pain. It is unknown if an autopsy was performed. On 11/06/202, The patient went to the emergency room. Patient experienced generalized weakness/asthenia and acute weakness/inability to walk, and had a pain index [score of] 0 points, generalized weakness and sallow facial complexion. GCS: E4V5M6. Medical history included HTN, DM, hyperlipidemia, CKD, Borderline dilated pancreatic duct, high amlase [sic: amylase], lipase, Chronic liver Disease, Bil. renal parenchymal disease.(ECHO 1090330) CBD dilate (echo 1090706) CLD Mild to moderate fatty liver, uneven fat distribution r/o Left hydronephorsis [sic: hydronephrosis] (echo 1090706) Left renal multiple cysts and stones (echo 1090706),BPH Insomnia, bronchtiis [sic: bronchitis], Smoker. Laboratory data included BP 148 / 81 mmHg, HR: 137 beats/minute, RR: 18 breaths/minute, BT: 38.1°C, SpO2: 97%. WBC21.86x1000/uLRBC2.41x10^6/uL, Hgb7.2g/dL, PLT450x1000/uL, ALP931IU/L, Tropo-I3.244ng/mL, Lactate2.6m mol/L, PT(INR)2.05, Sugar279mg/dL, Bil (Total)19.5mg/dL Bil (Direct)>10mg/dL, GOT185IU/L, GPT169IU/L, Lipase32U/L, CRP193.48mg/L, Urea N40.8mg/dL, Creatinine1.78mg/dL Na131.7mmol/L K4.2m mol/L, Tropo-I1.876ng/mL, Ammonia141µg/dL. On 10/06, the patient's COVID-19 nucleic acid test was negative. Concomitant medications included Piperacillin 2g+Tazobactam 0.25g (Tazocin compound/Vial) 1 Vial Q6H IVD Acetylsalicylic acid (Bokey 100mg/Cap) 3 Cap PO ST 1 day Ticagrelor (Brilinta 90mg/Tab) 2 Tab PO ST 1 day Pantoprazole (Pantoloc 40mg/Vial) 1 Vial Q12H IVD Albumin (Plasbumin 25%, 12.5g/50mL/Bot) 1 Bot ST IVD 1 day Tranexamic acid (Tranexamic acid 250mg/5mL/Amp) 2 Amp ST IVD 1 day 11/7 ER-expired. The patient received the first dose of the Moderna [vaccine] at Kaohsiung Veterans General Hospital on 07/15/2021 The relevant diagnosis results were sepsis, myocardial infarction (NSTEMI), gastrointestinal bleeding, unconfirmed suspected jaundice, inflammatory liver disease, and chronic kidney disease. Treatment for the events were not provided Company comment:This case concerns a 65-year-old male patient, with medical history of hypertension, diabetes, hyperlipidemia, chronic liver disease and smoker (reported in SD narrative), who experienced the serious unexpected events of hepatic failure and abdominal pain with fatal outcome after second dose of mRNA-1273. The patient experienced after vaccination chills, jaundice, generalized weakness, asthenia, inability to walk, had pain and sallow facial complexion. As per SD narrative the patient´s relevant diagnosis results were sepsis, myocardial infarction (NSTEMI), gastrointestinal bleeding, unconfirmed suspected jaundice, inflammatory liver disease, and chronic kidney disease. The fatal outcome occurred 17 days after second dose. Patient´s medical history could be contributing factors. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.

Case ID	Narrative (Complete)
[redacted]	This case was received via [redacted] (Reference number: [redacted]) on 30-Nov-2021 and was forwarded to Moderna on 30-Nov-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of BIOPSY LIVER ABNORMAL (Biopsy liver abnormal), ERYTHEMA (Erythema), HEPATIC ENZYME INCREASED (Hepatic enzyme increased), INFLAMMATION (Inflammation), LIVER INJURY (Liver injury) and SKIN LESION (Skin lesion) in a 49-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 032B21A and 026A211A) for an unknown indication. The patient's past medical history included Degenerative disc disease. Concurrent medical conditions included Anxiety, Acid reflux (oesophageal), Depression, Osteoarthritis, Rheumatoid arthritis, Drug allergy (Keflex), Drug allergy (Hydroxychloroquine.), Drug allergy (Codeine), Sensitive skin and Adhesive tape allergy. On 11-Mar-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 11-Mar-2021, received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 11-Mar-2021, the patient experienced BIOPSY LIVER ABNORMAL (Biopsy liver abnormal) (seriousness criteria disability and life threatening), ERYTHEMA (Erythema) (seriousness criteria disability and life threatening), HEPATIC ENZYME INCREASED (Hepatic enzyme increased) (seriousness criteria disability and life threatening), INFLAMMATION (Inflammation) (seriousness criteria disability and life threatening), LIVER INJURY (Liver injury) (seriousness criteria disability and life threatening) and SKIN LESION (Skin lesion) (seriousness criteria disability and life threatening). At the time of the report, BIOPSY LIVER ABNORMAL (Biopsy liver abnormal), ERYTHEMA (Erythema), HEPATIC ENZYME INCREASED (Hepatic enzyme increased), INFLAMMATION (Inflammation), LIVER INJURY (Liver injury) and SKIN LESION (Skin lesion) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 11-Nov-2021, Biopsy liver: abnormal (abnormal) mild injured liver due to toxic/metabolism injury.. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Other medications included Oxycodone 30mg product used for unknown indication. Treatment details was not reported by the reporter. Patient was allergic to Stapes, Stitches and moderna vaccine. On 11-NOV-2021 patient went for a liver biopsy results showed that had mild injured liver due to toxic and metabolism injury. Patient was dealing with all those issues since the first vaccination on 11-March. Reporter reported that patient's lesions came out in May after the second dose. Patient also had skin lesions red red sores all over the legs arms couple on face back . Patient had many treatments mini doctor visits about the stores which led up to getting the liver biopsy. Also had extreme inflammation after the vaccination so much that the doctor had to prescribed an EpiPen. Patient never had any liver issues before also at the end of March after the first vaccination. Patient tore partially tore the IT band on the right hip. Ever since got these vaccinations the body had gone downward spiral health. After patient got the first dose went to have blood work drawn due to having rheumatoid arthritis when it came back that the liver enzyme started to go up again went back the second dose on April 11 again after patient left hospital went to another Hospital to have blood work done again liver enzymes went up. Company Comment: This case concerns a 49-year-old female subject, with medical history of anxiety, acid reflux, depression, osteoarthritis, and rheumatoid arthritis, who experienced the unexpected and serious events of Liver injury, Erythema, Inflammation, Skin lesion, Hepatic enzyme increased, and biopsy liver abnormal. The events occurred the same day after an unknown dose of mRNA-1273 vaccine. The medical history remains confounder. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.

Case ID	Narrative (Complete)
[redacted]	This case was received via [redacted] (Reference number: [redacted]) on 30-Nov-2021 and was forwarded to Moderna on 30-Nov-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of ABDOMINAL PAIN (Abdominal pain), ACUTE KIDNEY INJURY (Acute kidney injury), ACUTE MYOCARDIAL INFARCTION (Acute myocardial infarction), ALANINE AMINOTRANSFERASE INCREASED (Alanine aminotransferase increased), ASPARTATE AMINOTRANSFERASE INCREASED (Aspartate aminotransferase increased), AUTOIMMUNE HEPATITIS (Autoimmune hepatitis), BLOOD BILIRUBIN (Blood bilirubin), BLOOD LACTIC ACID NORMAL (Blood lactic acid normal), DIARRHOEA (Diarrhoea), HYPOPHAGIA (Hypophagia), LIVER FUNCTION TEST INCREASED (Liver function test increased) and TROPONIN INCREASED (Troponin increased) in an 80-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 065F21A) for COVID-19 vaccination. The patient's past medical history included Atrial fibrillation, Anxiety, Arthritis, Back pain, Coronary artery disease, Cardiomyopathy, Carotid artery stenosis, Depression, Dyslipidemia, Thyroiditis NOS (thyroid disease) and Tobacco abuse. Concurrent medical conditions included Cancer, Congestive heart failure, COPD, Heart attack, Hypertension, Drug allergy (Allergies: Zantac - Hives), Drug allergy (Allergies: Baclofen - altered mental status) and Drug allergy (Allergies: Cymbalta - rash). On 18-Nov-2021, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 20-Nov-2021, the patient experienced ABDOMINAL PAIN (Abdominal pain) (seriousness criterion hospitalization), ACUTE KIDNEY INJURY (Acute kidney injury) (seriousness criterion hospitalization), ACUTE MYOCARDIAL INFARCTION (Acute myocardial infarction) (seriousness criterion hospitalization), ALANINE AMINOTRANSFERASE INCREASED (Alanine aminotransferase increased) (seriousness criterion hospitalization), ASPARTATE AMINOTRANSFERASE INCREASED (Aspartate aminotransferase increased) (seriousness criterion hospitalization), AUTOIMMUNE HEPATITIS (Autoimmune hepatitis) (seriousness criterion hospitalization), BLOOD BILIRUBIN (Blood bilirubin) (seriousness criterion hospitalization), BLOOD LACTIC ACID NORMAL (Blood lactic acid normal) (seriousness criterion hospitalization), DIARRHOEA (Diarrhoea) (seriousness criterion hospitalization), HYPOPHAGIA (Hypophagia) (seriousness criterion hospitalization), LIVER FUNCTION TEST INCREASED (Liver function test increased) (seriousness criterion hospitalization) and TROPONIN INCREASED (Troponin increased) (seriousness criterion hospitalization). At the time of the report, ABDOMINAL PAIN (Abdominal pain), ACUTE KIDNEY INJURY (Acute kidney injury), ACUTE MYOCARDIAL INFARCTION (Acute myocardial infarction), ALANINE AMINOTRANSFERASE INCREASED (Alanine aminotransferase increased), ASPARTATE AMINOTRANSFERASE INCREASED (Aspartate aminotransferase increased), AUTOIMMUNE HEPATITIS (Autoimmune hepatitis), BLOOD BILIRUBIN (Blood bilirubin), BLOOD LACTIC ACID NORMAL (Blood lactic acid normal), DIARRHOEA (Diarrhoea), HYPOPHAGIA (Hypophagia), LIVER FUNCTION TEST INCREASED (Liver function test increased) and TROPONIN INCREASED (Troponin increased) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 20-Nov-2021, Alanine aminotransferase: 179 (High) alt 179 at 18:40. On 20-Nov-2021, Aspartate aminotransferase: 210 (High) AST 210 at 18:40. On 20-Nov-2021, Blood bilirubin: 1.5 (High) total bilirubin 1.5 at 18:40. On 21-Nov-2021, Alanine aminotransferase: 1160 (High) ALT 1160 at 04:41. On 21-Nov-2021, Aspartate aminotransferase: 1475 (High) AST 1475 at 04:41. On 21-Nov-2021, Blood bilirubin: 2.8 (High) total bilirubin 2.8 at 04:41. On 21-Nov-2021, Troponin: 0.82 (High) Troponin 0.82 at 04:41. On 22-Nov-2021, Blood lactic acid: 6.4 (normal) Lactic acid up to 6.4 at 12:06. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Concomitant medications included as [redacted]HFA, alprazolam, aspirin, atorvastatin, Symbicort, Wellbutrin, collagenase, docusate, furosemide, guaifenesin, medihoney, [redacted], Duo-neb, Culturelle, loratadine, magnesium oxide, melatonin, metolazone, [redacted] XL, montelukast, pa Patient was experienced autoimmune hepatitis two days after vaccination and Symptoms elevated LFTs, abdominal pain had diarrhea and decreased oral intake. and acute renal failure with and NSTEMI. No treatment information was provided by the reporter. Company comment: This case concerns an 80-year-old female patient with relevant medical history who experienced serious unexpected events of acute kidney injury, acute myocardial infarction, abdominal pain, alanine aminotransferase increased, aspartate aminotransferase increased, autoimmune hepatitis, diarrhoea, hypophagia, troponin increased and liver function test increased. The events occurred approximately 2 days after the 3rd dose of the mRNA-1273 . Rechallenge was not applicable since the event occurred after the 3rd dose so, no rechallenge was done and recurrence was not applicable. Patient's advanced age and multiple comorbidities are possible confounders. The benefit-risk relationship of mRNA-1273 is not affected by this report.

Case ID	Narrative (Complete)
[redacted]	This case was received via [redacted] (Reference number: [redacted]) on 30-Nov-2021 and was forwarded to Moderna on 30-Nov-2021. This regulatory authority case was reported by a health care professional and describes the occurrence of ARTHRALGIA (Arthralgia), BLOOD TEST NORMAL (Blood test normal), COMPUTERISED TOMOGRAM ABNORMAL (Computerised tomogram abnormal), HEADACHE (Headache), HEPATIC FAILURE (Hepatic failure), HEPATIC STEATOSIS (Hepatic steatosis), IMPAIRED WORK ABILITY (Impaired work ability), MUSCULOSKELETAL CHEST PAIN (Musculoskeletal chest pain), PYREXIA (Pyrexia), SLEEP DISORDER (Sleep disorder) and ULTRASOUND SCAN NORMAL (Ultrasound scan normal) in a 44-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 038K20A) for an unknown indication. Concurrent medical conditions included Asthma. On 23-Feb-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 24-Feb-2021, the patient experienced ARTHRALGIA (Arthralgia) (seriousness criterion disability), BLOOD TEST NORMAL (Blood test normal) (seriousness criterion disability), COMPUTERISED TOMOGRAM ABNORMAL (Computerised tomogram abnormal) (seriousness criterion disability), HEADACHE (Headache) (seriousness criterion disability), HEPATIC FAILURE (Hepatic failure) (seriousness criteria disability and medically significant), HEPATIC STEATOSIS (Hepatic steatosis) (seriousness criterion disability), IMPAIRED WORK ABILITY (Impaired work ability) (seriousness criterion disability), MUSCULOSKELETAL CHEST PAIN (Musculoskeletal chest pain) (seriousness criterion disability), PYREXIA (Pyrexia) (seriousness criterion disability), SLEEP DISORDER (Sleep disorder) (seriousness criterion disability) and ULTRASOUND SCAN NORMAL (Ultrasound scan normal) (seriousness criterion disability). At the time of the report, ARTHRALGIA (Arthralgia), BLOOD TEST NORMAL (Blood test normal), COMPUTERISED TOMOGRAM ABNORMAL (Computerised tomogram abnormal), HEADACHE (Headache), HEPATIC FAILURE (Hepatic failure), HEPATIC STEATOSIS (Hepatic steatosis), IMPAIRED WORK ABILITY (Impaired work ability), MUSCULOSKELETAL CHEST PAIN (Musculoskeletal chest pain), PYREXIA (Pyrexia), SLEEP DISORDER (Sleep disorder) and ULTRASOUND SCAN NORMAL (Ultrasound scan normal) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In February 2021, Blood test: normal (normal) No-findings. In February 2021, Computerised tomogram: abnormal (abnormal) Abnormal-Fatty liver. In February 2021, Ultrasound scan: normal (normal) No findings. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Reporter mentioned Other Medications included Singulair, Xyzal, Omeprazole and Advair inhaler. Patient states that the night of the 24th their fever got up to 103.5 and stayed that way for a few hours, woke up that night with pain in the rib cage. Took a hot bath to help relax my muscles, that did not help so they drove to the ER. By the time they left the ER on the 24th with an antibiotic, the pain continued. Patient sought treatment again in September with doctor and had a CAT scan in October. I was diagnosed with a fatty liver with deterioration. The pain is slowly getting better and had to change diet. Company comment: This RA case concerns a 44 year old female patient , with no relevant medical history reported. who experienced Serious (Disability) , Unexpected events of Arthralgia, Blood test normal . Computerised tomogram abnormal , headache , hepatic failure, hepatic steatosis , impaired work ability , sleep disorder , ultrasound scan normal, musculoskeletal chest pain and pyrexia . These events occurred the day after vaccination with the 2nd dose of mRNA-1273 vaccine (Moderna Covid 19 vaccine) . The re-challenge for this case is not applicable since the events occurred after the 2nd dose and no additional dose will be given and also the outcome of the events was has not yet recovered. The benefit - risk relationship of mRNA -1273 (Moderna Covid 19 Vaccine) is not affected by this report.
[redacted]	This case was initially received via Takeda Pharmaceuticals (Reference number: [redacted]) on 01-Dec-2021. The most recent information was received on 07-Feb-2022 and was forwarded to Moderna on 14-Feb-2022. This case, initially reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by a physician, was received via the PMDA (Ref. [redacted]). On 07-Feb-2022, follow-up information was received from a physician. On 04-Dec-2020, the patient already had hepatic function disorder in another hospital. Blood test showed AST of 112 and ALT of 146. On 02-Apr-2021, the patient already had hepatic function disorder in another hospital. Blood test showed AST of 80 and ALT of 100. Administration of metformin hydrochloride 500 mg was started for diabetes mellitus. On an unknown date, body temperature before the vaccination: 36.1 degrees Celsius. On 07-Sep-2021, at 13:55, the patient received the 1st dose of the vaccine. On 10-Sep-2021, blood test showed AST of 152 and ALT of 179. It was presumed that hepatic function disorder developed. On an unknown date, body temperature before the vaccination: 36.1 degrees Celsius. On 05-Oct-2021, at 13:44, the patient received the 2nd dose of the vaccine. On 27-Oct-2021, pyrexia developed. On 03-Nov-2021, jaundice developed. On 07-Nov-2021, at 01:00, respiratory discomfort developed, and an emergency call was made. The patient experienced cardiopulmonary arrest in the ambulance. After transportation to the hospital, the heartbeat resumed. On arrival at the reporting hospital, the patient had haematemesis and underwent emergency endoscopy, and there was no bleeding point. The cause of cardio-respiratory arrest was uncertain by CT examination, a diagnosis of acute hepatic failure was made. The patient entered the ICU. Multimodality therapy including massive transfusion was also difficult to control upper gastrointestinal bleeding. The patient was confirmed dead. The cause of the death was circulatory failure, and there were no significant findings in the macroscopic findings. The outcome of pyrexia and cardio-respiratory arrest was unknown. The outcome of hepatic function disorder worsens, acute hepatic failure, upper gastrointestinal hemorrhage, and circulatory failure was reported as fatal. No follow-up investigation will be made. Reporter comments continuation: The onset of adverse events is not related to concomitant drugs. Lymphoma, which was not indicated, is suspected. The onset of adverse events is related to pathological factors of suspected lymphoma if hepatic infiltration is noted. Autopsy is ongoing. Follow-up received on 07-FEB-2022 Updated: Other Relevant History, Lab Data, Product Information, Event Information, Narrative, Reporter Comments Company Comment: The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.

Case ID	Narrative (Complete)
[redacted]	This case was received via [redacted] Reference number: [redacted] on 14-Dec-2021 and was forwarded to Moderna on 14-Dec-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of RESPIRATORY FAILURE (Respiratory failure), COVID-19 (COVID-19), MELAENA (Melaena), DYSPNOEA (Dyspnoea), OEDEMA (Oedema), ASTHENIA (Asthenia), ATRIAL FIBRILLATION (Atrial fibrillation), PULMONARY HYPERTENSION (Pulmonary hypertension), ACUTE LEFT VENTRICULAR FAILURE (Acute left ventricular failure), CHRONIC LEFT VENTRICULAR FAILURE (Chronic left ventricular failure), CONDITION AGGRAVATED (Condition aggravated), IMPAIRED SELF-CARE (Impaired self-care), HEPATOCELLULAR INJURY (Hepatocellular injury), FAECES DISCOLOURED (Faeces discoloured), ECHOCARDIOGRAM NORMAL (Echocardiogram normal), EJECTION FRACTION NORMAL (Ejection fraction normal), CHEST X-RAY NORMAL (Chest X-ray normal), HAEMOGLOBIN NORMAL (Haemoglobin normal), LIVER FUNCTION TEST DECREASED (Liver function test decreased), SARS-COV-2 TEST POSITIVE (SARS-CoV-2 test positive), TRANSAMINASES INCREASED (Transaminases increased) and ULTRASOUND ABDOMEN ABNORMAL (Ultrasound abdomen abnormal) in a 75-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 038K20A) for an unknown indication. The patient's past medical history included Obstructive sleep apnea syndrome, Lung nodule, Rhinitis (Non-allergic rhinitis), Venous insufficiency, Premature atrial contraction, Obesity (Digestive Class I obesity due to excess calories with body mass index (BMI) of 33.0 to 33.9 in adult), GERD, Hepatomegaly, Irritable bowel syndrome, Diarrhea, Glaucoma (Nervous Glaucoma), Urinary incontinence (Urinary incontinence in female), Periodic limb movement disorder, Colonic polyp, Hoarseness of voice, Visual field defect, Edema of lower extremities, Insomnia, Pelvic mass, Vertigo and Balance difficulty. Concurrent medical conditions included Allergy to chemicals (Betadine [Povidone Iodine]Rash), Dyspnea exertional, Lung disease obstructive, Acute hypoxic respiratory failure, Essential hypertension, Persistent atrial fibrillation, Diastolic heart failure (Acute on chronic diastolic heart failure), Atrial fibrillation with rapid ventricular response, Shoulder arthritis (Infectious/Inflammatory Arthritis of right shoulder region), Diverticulitis, COVID-19 (COVID-19 virus infection), Myelodysplastic syndrome (Hematologic MDS (myelodysplastic syndrome), Duplex kidneys (Genitourinary Duplicated renal collecting system), Multinodular goiter (Endocrine/Metabolic Non-toxic multinodular goiter), Prediabetes, Generalized anxiety disorder and Macrocytic anemia. On 12-Feb-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 26-Nov-2021, the patient experienced RESPIRATORY FAILURE (Respiratory failure) (seriousness criterion hospitalization), COVID-19 (COVID-19) (seriousness criterion hospitalization), MELAENA (Melaena) (seriousness criterion hospitalization), DYSPNOEA (Dyspnoea) (seriousness criterion hospitalization), OEDEMA (Oedema) (seriousness criterion hospitalization), ASTHENIA (Asthenia) (seriousness criterion hospitalization), ATRIAL FIBRILLATION (Atrial fibrillation) (seriousness criterion hospitalization), PULMONARY HYPERTENSION (Pulmonary hypertension) (seriousness criterion hospitalization), ACUTE LEFT VENTRICULAR FAILURE (Acute left ventricular failure) (seriousness criterion hospitalization), CHRONIC LEFT VENTRICULAR FAILURE (Chronic left ventricular failure) (seriousness criterion hospitalization), CONDITION AGGRAVATED (Condition aggravated) (seriousness criterion hospitalization), IMPAIRED SELF-CARE (Impaired self-care) (seriousness criterion hospitalization), HEPATOCELLULAR INJURY (Hepatocellular injury) (seriousness criterion hospitalization), FAECES DISCOLOURED (Faeces discoloured) (seriousness criterion hospitalization), ECHOCARDIOGRAM NORMAL (Echocardiogram normal) (seriousness criterion hospitalization), EJECTION FRACTION NORMAL (Ejection fraction normal) (seriousness criterion hospitalization), CHEST X-RAY NORMAL (Chest X-ray normal) (seriousness criterion hospitalization), HAEMOGLOBIN NORMAL (Haemoglobin normal) (seriousness criterion hospitalization), LIVER FUNCTION TEST DECREASED (Liver function test decreased) (seriousness criterion hospitalization), SARS-COV-2 TEST POSITIVE (SARS-CoV-2 test positive) (seriousness criterion hospitalization), TRANSAMINASES INCREASED (Transaminases increased) (seriousness criterion hospitalization) and ULTRASOUND ABDOMEN ABNORMAL (Ultrasound abdomen abnormal) (seriousness criterion hospitalization). At the time of the report, RESPIRATORY FAILURE (Respiratory failure), COVID-19 (COVID-19), MELAENA (Melaena), DYSPNOEA (Dyspnoea), OEDEMA (Oedema), ASTHENIA (Asthenia), ATRIAL FIBRILLATION (Atrial fibrillation), PULMONARY HYPERTENSION (Pulmonary hypertension), ACUTE LEFT VENTRICULAR FAILURE (Acute left ventricular failure), CHRONIC LEFT VENTRICULAR FAILURE (Chronic left ventricular failure), CONDITION AGGRAVATED (Condition aggravated), IMPAIRED SELF-CARE (Impaired self-care), HEPATOCELLULAR INJURY (Hepatocellular injury), FAECES DISCOLOURED (Faeces discoloured), ECHOCARDIOGRAM NORMAL (Echocardiogram normal), EJECTION FRACTION NORMAL (Ejection fraction normal), CHEST X-RAY NORMAL (Chest X-ray normal), HAEMOGLOBIN NORMAL (Haemoglobin normal), LIVER FUNCTION TEST DECREASED (Liver function test decreased), SARS-COV-2 TEST POSITIVE (SARS-CoV-2 test positive), TRANSAMINASES INCREASED (Transaminases increased) and ULTRASOUND ABDOMEN ABNORMAL (Ultrasound abdomen abnormal) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In 2021, Body mass index: increased (High) 33.0 to 33.9. In 2021, Computerised tomogram: abnormal (abnormal) Abnormal CT of the chest. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Patients other medications included Acetaminophen (TYLENOL) 325 MG tablet, Apixaban (ELIQUIS) 5 MG tablet atorvastatin (LIPITOR) 20 MG tablet benzonatate [redacted] 100 MG capsule Cholecalciferol (VITAMIN D PO) Cyanocobalamin (VITAMIN B-12 PO) dexamethasone (DECADRON) 6 MG tab. Patient was discharged from 8day inpatient admission and returned to ED same day for generalized weakness and inability to care for herself. She was requesting home care. The patient was admitted on 11/26/2021 with progressive SOB and edema secondary to acute on chronic diastolic heart failure in the setting of diuretic nonadherence. Patient had reported dark stool prior to admission as well. +COVID test on admission and fib with RVR present at time of admission. Patient was initiated on supplemental O2 and IV diuresis. Significant COVID pneumonia not suspected given CXR findings, respiratory failure felt to be secondary to CHF instead. Decadron was started, remdesivir held as no significant pneumonia on x-ray and transaminitis. RUQ U/S showed mild increased liver echogenicity, suggesting underlying hepatocellular disease. LFTs down trended. Recent echo 8/2021 with EF 61%, mild pulmonary HTN. Transitioned back to oral torsemide. Patient had reported melena on admission so home eliquis held initally. Hemoglobin remained stable without signs of bleeding and eliquis was resumed without evidence of bleeding. PT/OT evaluated and recommended discharge home with assist and HHC. Patient had stopped taking torsemide at home and patient had felt it was causing her to feel "unwell". Discharge plans coordinated with cardiology, advised discharge on lasix 40 mg daily with KCl 20meq. Cardiology arranged virtual appointment on 12/6. She was felt stable for discharge on 12/2. She will complete remaining 3 days of torsemide for 10day course. Patient was discharged home in stable condition with family.

Case ID	Narrative (Complete)
	Company comment:- This case concerns a 75 year old female patient with medical history of Chronic diastolic Congestive heart failure, atrial fibrillation, hypertension, hyperlipidemia, Obesity, Hepatomegaly, Lung disease obstructive, acute hypoxic respiratory failure,

Case ID	Narrative (Complete)
[redacted]	This spontaneous case was reported by a consumer and describes the occurrence of HEPATIC FAILURE (liver failure, person died with liver disease) in a female patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Chronic liver disease (chronic liver disease). On an unknown date, the patient received fourth dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On an unknown date, 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 HEPATIC FAILURE (liver failure, person died with liver disease) (seriousness criteria death, hospitalization and medically significant) and EXTRA DOSE ADMINISTERED (receiving two shots of the booster.). The patient died on an unknown date. The reported cause of death was Liver failure. It is unknown if an autopsy was performed. At the time of death, EXTRA DOSE ADMINISTERED (receiving two shots of the booster.) had resolved. Concomitant medication information was not provided by the reporter. Treatment medication information was not provided by the reporter. Reporter stated that a girl with chronic liver disease went into liver failure and had jaundice and also died in hospital after receiving two shots of the booster. Company comment: This is a spontaneous case concerning a female patient of an unknown age with concurrent medical condition of Chronic liver disease who experienced serious, unexpected event of hepatic failure. Vaccination dates and start date of the event were not provided. Reporter stated that a girl with chronic liver disease went into liver failure and had jaundice and also died in hospital after receiving two shots of the booster. Date of death was not disclosed. It is unknown if an autopsy was performed. Very limited information regarding this event has been provided at this time. Further information has been requested. Concurrent medical condition of Chronic liver disease remains a confounder. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 07-Jan-2022: Non-significant follow up appended

Case ID	Narrative (Complete)
[redacted]	This case was initially received via European Medicines Agency (Reference number: [redacted] on 24-Dec-2021. The most recent information was received on 07-Jun-2022 and was forwarded to Moderna on 07-Jun-2022. This regulatory authority case was reported by a consumer and describes the occurrence of CHEST PAIN (Chest pain), DYSPNOEA (Breathlessness), PERICARDITIS (MRI CONFIRM PERICARDITIS AND NOT MYOCARDITIS AS FIRST EXPECTED), AUTOIMMUNE HEPATITIS (AUTO IMMUNE HEPATITIS), CHOLANGITIS SCLEROSING (PRIMARY SCLEROSING CHOLANGITIS) and PALPITATIONS (Palpitations) in a 58-year-old female patient who received mRNA-1273 (Spikevax) (batch nos. 3001650-031021 and 3001942) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Arm fracture. Concurrent medical conditions included SLE, Osteoporosis and Crohn's. Concomitant products included ZOLEDRONIC ACID (ACLASTA) for Osteoporosis. On 27-Apr-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 27-May-2021, received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. On 11-Jun-2021, the patient experienced CHEST PAIN (Chest pain) (seriousness criterion medically significant), DYSPNOEA (Breathlessness) (seriousness criterion medically significant) and PALPITATIONS (Palpitations) (seriousness criterion medically significant). 11-Jun-2021, the patient experienced PERICARDITIS (MRI CONFIRM PERICARDITIS AND NOT MYOCARDITIS AS FIRST EXPECTED) (seriousness criterion medically significant). In May 2022, the patient experienced SYSTEMIC LUPUS ERYTHEMATOSUS (VACCINE TRIGGERED A FLARE UP IN SLE (LUPUS)) and AUTOIMMUNE HEPATITIS (AUTO IMMUNE HEPATITIS) (seriousness criterion medically significant). May 2022, the patient experienced CHOLANGITIS SCLEROSING (PRIMARY SCLEROSING CHOLANGITIS) (seriousness criterion medically significant) and LIVER FUNCTION TEST ABNORMAL (VERY HIGH LIVER READINGS). At the time of the report, CHEST PAIN (Chest pain), SYSTEMIC LUPUS ERYTHEMATOSUS (VACCINE TRIGGERED A FLARE UP IN SLE (LUPUS)), DYSPNOEA (Breathlessness), PERICARDITIS (MRI CONFIRM PERICARDITIS AND NOT MYOCARDITIS AS FIRST EXPECTED), AUTOIMMUNE HEPATITIS (AUTO IMMUNE HEPATITIS), CHOLANGITIS SCLEROSING (PRIMARY SCLEROSING CHOLANGITIS), LIVER FUNCTION TEST ABNORMAL (VERY HIGH LIVER READINGS) and PALPITATIONS (Palpitations) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 20-Mar-2022, Magnetic resonance imaging heart: awaiting further results Confirmed Pericarditis and not Myocarditis as first expected. On an unknown date, Electrocardiogram: clear (normal) Clear. No treatment medications provided by the reporter. Company comment: This is a Regulatory Authority case concerning a 58-year-old female patient, with relevant medical conditions of systemic lupus erythematosus and Crohn´s, who experienced the expected and serious (due to medically significant) AESI of Pericarditis, and the unexpected and serious (due to medically significant) events of Autoimmune hepatitis (AESI), Cholangitis sclerosing, Palpitations, Chest pain and Dyspnoea. Non-serious event of Systemic lupus erythematosus flare was also reported. 14 days after the second dose of mRNA-1273 vaccine, the patient experienced Pericarditis, Chest pain, Dyspnoea and Palpitations. The events of Autoimmune hepatitis and Cholangitis sclerosing occurred 1 year after the second dose of mRNA-1273 vaccine. Magnetic resonance imaging heart was performed and confirmed pericarditis and not myocarditis as first expected. Electrocardiogram was clear. At the time of the report, the events had not resolved. No information disclosed about treatments received. Palpitations, Chest pain and Dyspnoea, could probably be related with Pericarditis. Relevant medical condition of systemic lupus erythematosus remains a confounder for Pericarditis and Autoimmune hepatitis. History of relevant condition of Crohn´s, remains a confounder for Cholangitis sclerosing. Systemic lupus erythematosus can present relapses as part of the natural history of disease, so that confounds the case. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 07-Jun-2022: Significant follow up appended_Events added

Case ID	Narrative (Complete)
[redacted]	This case was received via European Medicines Agency (Reference number: [redacted] on 27-Dec-2021 and was forwarded to Moderna on 27-Dec-2021. This regulatory authority case was reported by a consumer and describes the occurrence of AUTOIMMUNE HEPATITIS (Aggressive flare-up of autoimmune hepatitis) in a 61-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 immunisation. Previously administered products included for COVID-19 immunisation: SPIKEVAX on 25-Jun-2021. Past adverse reactions to the above products included No adverse event with SPIKEVAX. Concurrent medical conditions included Autoimmune hepatitis (Started in 2012 and has burned out in 2014. No treatment.) since 2012. On 03-Aug-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 01-Sep-2021, after starting mRNA-1273 (Spikevax), the patient experienced AUTOIMMUNE HEPATITIS (Aggressive flare-up of autoimmune hepatitis) (seriousness criterion medically significant). At the time of the report, AUTOIMMUNE HEPATITIS (Aggressive flare-up of autoimmune hepatitis) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In 2021, Blood test: increased (unspecified) (High) Increased (unspecified). In 2021, Computerised tomogram: enlarged liver (abnormal) Enlarged liver. No concomitant medication details were reported. No treatment medication details were reported. Company comment: This is a regulatory authority case concerning a 61-year-old female patient with medical history of Autoimmune hepatitis (Started in 2012 and has burned out in 2014. No treatment), who experienced unexpected event of autoimmune hepatitis (reported as Aggressive flare-up of autoimmune hepatitis) (seriousness criterion medically significant). The event occurred 29 days after the second dose of mRNA-1273 vaccine. No information about the first dose was disclosed. CT scan showed enlarged liver. Clinical course and treatment details were not provided. Medical history of Autoimmune hepatitis remains a confounder. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 12-May-2022: Due to case creation with incorrect initial receipt date, this case is amended to reflect the actual initial receipt date within the narrative. This case was submitted on-time based on the actual initial receipt date. The actual initial receipt date for this case is 24-Dec-2021.

Case ID	Narrative (Complete)
[redacted]	This case was initially received via European Medicines Agency (Reference number: [redacted] on 27-Dec-2021. The most recent information was received on 13-Jan-2022 and was forwarded to Moderna on 13-Jan-2022. This regulatory authority case was reported by a physician and describes the occurrence of ASTHENIA (Progressive onset following dose II of the Moderna covid19 vaccine of asthenia, lack of appetite, abdominal pain and hyperchromic urine, with the aforementioned diagnosis of hepatitis frank.), HEPATITIS ACUTE (Progressive onset following dose II of the Moderna covid19 vaccine of asthenia, lack of appetite, abdominal pain and hyperchromic urine, with the aforementioned diagnosis of hepatitis frank.), ABDOMINAL PAIN (Progressive onset following dose II of the Moderna covid19 vaccine of asthenia, lack of appetite, abdominal pain and hyperchromic urine, with the aforementioned diagnosis of hepatitis frank.), DECREASED APPETITE (Progressive onset following dose II of the Moderna covid19 vaccine of asthenia, lack of appetite, abdominal pain and hyperchromic urine, with the aforementioned diagnosis of hepatitis frank.) and CHROMATURIA (Progressive onset following dose II of the Moderna covid19 vaccine of asthenia, lack of appetite, abdominal pain and hyperchromic urine, with the aforementioned diagnosis of hepatitis frank.) in a 30-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The patient's past medical history included COVID-19 on 01-Nov-2020. Previously administered products included for SARS-CoV-2 vaccination: SPIKEVAX on 03-Sep-2021. Past adverse reactions to the above products included No adverse reaction with SPIKEVAX. Concurrent medical conditions included Hashimoto's thyroiditis on 01-Jan-2007. On 08-Oct-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 19-Nov-2021, the patient experienced ASTHENIA (Progressive onset following dose II of the Moderna covid19 vaccine of asthenia, lack of appetite, abdominal pain and hyperchromic urine, with the aforementioned diagnosis of hepatitis frank.) (seriousness criterion hospitalization), HEPATITIS ACUTE (Progressive onset following dose II of the Moderna covid19 vaccine of asthenia, lack of appetite, abdominal pain and hyperchromic urine, with the aforementioned diagnosis of hepatitis frank.) (seriousness criterion hospitalization), ABDOMINAL PAIN (Progressive onset following dose II of the Moderna covid19 vaccine of asthenia, lack of appetite, abdominal pain and hyperchromic urine, with the aforementioned diagnosis of hepatitis frank.) (seriousness criterion hospitalization), DECREASED APPETITE (Progressive onset following dose II of the Moderna covid19 vaccine of asthenia, lack of appetite, abdominal pain and hyperchromic urine, with the aforementioned diagnosis of hepatitis frank.) (seriousness criterion hospitalization) and CHROMATURIA (Progressive onset following dose II of the Moderna covid19 vaccine of asthenia, lack of appetite, abdominal pain and hyperchromic urine, with the aforementioned diagnosis of hepatitis frank.) (seriousness criterion hospitalization). At the time of the report, ASTHENIA (Progressive onset following dose II of the Moderna covid19 vaccine of asthenia, lack of appetite, abdominal pain and hyperchromic urine, with the aforementioned diagnosis of hepatitis frank.), HEPATITIS ACUTE (Progressive onset following dose II of the Moderna covid19 vaccine of asthenia, lack of appetite, abdominal pain and hyperchromic urine, with the aforementioned diagnosis of hepatitis frank.), ABDOMINAL PAIN (Progressive onset following dose II of the Moderna covid19 vaccine of asthenia, lack of appetite, abdominal pain and hyperchromic urine, with the aforementioned diagnosis of hepatitis frank.), DECREASED APPETITE (Progressive onset following dose II of the Moderna covid19 vaccine of asthenia, lack of appetite, abdominal pain and hyperchromic urine, with the aforementioned diagnosis of hepatitis frank.) and CHROMATURIA (Progressive onset following dose II of the Moderna covid19 vaccine of asthenia, lack of appetite, abdominal pain and hyperchromic urine, with the aforementioned diagnosis of hepatitis frank.) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 19-Nov-2021, Alpha-1 anti-trypsin: inconclusive (Inconclusive) Inconclusive. On 19-Nov-2021, Antibody test: inconclusive (Inconclusive) Inconclusive. On 19-Nov-2021, Antinuclear antibody: inconclusive (Inconclusive) Inconclusive. On 19-Nov-2021, Beta 2 microglobulin: inconclusive (Inconclusive) Inconclusive. On 19-Nov-2021, Blood alkaline phosphatase: inconclusive (Inconclusive) Inconclusive. On 19-Nov-2021, Ceruloplasmin: inconclusive (Inconclusive) Inconclusive. On 19-Nov-2021, Differential white blood cell count: inconclusive (Inconclusive) Inconclusive. On 19-Nov-2021, Epstein-Barr virus antibody: inconclusive (Inconclusive) Inconclusive. On 19-Nov-2021, Gamma-glutamyltransferase: inconclusive (Inconclusive) Inconclusive. On 19-Nov-2021, Hepatitis A antibody: inconclusive (Inconclusive) Inconclusive. On 19-Nov-2021, Hepatitis B surface antigen: inconclusive (Inconclusive) Inconclusive. On 19-Nov-2021, Hepatitis C antibody: inconclusive (Inconclusive) Inconclusive. On 19-Nov-2021, Hyperbilirubinaemia: inconclusive (Inconclusive) Inconclusive. On 19-Nov-2021, Immunoglobulins: inconclusive (Inconclusive) Inconclusive. On 19-Nov-2021, Toxoplasmosis: inconclusive (Inconclusive) Inconclusive. On 19-Nov-2021, Transaminases: inconclusive (Inconclusive) Inconclusive. On 19-Nov-2021, Ultrasound abdomen: inconclusive (Inconclusive) Inconclusive. On 25-Nov-2021, Biopsy liver: inconclusive (Inconclusive) Inconclusive. On 10-Dec-2021, Specialist consultation: inconclusive (Inconclusive) Inconclusive. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. On an unknown date, biopsy was taken which identified aggressive chronic hepatitis. Liver biopsy showed evidence of aggressive hepatitis compatible with autoimmune damage. Patient parameters were improving. Blood chemical investigations ruled out Viral hepatitis or accumulation diseases. Highlighted positive for ANA 1/640 autoantibodies. Relevant concomitant product usage were not reported by the reporter. No treatment details were added. Company comment:This is a regulatory case concerning a 30-year-old female patient with no relevant medical history, who experienced the serious unexpected events of Hepatitis acute, Decreased appetite, Abdominal pain, and Asthenia(seriousness criterion hospitalization). These events occurred approximately 1 month after the patient received second dose of mRNA-1273 (Spikevax). The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report. Events seriousness assessed as per Regulatory Authority reporting.

Case ID	Narrative (Complete)
	Company comment: This is a regulatory case concerning a 30 -year-old, female patient with a history of Autoimmune thyroiditis and COVID-19, who experienced the serious unexpected, according CCDS, events of Hepatitis acute, Decreased appetite, Abdominal pain, Asthenia and Chromaturia. The events Decreased appetite, Abdominal pain, Asthenia and Chromaturia could be in association with acute hepatitis event. The events occurred approximately 42 days after the mRNA-1273 vaccine, dose number not provided. The rechallenge was not applicable. The patient was hospitalized due to Hepatitis of an autoimmune nature in a predisposed patient. The medical history, of Autoimmune thyroiditis and COVID-19, remain as confounders. The case was assessed as serious as per Regulatory Authority´s report due to hospitalization. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 12-Jan-2022: Due to incorrect follow-up receipt date, this case is amended to reflect the actual follow-up receipt date/Date FU Rcvd by Safety. This case was submitted on-time based on the actual follow-up receipt date. The actual follow-up receipt date/ Date FU Rcvd by Safety for thi

Case ID	Narrative (Complete)
[redacted]	This case was received via [redacted] [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 PYREXIA (High temperature) and LIVER INJURY (Damage liver) in a 56-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) (batch no. 3004732) for an unknown indication. Concurrent medical conditions included Suspected COVID-19 since 04-Dec-2021. Concomitant products included COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (COVID-19 VACCINE ASTRAZENECA) from 16-Mar-2021 to an unknown date for an unknown indication. On 30-Nov-2021, the patient received third dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 04-Dec-2021, after starting mRNA-1273 (Moderna CoviD-19 Vaccine), the patient experienced PYREXIA (High temperature) (seriousness criterion medically significant). On an unknown date, the patient experienced LIVER INJURY (Damage liver) (seriousness criterion medically significant). At the time of the report, PYREXIA (High temperature) and LIVER INJURY (Damage liver) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 05-Dec-2021, SARS-CoV-2 test: negative (Negative) Negative. The action taken with mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown) was unknown. Patient had temperature of 40 degrees for 4 days, fever, sweating, headache, dry kidney, liver infection and stomach upset. Patient had unspecified blood tests and follow-up one week later Treatment information was not provided. Company comment: This is a regulatory case concerning a 56 year-old, male patient with a history of Suspected COVID-19 and Interchange of vaccine products (reported vaccination with one dose of COVID-19 vaccine AstraZeneca approximately 8 months prior), who experienced the serious (due to medically important condition), according CCDS, AESI of liver injury and the serious (due to medically important condition), according CCDS, event of pyrexia. The event pyrexia occurred approximately 4 days after the booster dose of mRNA-1273 vaccine and the event liver injury on an unknown date. The outcome of the events was reported as recovering. The rechallenge was not applicable, as the events were reported exclusively after the booster dose. The medical history, of Suspected COVID-19 and Interchange of vaccine products (reported vaccination with one dose of COVID-19 vaccine AstraZeneca approximately 8 months prior) remain as confounders. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.

Case ID	Narrative (Complete)
[redacted]	This case was received via [redacted] (Reference number: [redacted], on 09-Nov-2021 and was forwarded to Moderna on 28-Dec-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of AUTOIMMUNE DISORDER (Autoimmune disorder), AUTOIMMUNE HEPATITIS (Autoimmune hepatitis), ANTINUCLEAR ANTIBODY INCREASED (Antinuclear antibody increased), CRYOGLOBULINS PRESENT (Cryoglobulins present) and CYTOMEGALOVIRUS TEST POSITIVE (Cytomegalovirus test positive) in a 49-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 025A21A) for an unknown indication. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Mixed connective tissue disease, Sjogren's disease and Thyroid disorder (Thyroid Disease). On 26-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 09-Apr-2021, the patient experienced AUTOIMMUNE DISORDER (Autoimmune disorder), AUTOIMMUNE HEPATITIS (Autoimmune hepatitis), ANTINUCLEAR ANTIBODY INCREASED (Antinuclear antibody increased), CRYOGLOBULINS PRESENT (Cryoglobulins present), CYTOMEGALOVIRUS TEST POSITIVE (Cytomegalovirus test positive), EPSTEIN-BARR VIRUS TEST POSITIVE (Epstein-Barr virus test positive), HEPATIC ENZYME INCREASED (Hepatic enzyme increased), METABOLIC FUNCTION TEST (Metabolic function test) and PALPITATIONS (Palpitations). At the time of the report, AUTOIMMUNE DISORDER (Autoimmune disorder), AUTOIMMUNE HEPATITIS (Autoimmune hepatitis), ANTINUCLEAR ANTIBODY INCREASED (Antinuclear antibody increased), CRYOGLOBULINS PRESENT (Cryoglobulins present), CYTOMEGALOVIRUS TEST POSITIVE (Cytomegalovirus test positive), EPSTEIN-BARR VIRUS TEST POSITIVE (Epstein-Barr virus test positive), HEPATIC ENZYME INCREASED (Hepatic enzyme increased), METABOLIC FUNCTION TEST (Metabolic function test) and PALPITATIONS (Palpitations) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 09-Apr-2021, Cytomegalovirus test: results not reported Results not reported. On 09-Apr-2021, Epstein-Barr virus test: results not reported Results not reported. On 09-Apr-2021, Metabolic function test: results not reported Results not reported. On 20-Apr-2021, Cytomegalovirus test: results not reported Results not reported. On 20-Apr-2021, Epstein-Barr virus test: results not reported Results not reported. On 20-Apr-2021, Metabolic function test: results not reported Results not reported. On 28-Apr-2021, Cytomegalovirus test: results not reported Results not reported. On 28-Apr-2021, Epstein-Barr virus test: results not reported Results not reported. On 28-Apr-2021, Metabolic function test: results not reported Results not reported. On 01-May-2021, Cytomegalovirus test: results not reported Results not reported. On 01-May-2021, Epstein-Barr virus test: results not reported Results not reported. On 01-May-2021, Metabolic function test: results not reported Results not reported. On 05-May-2021, Cytomegalovirus test: results not reported Results not reported. On 05-May-2021, Epstein-Barr virus test: results not reported Results not reported. On 05-May-2021, Metabolic function test: results not reported Results not reported. On 07-May-2021, Cytomegalovirus test: results not reported Results not reported. On 07-May-2021, Epstein-Barr virus test: results not reported Results not reported. On 07-May-2021, Metabolic function test: results not reported Results not reported. On 13-May-2021, Cytomegalovirus test: results not reported Results not reported. On 13-May-2021, Epstein-Barr virus test: results not reported Results not reported. On 13-May-2021, Metabolic function test: results not reported Results not reported. On 17-May-2021, Cytomegalovirus test: results not reported Results not reported. On 17-May-2021, Epstein-Barr virus test: results not reported Results not reported. On 17-May-2021, Metabolic function test: results not reported Results not reported. On 20-May-2021, Cytomegalovirus test: results not reported Results not reported. On 20-May-2021, Epstein-Barr virus test: results not reported Results not reported. On 20-May-2021, Metabolic function test: results not reported Results not reported. On 02-Jun-2021, Cytomegalovirus test: results not reported Results not reported. On 02-Jun-2021, Epstein-Barr virus test: results not reported Results not reported. On 02-Jun-2021, Metabolic function test: results not reported Results not reported. On 21-Jun-2021, Cytomegalovirus test: results not reported Results not reported. On 21-Jun-2021, Epstein-Barr virus test: results not reported Results not reported. On 21-Jun-2021, Metabolic function test: results not reported Results not reported. On 16-Jul-2021, Cytomegalovirus test: results not reported Results not reported. On 16-Jul-2021, Epstein-Barr virus test: results not reported Results not reported. On 16-Jul-2021, Metabolic function test: results not reported Results not reported. On 10-Aug-2021, Cytomegalovirus test: results not reported Results not reported. On 10-Aug-2021, Epstein-Barr virus test: results not reported Results not reported. On 10-Aug-2021, Metabolic function test: results not reported Results not reported. On 08-Sep-2021, Cytomegalovirus test: results not reported Results not reported. On 08-Sep-2021, Epstein-Barr virus test: results not reported Results not reported. On 08-Sep-2021, Metabolic function test: results not reported Results not reported. On 28-Sep-2021, Cytomegalovirus test: results not reported Results not reported. On 28-Sep-2021, Epstein-Barr virus test: results not reported Results not reported. On 28-Sep-2021, Metabolic function test: results not reported Results not reported. On 18-Oct-2021, Cytomegalovirus test: results not reported Results not reported. On 18-Oct-2021, Epstein-Barr virus test: results not reported Results not reported. On 18-Oct-2021, Metabolic function test: results not reported Results not reported. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown) was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments.

Case ID	Narrative (Complete)
	It was reported that patient had lab work done with many metabolic panels in addition to Epstein Barr virus, Cytomegalovirus and other things on April 9, 20, 28 May 1, 5, 7, 13, 17, 20 June 2, 21 July 16 August 10 Sept 8, 28 October 18 for which results were not provided. Treatment information was not provided by reporter. Other medication also included hydroxychloroquine 200mg per day, Synthroid 75 mcg per day, xiidra eye drops, Vitamin B Complex, Vitamin D Ibuprofen as needed. It was reported patient had an autoimmune reaction following the Moderna vaccine which led to elevated liver enzymes which started to show in labs 6 weeks post vaccine, continued to increase for about a month and then gradually subsided over the next several months. Doctor believed that the MRNA triggered autoimmune disease which triggered antibodies to target liver causing autoimmune hepatitis. Patient also reported elevated ANA screen IFA, ANA pattern 1; ANA Titer positive for cryoglobulins reactivation of EBV and CMV heart palpitations for about a month whenever lie down. Company comment: This case concerns a 49-year-old, female patient with medical history of Mixed connective tissue disease, Sjogren's disease and Thyroid disorder, who experienced the unexpected events of Autoimmune disorder, Autoimmune hepatitis, Antinuclear antibody increased, Cryoglobulins present, Cytomegalovirus test positive, Epstein-Barr virus test positive, Hepatic enzyme increased, Metabolic function test and Palpitations. The events occurred approximately 42 days after the first dose of mRNA-1273. As reported, the patient had an autoimmune reaction following the Moderna vaccine which led to elevated liver enzymes which started to show in labs 6 weeks post vaccine, continued to increase for about a month and then gradually subsided over the next several months. Doctor believed that the MRNA triggered autoimmune disease which triggered antibodi

Case ID	Narrative (Complete)
[redacted]	This case was received via [redacted] (Reference number: [redacted]) on 26-Dec-2021 and was forwarded to Moderna on 26-Dec-2021. This regulatory authority case was reported by a physician and describes the occurrence of ACUTE HEPATIC FAILURE (Acute liver failure), THROMBOCYTOPENIA (platelet count less than 150 Ã— 109/L), FATIGUE (Fatigue) and PYREXIA (Fever) in a 55-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for an unknown indication. The patient's past medical history included Immunodeficiency (Taking other treatments or medicines, not listed above, known to lower the immune response and i...) and Smoker. Previously administered products included for Angina pectoris: NEBIVOLOL, ASPIRIN and ATORVASTATIN. Past adverse reactions to the above products included No adverse event with ASPIRIN, ATORVASTATIN and NEBIVOLOL. Concurrent medical conditions included Angina pectoris (Patient was known to have angina- takes aspirin, atorvastatin, nebivolol. no other co-morbidities.) and Suspected COVID-19 since 19-Dec-2021. On 15-Dec-2021, the patient received third dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 24-Dec-2021, the patient experienced ACUTE HEPATIC FAILURE (Acute liver failure) (seriousness criterion medically significant). On an unknown date, the patient experienced THROMBOCYTOPENIA (platelet count less than 150 Ã— 109/L) (seriousness criterion medically significant), FATIGUE (Fatigue) (seriousness criterion medically significant) and PYREXIA (Fever) (seriousness criterion medically significant). At the time of the report, ACUTE HEPATIC FAILURE (Acute liver failure) had not resolved and THROMBOCYTOPENIA (platelet count less than 150 Ã— 109/L), FATIGUE (Fatigue) and PYREXIA (Fever) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Electrocardiogram: no results provided No results provided. On an unknown date, Fibrin D dimer: d-dimer was not greater than 4000 (abnormal) D-dimer was not greater than 4000. The action taken with mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown) was unknown. For mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Patient had not tested positive for COVID-19 since having the vaccine Patient vapes and drinks 60 ml vodka 5 days a week Not had a COVID-19 test Thromboembolic event / Thombocytopenia additional questions Please specify the details of the event: "platelets- 48" What was the date of diagnosis?: 24-Dec-2021 What date was the platelet count measured?: 24-Dec-2021 What date was the D-dimer measured?: 24-Dec-2021 Myocarditis and pericarditis Was the patient admitted to hospital?: "Yes" If the patient was hospitalised, how long did they stay in hospital for?: "still in hospital" What treatment was provided to the patient? For example, NSAIDs, steroids or other anti inflammatory agents: "yes" Was the cardiac troponin normal or raised? : "high" What was the peak troponin value?: "150" What was the troponin reference range?: "less than 13" If an ECG was carried out, please can you provide the date and results: "normal on 24-Dec-2021" No concomitant medications reported. No treatment information reported.

Case ID	Narrative (Complete)
[redacted]	This case was received via [redacted] (Reference number: [redacted]) on 28-Dec-2021 and was forwarded to Moderna on 28-Dec-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of ALANINE AMINOTRANSFERASE INCREASED (Alanine aminotransferase increased), ASPARTATE AMINOTRANSFERASE INCREASED (Aspartate aminotransferase increased), AUTOIMMUNE HEPATITIS (Autoimmune hepatitis), BLOOD ALKALINE PHOSPHATASE INCREASED (Blood alkaline phosphatase increased), BLOOD BILIRUBIN INCREASED (Blood bilirubin increased), JAUNDICE (Jaundice) and LIVER FUNCTION TEST INCREASED (Liver function test increased) in a 72-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for an unknown indication. Concurrent medical conditions included Drug allergy, Dementia and UTI. On 01-Dec-2021, the patient received dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 05-Dec-2021, the patient experienced ALANINE AMINOTRANSFERASE INCREASED (Alanine aminotransferase increased) (seriousness criterion hospitalization), ASPARTATE AMINOTRANSFERASE INCREASED (Aspartate aminotransferase increased) (seriousness criterion hospitalization), AUTOIMMUNE HEPATITIS (Autoimmune hepatitis) (seriousness criterion hospitalization), BLOOD ALKALINE PHOSPHATASE INCREASED (Blood alkaline phosphatase increased) (seriousness criterion hospitalization), BLOOD BILIRUBIN INCREASED (Blood bilirubin increased) (seriousness criterion hospitalization), JAUNDICE (Jaundice) (seriousness criterion hospitalization) and LIVER FUNCTION TEST INCREASED (Liver function test increased) (seriousness criterion hospitalization). At the time of the report, ALANINE AMINOTRANSFERASE INCREASED (Alanine aminotransferase increased), ASPARTATE AMINOTRANSFERASE INCREASED (Aspartate aminotransferase increased), AUTOIMMUNE HEPATITIS (Autoimmune hepatitis), BLOOD ALKALINE PHOSPHATASE INCREASED (Blood alkaline phosphatase increased), BLOOD BILIRUBIN INCREASED (Blood bilirubin increased), JAUNDICE (Jaundice) and LIVER FUNCTION TEST INCREASED (Liver function test increased) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Aspartate aminotransferase: 312 h (Inconclusive) 312 H. On an unknown date, Blood alkaline phosphatase: 1288 (Inconclusive) 1288. On an unknown date, Blood bilirubin: 9.1 h (Inconclusive) 9.1 H. On an unknown date, Liver function test: results not provided (Inconclusive) Results not provided. 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. Other Medications include Gabapentin; Ezetimbe; Levothyroxine; Memantine. Patient presented with severe jaundice and elevated LFTs. Assessed by gastroenterology team who believe that Moderna booster may have led to an autoimmune hepatitis-like picture. LFTs are slowly resolving, on Prednisolone Company Comment: This is a regulatory case concerning a 72-year-old, female patient with no relevant medical history, who experienced the unexpected serious AESI event of Autoimmune hepatitis and unexpected serious event of Jaundice. The events occurred 4 days after an unknown dose of mRNA-1273 vaccine. Alanine aminotransferase increased, Aspartate aminotransferase increased, Blood alkaline phosphatase increased, Blood bilirubin increased, and Liver function test increased were also reported. The outcome of the events was reported as unknown. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. The case was assessed as serious as per Regulatory Authoritys report due to hospitalization.
[redacted]	This regulatory authority case was reported by a consumer and describes the occurrence of AUTOIMMUNE HEPATITIS (Trigger of autoimmune hepatitis) in a 57-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) (batch no. 3002912) for COVID-19 vaccination. Concurrent medical conditions included Gluten intolerance and Pollen allergy. On 15-May-2021, the patient received dose of mRNA-1273 (COVID-19 Vaccine Moderna) (unknown route) 1 dosage form. On 12-Jun-2021, received dose of mRNA-1273 (COVID-19 Vaccine Moderna) (unknown route) dosage was changed to 1 dosage form. On 26-Jul-2021, after starting mRNA-1273 (COVID-19 Vaccine Moderna), the patient experienced AUTOIMMUNE HEPATITIS (Trigger of autoimmune hepatitis) (seriousness criterion medically significant). At the time of the report, AUTOIMMUNE HEPATITIS (Trigger of autoimmune hepatitis) had not resolved. Concomitant product was not provided by the reporter. Treatment information was not provided. Company comment: This regulatory authority case concerns a 57-year-old male patient with no relevant medical history who experienced serious unexpected event of autoimmune hepatitis, that occurred approximately 1.5 months after the 2nd dose of the mRNA-1273. The rechallenge was not applicable since due to occurrence after the third dose , no rechallenge was done and recurrence was not applicable. The benefit-risk relationship of mRNA-1273 is not affected by this report.

Case ID	Narrative (Complete)
[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 consumer and describes the occurrence of AUTOIMMUNE HEPATITIS (initial diagnosis of autoimmune hepatitis.) in a 36-year-old female patient who received mRNA-1273 (Spikevax) for Prophylactic vaccination. 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 07-Jun-2021, the patient experienced AUTOIMMUNE HEPATITIS (initial diagnosis of autoimmune hepatitis.) (seriousness criterion medically significant). At the time of the report, AUTOIMMUNE HEPATITIS (initial diagnosis of autoimmune hepatitis.) was resolving. No relevant concomitant medications were reported. Information on risk factors or pre-existing illnesses ulcerative colitis and PSC in regular care/increase in liver tests without any other cause. Extended laboratory revealed an IgG increase and corresponding AK, liver biopsy compatible with AIH. Initiation of cortisone trosis therapy and immunosuppression. Therapy with azathioprine. The diagnosis was made during an inpatient stay on the basis of the PSC. Most recent FOLLOW-UP information incorporated above includes: On 12-May-2022: Due to case creation with incorrect initial receipt date, this case is amended to reflect the actual initial receipt date within the narrative. This case was submitted on-time based on the actual initial receipt date. The actual initial receipt date for this case is 04-Jan-2022.
[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 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 consumer and describes the occurrence of LIVER INJURY (Suspected liver damage) in a 32-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3005697) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Hyperhidrosis, Depression and Panic attacks. Concomitant products included DIAZEPAM, OXYBUTYNIN HYDROCHLORIDE (DITROPAN) and CYANOCOBALAMIN (SL B12) for an unknown indication. On 14-Sep-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 14-Sep-2021, the patient experienced VACCINATION SITE PAIN (Pain at the site of Vaccination) and VACCINATION SITE ERYTHEMA (Redness at the site of vaccination). On 15-Sep-2021, the patient experienced MALAISE (General malaise) and DIARRHOEA (Diarrhoeal). On 16-Sep-2021, the patient experienced FATIGUE (Weariness), the first episode of PYREXIA (Feber), CHILLS (OVERINDULGE) and MYALGIA (Myalgia). On 17-Sep-2021, the patient experienced LYMPHADENOPATHY (Swollen Lymph nodes). On 18-Sep-2021, the patient experienced LIVER INJURY (Suspected liver damage) (seriousness criterion medically significant), AGGRESSION (Aggressiveness), MOOD SWINGS (Mood swings), DYSPNOEA (Respiratory disorders), HYPERHIDROSIS (Secondary Hyperhidrosis), DIZZINESS (YRSEL), RASH (Rash other than the site of Vaccination), NAUSEA (Nauseous), HEADACHE (Headaches) and the second episode of PYREXIA (Feber). On 20-Sep-2021, the patient experienced VOMITING (Vomiting). On 22-Sep-2021, the patient experienced ARTHRITIS (Inflammation,Joints/Neck). On 16-Sep-2021, VACCINATION SITE ERYTHEMA (Redness at the site of vaccination) had resolved. On 18-Sep-2021, VACCINATION SITE PAIN (Pain at the site of Vaccination) had resolved. On 22-Sep-2021, LYMPHADENOPATHY (Swollen Lymph nodes) had resolved with sequelae. At the time of the report, LIVER INJURY (Suspected liver damage), AGGRESSION (Aggressiveness), ARTHRITIS (Inflammation,Joints/Neck), MOOD SWINGS (Mood swings), DYSPNOEA (Respiratory disorders), MALAISE (General malaise), DIARRHOEA (Diarrhoeal), DIZZINESS (YRSEL), FATIGUE (Weariness), NAUSEA (Nauseous), HEADACHE (Headaches), VOMITING (Vomiting), CHILLS (OVERINDULGE) and MYALGIA (Myalgia) had not resolved, HYPERHIDROSIS (Secondary Hyperhidrosis) and the last episode of PYREXIA (Feber) had resolved with sequelae and RASH (Rash other than the site of Vaccination) was resolving. The action taken with mRNA-1273 (Spikevax) (Unknown) was unknown. Concomitant medication was not reported. Treatment information was not reported.

Case ID	Narrative (Complete)
[redacted]	This spontaneous case was reported by a consumer and describes the occurrence of HEPATITIS (Hepatitis with rapid onset of liver injury) and LIVER INJURY (Hepatitis with rapid onset of liver injury) in a male patient of an unknown age who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination. No Medical History information was reported. On an unknown date, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 100 microgram. On an unknown date, received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) dosage was changed to 100 microgram. On an unknown date, the patient experienced HEPATITIS (Hepatitis with rapid onset of liver injury) (seriousness criterion medically significant) and LIVER INJURY (Hepatitis with rapid onset of liver injury) (seriousness criterion medically significant). At the time of the report, HEPATITIS (Hepatitis with rapid onset of liver injury) and LIVER INJURY (Hepatitis with rapid onset of liver injury) outcome was unknown. No concomitant medication was provided by the reporter. The patient posted via Facebook that based on the case they demonstrated it showed that there was a conclusive evidence of vaccine-induced immune-mediated hepatitis with a rapid onset of liver injury after the first Moderna dose, which on re-exposure led to acute severe autoimmune hepatitis. No treatment medication was provided by the reporter. Company comment: This case concerns a male patient with no reported medical history who experienced serious unexpected events of hepatitis and liver injury, reported as hepatitis with rapid onset of liver injury, that occurred after the 1st dose of the mRNA-1273. Reportedly, there was an evidence of vaccine-induced immune-mediated hepatitis with a rapid onset of liver injury after the first dose, which led to acute severe autoimmune hepatitis on re-exposure. The rechallenge was positive due to reoccurrence after the re-exposure with the 2nd dose. The benefit-risk relationship of mRNA-1273 is not affected by this report. Reporter did not allow further contact

Case ID	Narrative (Complete)
[redacted]	This regulatory authority case was reported by a consumer and describes the occurrence of AUTOIMMUNE HEPATITIS (progressive increase in transmamminase diagnosis hepatologist autoimmune hepatitis by drugs in therapy since december 2020 with monoclonal antibodies but increased transaminase only after Moderna vaccine doses) and TRANSAMINASES INCREASED (progressive increase in transmamminase diagnosis hepatologist autoimmune hepatitis by drugs in therapy since december 2020 with monoclonal antibodies but increased transaminase only after Moderna vaccine doses) in an 81-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 3001941) for COVID-19 vaccination. Co-suspect products included non-company products TRASTUZUMAB (TRAZIMERA [TRASTUZUMAB]) for Breast cancer, PERTUZUMAB (PERJETA) for Breast cancer and ANASTROZOLE ([redacted] for Breast carcinoma. Patient medical history includes Ex-smoker, Ex-metal mechanics, On 2015 total thyroidectomy for toxic multinodular goiter, On 1996 K infiltrating ductal breast and On 2020 brain, Hepatic and bone secondary illnesses. Concomitant products included FUROSEMIDE, SPIRONOLACTONE [redacted] from 01-Jan-2021 to an unknown date for Edematous feet, LEVOTHYROXINE SODIUM (TIROSINT) from 01-Mar-2015 to an unknown date for Hypothyroidism. On 24-Dec-2020, the patient started TRASTUZUMAB (TRAZIMERA [TRASTUZUMAB]) (Intravenous) at an unspecified dose and PERTUZUMAB (PERJETA) (Intravenous) at an unspecified dose. On 01-May-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form and ANASTROZOLE ([redacted] (Oral) 1 milligram once a day. On 01-May-2021, the patient experienced AUTOIMMUNE HEPATITIS (progressive increase in transmamminase diagnosis hepatologist autoimmune hepatitis by drugs in therapy since december 2020 with monoclonal antibodies but increased transaminase only after Moderna vaccine doses) (seriousness criterion life threatening). 01-May-2021, the patient experienced TRANSAMINASES INCREASED (progressive increase in transmamminase diagnosis hepatologist autoimmune hepatitis by drugs in therapy since december 2020 with monoclonal antibodies but increased transaminase only after Moderna vaccine doses) (seriousness criterion life threatening). At the time of the report, AUTOIMMUNE HEPATITIS (progressive increase in transmamminase diagnosis hepatologist autoimmune hepatitis by drugs in therapy since december 2020 with monoclonal antibodies but increased transaminase only after Moderna vaccine doses) and TRANSAMINASES INCREASED (progressive increase in transmamminase diagnosis hepatologist autoimmune hepatitis by drugs in therapy since december 2020 with monoclonal antibodies but increased transaminase only after Moderna vaccine doses) had not resolved. Treatment details was not reported by the reporter. Reporter mentioned that suspected adverse reactions during triple oncology therapy started after administration of the second dose of comirnaty. Company Comment - This regulatory authority case concerns a 81 year old female patient with medical history of Breast carcinoma and hypothyroidism, who experienced the serious (life threatening) unexpected event of autoimmune hepatitis and Transaminases increased. The event occurred on the same day after a dose of mRNA-1273 vaccine, and had not resolved at the time of the report. Treatment details was not reported. Patient's medical history of hypothyroidism and Breast carcinoma remains a confounder. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 13-Jan-2022: Follow-up document contains no new information. On 07-Feb-2022: Event added.

Case ID	Narrative (Complete)
[redacted]	This case was initially received via European Medicines Agency (Reference number: [redacted] on 12-Jan-2022. The most recent information was received on 13-Jan-2022 and was forwarded to Moderna on 13-Jan-2022. This regulatory authority case was reported by a physician and describes the occurrence of AUTOIMMUNE HEPATITIS (The patient presented with autoimmune hepatitis of recent onset, probably favored by SARS-CoV-2 vaccination) in a 79-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The patient's past medical history included Sideropenic anaemia (history of iron deficiency anemia), Acute myocardial infarction (December 2017 IMA lower site treated with PTCA and implantation of 2 stents on the right coronary artery.), Mitral insufficiency, Depression (Depressive episode 5-6 years after menopause treated with lithium and other antidepressants is not precise), Acute calculous cholecystitis (In march 20219 admission for acute lithiasis cholecystitis) and Ovariectomy (In September 2020 bilateral ovariectomy for left ovary neoformation (ovarian tecoma) and colecistect). Concurrent medical conditions included Hypertension arterial (BBsN from 2013), Hypothyroidism (Hypothyroidism from about 30 years, in replacement t) and Type 2 diabetes mellitus (DMT2 in tp since 2010). Concomitant products included EMPAGLIFLOZIN for an unknown indication. On 08-Apr-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) .5 milliliter. On an unknown date, the patient experienced AUTOIMMUNE HEPATITIS (The patient presented with autoimmune hepatitis of recent onset, probably favored by SARS-CoV-2 vaccination) (seriousness criterion medically significant). At the time of the report, AUTOIMMUNE HEPATITIS (The patient presented with autoimmune hepatitis of recent onset, probably favored by SARS-CoV-2 vaccination) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 15-Jul-2021, Alanine aminotransferase: 283 283 INTERNATIONAL UNIT(S)-(UNDER 1000). On 15-Jul-2021, Aspartate aminotransferase: 247 247 INTERNATIONAL UNIT(S)-(UNDER 1000). On 15-Jul-2021, Gamma-glutamyltransferase: 770 770 INTERNATIONAL UNIT(S)-(UNDER 1000). On 29-Jul-2021, Alanine aminotransferase: 304 304 INTERNATIONAL UNIT(S)-(UNDER 1000). On 29-Jul-2021, Aspartate aminotransferase: 256 256 INTERNATIONAL UNIT(S)-(UNDER 1000). On 29-Jul-2021, Blood alkaline phosphatase: 745 745 INTERNATIONAL UNIT(S)-(UNDER 1000). On 29-Jul-2021, Gamma-glutamyltransferase: 775 775 INTERNATIONAL UNIT(S)-(UNDER 1000). On 16-Aug-2021, Alanine aminotransferase: 344 344 INTERNATIONAL UNIT(S)-(UNDER 1000). On 16-Aug-2021, Aspartate aminotransferase: 293 293 INTERNATIONAL UNIT(S)-(UNDER 1000). On 16-Aug-2021, Blood alkaline phosphatase: 742 742 INTERNATIONAL UNIT(S)-(UNDER 1000). On 16-Aug-2021, Gamma-glutamyltransferase: 754 754 INTERNATIONAL UNIT(S)-(UNDER 1000). For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No treatment medication was provided. Company comment:This case concerns a 79-year-old, female subject with a medical history of diabetes and hypothyroidism, who experienced the serious (seriousness criterion= Other medically important condition) unexpected event of Autoimmune hepatitis. The event occurred unknown number of days after receiving a dose of mRNA-1273 vaccine, dose number unknown. Liver enzymes were elevated. There was no available information regarding treatment medication. At the time of the report, autoimmune hepatitis was resolving. Rechallenge is not applicable as dose number is inknown. The patient's gender and medical history of diabetes remain as confounders. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 13-Jan-2022: Medical history comments updated.Indication for use in the case updated. On 04-Feb-2022: Follow up received wherein no new information was added. On 18-Mar-2022: No new significant information received On 18-Mar-2022: Non significant translation document received on 25-Mar-2022 contains updated event verbatim.

Case ID	Narrative (Complete)
[redacted]	This spontaneous case was reported by a consumer and describes the occurrence of AUTOIMMUNE HEPATITIS (diagnosed as autoimmune hepatitis) in a 32-year-old male patient who received mRNA-1273 (COVID 19 Vaccine Moderna) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Previously administered products included for Product used for unknown indication: Sinopharm (Sinopharm vaccine dose 2) and Sinopharm (Sinopharm vaccine dose 1). Past adverse reactions to the above products included No adverse event with Sinopharm and Sinopharm. On an unknown date, the patient received third dose of mRNA-1273 (COVID 19 Vaccine Moderna) (unknown route) 1 dosage form. On an unknown date, the patient experienced AUTOIMMUNE HEPATITIS (diagnosed as autoimmune hepatitis) (seriousness criterion medically significant) and INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (Moderna Covid-19 as a third dose after 6 months of 2 doses of sinopharm). an unknown date, the patient experienced PYREXIA (complained of fever (38-39 degree celsius)) and FATIGUE (Fatigue). At the time of the report, AUTOIMMUNE HEPATITIS (diagnosed as autoimmune hepatitis), PYREXIA (complained of fever (38-39 degree celsius)) and FATIGUE (Fatigue) outcome was unknown and INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (Moderna Covid-19 as a third dose after 6 months of 2 doses of sinopharm) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 17-Jan-2022, Alanine aminotransferase (7-40): 672 (High) 672 U/L In this test Hepatitis markers are recommended and 645 (High) 645 U/L. On 17-Jan-2022, Aspartate aminotransferase (0-50): 438 (High) 438 U/L. On 17-Jan-2022, Basophil count (0-0.1): 0.15 (High) 0.15 x10^9/L (1.5%). On 17-Jan-2022, Blood lactate dehydrogenase (120-246): 707 (High) 707 U/L. On 17-Jan-2022, C-reactive protein: 31 (High) 31 mg/L (Normal range Less Than 5) and 37.6 (High) 37.6 mg/L. On 17-Jan-2022, Eosinophil count (0.1-0.45): 0.06 (Low) 0.06 x10^9/L (0.6 percent). On 17-Jan-2022, Lymphocyte count (1-4.8): 7.73 (High) 7.73 x10^9/L (76.6 percent). On 17-Jan-2022, Monocyte count (0.2-1): 0.45 (High) 0.45 x10^9/L (4.5 percent). On 17-Jan-2022, Neutrophil count (2-7): 1.70 (Low) 1.70 x10^9/L (16.8 percent). On 17-Jan-2022, Serum ferritin (30-400): 1106 (High) 1106 ng/ml. On an unknown date, Body temperature: 38-39 (High) 38-39 Degree Celsius. On an unknown date, SARS-CoV-2 test: negative (Negative) Negative. No concomitant medication information was provided. No treatment information was provided. The patient was medically free. Hepatic virus analysis was Negative. Laboratory test included: RDW-CV 12.7 percent, RBCs Count (EDTA Blood) 4.79 Millions/ cmm, Platelet Count (EDTA Blood) 189 percent, MCV 93.5 fl, MCHC 33.9 g/dl, MCH 31.7 pg, Haemoglobin (EDTA) blood 15.2 g/dL, Haematocrit (PCV) 44.8 percent, Serum creatinine 1.07 mg/dl, Albumin, serum 4.0 g/dl. The patient's HCV Antibody 3rd Generation was Negative, HBs Antigen Negative, HAV antibody - IgG Negative, HAV antibodies - IgM Negative and the reference range for all these were Negative. Company Comment: This is a case of Interchange of vaccine products for this 32-year-old male subject, with a medical history of prior vaccination with two doses of COVID-19 VACCINE Sinopharm, who experienced the serious unexpected event of Autoimmune hepatitis, and non-serious expected events of Pyrexia and Fatigue. Events Pyrexia and Fatigue occurred 10 days after receiving the third dose of mRNA-13 vaccine, date of administration unknown, while event autoimmune hepatitis occurred unknown number of days after vaccination. Liver enzymes (ALT= 672 U/L, AST=438 U/L), C-reactive protein (37.6mg/L), Ferritin (1106 ng/mL), and serum LDH (707 U/L) were elevated while Hepa profile was negative. COVID-19 virus test was negative. There was no available information regarding clinical course and treatment medication. Rechallenge was not applicable as no additional dose is expected to be given. The patient's medical history of prior vaccination with COVID-19 VACCINE Sinopharm remains a confounder. The benefit-risk relationship of mRNA 1273 Vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 19-Jan-2022: Translation received on 23-Jan-2022, laboratory data added.

Case ID	Narrative (Complete)
[redacted]	This case was received via European Medicines Agency (Reference number [redacted] on 25-Jan-2022 and was forwarded to Moderna on 25-Jan-2022. This regulatory authority case was reported by a physician and describes the occurrence of HYPERTRANSAMINASAEMIA (Hypertransaminasemia from late August and increased to november (ALT 10X) with IgG1749/1600 and positivity for ANA 1:640 (onset of autoimmune acute hepatitis), then slow decline [redacted]2022 ALT 4X)) and AUTOIMMUNE HEPATITIS (Hypertransaminasemia from late August and increased to november (ALT 10X) with IgG1749/1600 and positivity for ANA 1:640 (onset of autoimmune acute hepatitis), then slow decline [redacted]2022 ALT 4X)) in a 26-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3004498) for COVID-19 vaccination. No Medical History information was reported. On 21-Jul-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 23-Aug-2021, the patient experienced HYPERTRANSAMINASAEMIA (Hypertransaminasemia from late August and increased to november (ALT 10X) with IgG1749/1600 and positivity for ANA 1:640 (onset of autoimmune acute hepatitis), then slow decline [redacted]2022 ALT 4X)) (seriousness criterion medically significant) and AUTOIMMUNE HEPATITIS (Hypertransaminasemia from late August and increased to november (ALT 10X) with IgG1749/1600 and positivity for ANA 1:640 (onset of autoimmune acute hepatitis), then slow decline [redacted]2022 ALT 4X)) (seriousness criterion medically significant). At the time of the report, HYPERTRANSAMINASAEMIA (Hypertransaminasemia from late August and increased to november (ALT 10X) with IgG1749/1600 and positivity for ANA 1:640 (onset of autoimmune acute hepatitis), then slow decline [redacted]2022 ALT 4X)) and AUTOIMMUNE HEPATITIS (Hypertransaminasemia from late August and increased to november (ALT 10X) with IgG1749/1600 and positivity for ANA 1:640 (onset of autoimmune acute hepatitis), then slow decline [redacted]2022 ALT 4X)) was resolving. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. The patient was only taking multivitamin supplements, maltoestrins and branched amino acids taken from time to time for years, this intake was discontinued in July 2021. Occurrence of acute autoimmune hepatitis arising after II administration of Moderna vaccine. This is a regulatory authority case concerning a 26-year-old, male patient with no reported medical history, who experienced the unexpected serious events of Hypertransaminasaemia and Autoimmune hepatitis. The events occurred approximately 1 month after the unknown dose of mRNA-1273 COVID 19 Vaccine. The rechallenge was not applicable, as information about further dosing was not disclosed. The events were reported as resolving. The benefit-risk relationship of mRNA-1273 COVID 19 Vaccine, is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 25-Jan-2022: Non significant follow-up received includes translation doc in which event verbatim updated. On 28-Jan-2022: Non Significant Follow Up received contains no new information. On 14-Feb-2022: Follow up information included no new information

Case ID	Narrative (Complete)
[redacted]	This case was received via European Medicines Agency (Reference number: [redacted] on 29-Jan-2022 and was forwarded to Moderna on 29-Jan-2022. This regulatory authority case was reported by a physician and describes the occurrence of HEPATITIS ACUTE (acute icteric hepatitis, ALT 60X, gamma globulin 17.6 g/L, ANA 1:640, liver biopsy grading 9, staging 1) and JAUNDICE (acute icteric hepatitis, ALT 60X, gamma globulin 17.6 g/L, ANA 1:640, liver biopsy grading 9, staging 1) in a 30-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 3005687) for COVID-19 vaccination. No Medical History information was reported. On 08-Oct-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 19-Nov-2021, the patient experienced HEPATITIS ACUTE (acute icteric hepatitis, ALT 60X, gamma globulin 17.6 g/L, ANA 1:640, liver biopsy grading 9, staging 1) (seriousness criterion medically significant) and JAUNDICE (acute icteric hepatitis, ALT 60X, gamma globulin 17.6 g/L, ANA 1:640, liver biopsy grading 9, staging 1) (seriousness criterion medically significant). At the time of the report, HEPATITIS ACUTE (acute icteric hepatitis, ALT 60X, gamma globulin 17.6 g/L, ANA 1:640, liver biopsy grading 9, staging 1) and JAUNDICE (acute icteric hepatitis, ALT 60X, gamma globulin 17.6 g/L, ANA 1:640, liver biopsy grading 9, staging 1) was resolving. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medications were reported. No treatment medications were reported. Company Comment: This case concerns a 30-year-old female patient with no previous medical history reported, who experienced the serious unexpected events of Hepatitis acute and Jaundice which occurred 1 month and 12 days after a dose of mRNA-1273 received for COVID-19 Vaccination. It was also reported that it was an acute event of icteric hepatitis, ALT 60X, gamma globulin 17.6 g/L, ANA 1:640, and liver biopsy grading 9, staging 1. Jaundice could remain as a sign related to Hepatitis. No concomitant medication or treatment information was reported. At the time of the report the events were resolving. 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 29-Jan-2022: Translation document received on 01-Feb-2022 with Event verbatim translated and updated. On 16-Feb-2022: Follow up contains no new information

Case ID	Narrative (Complete)
[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 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)
[redacted]	This case was received via [redacted] (Reference number: [redacted]) on 01-Feb-2022 and was forwarded to Moderna on 01-Feb-2022. This regulatory authority case was reported by a consumer and describes the occurrence of LIVER INJURY (Damage liver) in a 64-year-old female patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) (batch no. 000022A) for an unknown indication. Co-suspect product included non-company product TOZINAMERAN (COVID-19 MRNA VACCINE BNT162B2) for an unknown indication. Concurrent medical conditions included Psoriatic arthritis (On Secukinimab for Psoriatic Arthritis) and Rheumatoid arthritis (Taking regular medicines for rheumatoid arthritis (or other types of arthritis except osteoarthr...). Concomitant products included SECUKINUMAB from 07-Mar-2016 to an unknown date for Psoriatic arthritis, OMEPRAZOLE for an unknown indication. On 14-Jan-2022, the patient received fourth dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On an unknown date, the patient received dose of TOZINAMERAN (COVID-19 MRNA VACCINE BNT162B2) (unknown route) 1 dosage form. On 15-Jan-2022, the patient experienced LIVER INJURY (Damage liver) (seriousness criterion medically significant). At the time of the report, LIVER INJURY (Damage liver) 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) No - Negative COVID-19 test. The action taken with mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown) was unknown. Concomitant product included SARS-COV-2 VIRUS for COVID-19 vaccination taken on 14 Oct 2021. Laboratory tests included blood test on 17 Jan 2022 showed ALT level of 92. ALT level was raised to 77 in blood test 30 Nov 2021 and 70 in blood test 14 Dec 2021 as being monitored after ALT was raised after previous covid 19 Pfizer vaccine 14 Oct 2021. Had no problem with raised ALT levels after 2 Astra Zeneca vaccines. Patient had not tested positive for COVID-19 since having the vaccine. Patient was not enrolled in clinical trial The report did not relate to possible inflammation of the heart myocarditis or pericarditis. No treatment medications were reported. This case concerns a 23-year-old female patient with no relevant medical history, who experienced the unexpected serious event of Liver Injury, the event was reported as medically significant by the regulatory authority. The event occurred in 2 days after receiving the fourth dose of mRNA-1273 Vaccine and on an unknown interval after receiving an unspecified dose of the Co-suspect non-company product TOZINAMERAN (COVID-19 MRNA VACCINE BNT162B2). SARS-CoV-2 test yielded negative results, no other 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 case was received via European Medicines Agency (Reference number: [redacted]) on 08-Feb-2022 and was forwarded to Moderna on 08-Feb-2022. This regulatory authority case was reported by a physician and describes the occurrence of JAUNDICE (Jaundice) and HEPATOCELLULAR INJURY (Hepatocellular damage) in a 48-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Gastrooesophageal reflux. On 08-Jan-2022, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 08-Jan-2022, after starting mRNA-1273 (Spikevax), the patient experienced INFLUENZA LIKE ILLNESS (Influenza like illness). In January 2022, the patient experienced JAUNDICE (Jaundice) (seriousness criterion medically significant) and HEPATOCELLULAR INJURY (Hepatocellular damage) (seriousness criterion medically significant). At the time of the report, JAUNDICE (Jaundice) and HEPATOCELLULAR INJURY (Hepatocellular damage) had not resolved and INFLUENZA LIKE ILLNESS (Influenza like illness) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, SARS-CoV-2 test: negative (Negative) Negative. 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. Company Comment - This regulatory authority case concerns a 48 year old male patient with no relevant medical history, who experienced the serious unexpected events of jaundice and hepatocellular injury. The events occurred on an unknown date after a dose of mRNA-1273 vaccine. 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.

Case ID	Narrative (Complete)
[redacted]	This case was initially received via European Medicines Agency (Reference number: [redacted]) on 09-Feb-2022. The most recent information was received 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 RECTAL HAEMORRHAGE (Asthenia, lack of appetite and low-grade fever. From 17/01 hospitalization and worsening liver failure (fulminant hepatitis). Currently on the national emergency transplant list.), HEPATITIS FULMINANT (Asthenia, lack of appetite and low-grade fever. From 17/01 hospitalization and worsening liver failure (fulminant hepatitis). Currently on the national emergency transplant list.), ACUTE HEPATIC FAILURE (Asthenia, lack of appetite and low-grade fever. From 17/01 hospitalization and worsening liver failure (fulminant hepatitis). Currently on the national emergency transplant list.), DECREASED APPETITE (Asthenia, lack of appetite and low-grade fever. From 17/01 hospitalization and worsening liver failure (fulminant hepatitis). Currently on the national emergency transplant list.), PYREXIA (Asthenia, lack of appetite and low-grade fever. From 17/01 hospitalization and worsening liver failure (fulminant hepatitis). Currently on the national emergency transplant list.), ASTHENIA (Asthenia, lack of appetite and low-grade fever. From 17/01 hospitalization and worsening liver failure (fulminant hepatitis). Currently on the national emergency transplant list.), VOMITING (Asthenia, lack of appetite and low-grade fever. From 17/01 hospitalization and worsening liver failure (fulminant hepatitis). Currently on the national emergency transplant list.) and HEPATIC ENCEPHALOPATHY (Asthenia, lack of appetite and low-grade fever. From 17/01 hospitalization and worsening liver failure (fulminant hepatitis). Currently on the national emergency transplant list.) in a 46-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 3005698) for COVID-19 vaccination. The patient's past medical history included Breast carcinoma (12/2021 diagnosis of intraductal right breast cancer, candidate for neoadjuvant chemotherapy and). On 12-Jan-2022, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 13-Jan-2022, the patient experienced RECTAL HAEMORRHAGE (Asthenia, lack of appetite and low-grade fever. From 17/01 hospitalization and worsening liver failure (fulminant hepatitis). Currently on the national emergency transplant list.) (seriousness criterion life threatening), HEPATITIS FULMINANT (Asthenia, lack of appetite and low-grade fever. From 17/01 hospitalization and worsening liver failure (fulminant hepatitis). Currently on the national emergency transplant list.) (seriousness criterion life threatening), ACUTE HEPATIC FAILURE (Asthenia, lack of appetite and low-grade fever. From 17/01 hospitalization and worsening liver failure (fulminant hepatitis). Currently on the national emergency transplant list.) (seriousness criterion life threatening), DECREASED APPETITE (Asthenia, lack of appetite and low-grade fever. From 17/01 hospitalization and worsening liver failure (fulminant hepatitis). Currently on the national emergency transplant list.) (seriousness criterion life threatening), PYREXIA (Asthenia, lack of appetite and low-grade fever. From 17/01 hospitalization and worsening liver failure (fulminant hepatitis). Currently on the national emergency transplant list.) (seriousness criterion life threatening), ASTHENIA (Asthenia, lack of appetite and low-grade fever. From 17/01 hospitalization and worsening liver failure (fulminant hepatitis). Currently on the national emergency transplant list.) (seriousness criterion life threatening), VOMITING (Asthenia, lack of appetite and low-grade fever. From 17/01 hospitalization and worsening liver failure (fulminant hepatitis). Currently on the national emergency transplant list.) (seriousness criterion life threatening) and HEPATIC ENCEPHALOPATHY (Asthenia, lack of appetite and low-grade fever. From 17/01 hospitalization and worsening liver failure (fulminant hepatitis). Currently on the national emergency transplant list.) (seriousness criterion life threatening). At the time of the report, RECTAL HAEMORRHAGE (Asthenia, lack of appetite and low-grade fever. From 17/01 hospitalization and worsening liver failure (fulminant hepatitis). Currently on the national emergency transplant list.), HEPATITIS FULMINANT (Asthenia, lack of appetite and low-grade fever. From 17/01 hospitalization and worsening liver failure (fulminant hepatitis). Currently on the national emergency transplant list.), ACUTE HEPATIC FAILURE (Asthenia, lack of appetite and low-grade fever. From 17/01 hospitalization and worsening liver failure (fulminant hepatitis). Currently on the national emergency transplant list.), DECREASED APPETITE (Asthenia, lack of appetite and low-grade fever. From 17/01 hospitalization and worsening liver failure (fulminant hepatitis). Currently on the national emergency transplant list.), PYREXIA (Asthenia, lack of appetite and low-grade fever. From 17/01 hospitalization and worsening liver failure (fulminant hepatitis). Currently on the national emergency transplant list.), ASTHENIA (Asthenia, lack of appetite and low-grade fever. From 17/01 hospitalization and worsening liver failure (fulminant hepatitis). Currently on the national emergency transplant list.), VOMITING (Asthenia, lack of appetite and low-grade fever. From 17/01 hospitalization and worsening liver failure (fulminant hepatitis). Currently on the national emergency transplant list.) and HEPATIC ENCEPHALOPATHY (Asthenia, lack of appetite and low-grade fever. From 17/01 hospitalization and worsening liver failure (fulminant hepatitis). Currently on the national emergency transplant list.) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Blood fibrinogen: inconclusive (Inconclusive) INCONCLUSIVE. On an unknown date, Blood test: inconclusive (Inconclusive) INCONCLUSIVE. On an unknown date, Hepatic enzyme: inconclusive (Inconclusive) INCONCLUSIVE. On an unknown date, International normalised ratio: 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 information was provided. No treatment information was provided. Reporter's comment: Recent diagnosis (Dec-2021) of intraductal k right breast, indicated neoadjuvant chemo in intervention, not yet started). In estrogen-progestogen therapy. On 12/01/22 administered third dose of sars-cov2 vaccine with Moderna. From the next day begins inappetence, asthenia and low-grade fever. So he went to the emergency room on 17/01, during his hospitalization, a significant increase in hepatic cytolysis enzymes and ammonia with a fulminant hepatic insufficiency and coma. Company comment: This regulatory authority case concerns a 46-year-old female patient, with medical history of Breast carcinoma (12/2021 diagnosis of intraductal right breast cancer, candidate for neoadjuvant chemotherapy) and concomitant use of progesterone, who experienced the unexpected serious (life threatening) AESI of HEPATITIS FULMINANT, HEPATIC ENCEPHALOPATHY and ACUTE HEPATIC FAILURE, and the unexpected serious (life threatening) events of ASTHENIA, VOMITING, PYREXIA, DECREASED APPETITE and RECTAL HAEMORRHAGE, which started on the following day and developed within the following 5 days after receiving a dose of mRNA-1273 vaccine, considered as the third dose of her COVID-19 vaccination schedule. It was reported that hepatic enzimes, blood fibrinogen and INR were inconclusive, however narrative states that "important rise of liver cytolysis and ammonemia enzymes with a picture of fulminant hepatic insufficiency and coma". Currently on the national emergency transplant list. The mentioned medical history remains as a confounder. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.

Case ID	Narrative (Complete)
	Most recent FOLLOW-UP

Case ID	Narrative (Complete)
[redacted]	This case was received via European Medicines Agency (Reference number: [redacted] on 16-Feb-2022 and was forwarded to Moderna on 16-Feb-2022. This regulatory authority case was reported by a physician and describes the occurrence of JAUNDICE (on 31.12.21 icteric skin color) and LIVER INJURY (AHI) in a 48-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 3005697) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Previously administered products included for Product used for unknown indication: Vaxzevria on 26-Feb-2021 and Vaxzevria on 28-May-2021. Past adverse reactions to the above products included No adverse event with Vaxzevria and Vaxzevria. Concurrent medical conditions included Adiposis and Arterial hypertension. On 03-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 04-Dec-2021, the patient experienced SOMNOLENCE (exhaustion) and FATIGUE (increasing fatigue, fatigue from 4.12.21 onwards). On 31-Dec-2021, the patient experienced JAUNDICE (on 31.12.21 icteric skin color) (seriousness criterion hospitalization) and LIVER INJURY (AHI) (seriousness criteria hospitalization and life threatening). At the time of the report, SOMNOLENCE (exhaustion), JAUNDICE (on 31.12.21 icteric skin color), FATIGUE (increasing fatigue, fatigue from 4.12.21 onwards) and LIVER INJURY (AHI) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 31-Dec-2021, Alanine aminotransferase: 810 u/l 810 U/l. On 31-Dec-2021, Aspartate aminotransferase: 1796 u/l 1796 U/l. On 31-Dec-2021, Blood bilirubin: 12,6 mg/dl 12,6 mg/dl. On 31-Dec-2021, Gamma-glutamyltransferase: 286 u/l 286 U/l. On 31-Dec-2021, International normalised ratio: 3,0 3,0. For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered SOMNOLENCE (exhaustion), JAUNDICE (on 31.12.21 icteric skin color), FATIGUE (increasing fatigue, fatigue from 4.12.21 onwards) and LIVER INJURY (AHI) to be probably related. Concomitant medications were not provided by the reporter. Treatment information was not provided. Company comment: This is a regulatory case concerning a 48 year-old, female patient with no relevant medical history and Interchange of vaccine products (vaccination with two doses of COVID-19 vaccine AstraZeneca approximately 6 months prior), who experienced the serious (due to life-threatening and hospitalization) unexpected, AESI of liver injury and the serious (due to hospitalization) event of jaundice, approximately 28 days after the third dose of mRNA-1273 vaccine. The outcome of both events was reported as not recovered. Laboratory tests informed: Alanine aminotransferase 810 U/l, Aspartate aminotransferase 1796 U/l, Bilirubin 12,6 mg/dl, Gamma-glutamyltransferase 286 U/l and INR 3. No further information was available in the case. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.

Case ID	Narrative (Complete)
[redacted]	This case was received via European Medicines Agency (Reference number: [redacted] on 18-Feb-2022 and was forwarded to Moderna on 18-Feb-2022. This regulatory authority case was reported by a consumer and describes the occurrence of ABDOMINAL PAIN (Abdominal pain) and LIVER INJURY (liver damage) in a 44-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 214011) for COVID-19 vaccination. The patient's past medical history included Behcet's syndrome (suspected). Concurrent medical conditions included Drug allergy (NSAIDs, macrolide, aspirin). On 16-Aug-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. In October 2021, the patient experienced ABDOMINAL PAIN (Abdominal pain) (seriousness criterion medically significant) and LIVER INJURY (liver damage) (seriousness criterion medically significant). In January 2022, ABDOMINAL PAIN (Abdominal pain) had resolved. At the time of the report, LIVER INJURY (liver damage) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 05-Oct-2021, Alanine aminotransferase: 171 171 [iU]/L (international unit per litre). On 05-Oct-2021, Aspartate aminotransferase: 251 251 [iU]/L (international unit per litre). On 05-Oct-2021, Blood alkaline phosphatase: 79 79 [iU]/L (international unit per litre). On 05-Oct-2021, Gamma-glutamyltransferase: 157 157 [iU]/L (international unit per litre). No concomitant medication was reported. No treatment information was reported. Company Comment: This regulatory case concerns a 44-year-old, female patient with a past medical history of Behcet's syndrome (suspected), who experienced the unexpected serious AESI event of Liver injury and unexpected serious event of Abdominal pain (seriousness criteria medically significant) which occurred approximately 1 month after the first dose of mRNA-1273 vaccine. Alanine aminotransferase: 171[iU]/L, Aspartate aminotransferase:251 [iU]/L, Blood alkaline phosphatase:79 [iU]/L and Gamma-glutamyltransferase:157 [iU]/L were reported as on 05-Oct-2021. Patients past medical history of Behcet's syndrome remains as a confounder. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Event seriousness assessed as per Regulatory Authority reporting.
[redacted]	This regulatory authority case was reported by a consumer and describes the occurrence of HEPATITIS ACUTE (of unclear etiology) in a 24-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. No Medical History information was reported. On 15-May-2021, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 31-May-2021, the patient experienced HEPATITIS ACUTE (of unclear etiology) (seriousness criterion medically significant). At the time of the report, HEPATITIS ACUTE (of unclear etiology) had resolved. The action taken with mRNA-1273 (Spikevax) (Unknown) was unknown. No concomitant medications were mentioned. No specific treatment details were reported. It was reported that for patient statistic hospital stay was required for hepatitis of unclear etiology infection exclude liver biopsy, as improvement. This is a regulatory authority case concerning a 24-year-old, male patient with no reported medical history, who experienced the unexpected serious event of Hepatits Acute. The event occurred 16 days after the unspecified dose of mRNA-1273 COVID 19 Vaccine. Treatment details were not reported. The event were reported as resolved. The benefit-risk relationship of mRNA-1273 COVID 19 Vaccine, is not affected by this report.

Case ID	Narrative (Complete)
[redacted]	This case was received via European Medicines Agency (Reference number: [redacted] on 01-Mar-2022 and was forwarded to Moderna on 01-Mar-2022. This regulatory authority case was reported by a consumer and describes the occurrence of AUTOIMMUNE HEPATITIS (Autoimmune hepatitis) in a 20-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. Patients family history included father with Rheumatism, brother with Crohn's disease, grandmother with increased scleroderma. Previously administered products included for Prophylactic vaccination: Vaxzevria COVID-19 Vaccine (ChAdOx1-S [recombinant])COVID-19 Vaccine AstraZeneca suspension for injectionCOVID-19 Vaccine AstraZeneca on 26-Mar-2021. Past adverse reactions to the above products included No adverse event with Vaxzevria COVID-19 Vaccine (ChAdOx1-S [recombinant])COVID-19 Vaccine AstraZeneca suspension for injectionCOVID-19 Vaccine AstraZeneca. On 18-Jun-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. In July 2021, the patient experienced AUTOIMMUNE HEPATITIS (Autoimmune hepatitis). At the time of the report, AUTOIMMUNE HEPATITIS (Autoimmune hepatitis) had not resolved. No concomitant medication provided. No treatment medication reported. patient undergoes Liver values, acute thrust of the disease End of October. Company comment: This is a regulatory case concerning a 20-year-old, female patient with family history of Rheumatism, Crohn's Disease & Scleroderma and concomitant product of Vaxzevria for COVID-19, who experienced the unexpected non-serious event of Autoimmune Hepatitis (AESI). The events started the following month on an unknown date after the patient received the second dose of mRNA-1273 vaccine. The family history of Rheumatism, Crohn's Disease & Scleroderma; and the inappropriate schedule of vaccine administration as the first dose administered were noncompany products of Vaxzevria and only the second dose was a mRNA-1273 and not as indicated in the RSI at the time; and that could be confounders. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report. Events seriousness assessed as per Regulatory Authority reporting.
[redacted]	This case was received via European Medicines Agency (Reference number: [redacted] on 02-Mar-2022 and was forwarded to Moderna on 02-Mar-2022. This regulatory authority case was reported by a physician and describes the occurrence of ASCITES (acute hepatitis, ascites in chronic ethylist and sars cov 2 infection), HEPATITIS ACUTE (acute hepatitis, ascites in chronic ethylist and sars cov 2 infection) and COVID-19 (acute hepatitis, ascites in chronic ethylist and sars cov 2 infection) in a 49-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The patient's past medical history included Alcoholic. On an unknown date, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) .5 milliliter. On 28-Jan-2022, the patient experienced ASCITES (acute hepatitis, ascites in chronic ethylist and sars cov 2 infection) (seriousness criterion hospitalization), HEPATITIS ACUTE (acute hepatitis, ascites in chronic ethylist and sars cov 2 infection) (seriousness criterion hospitalization) and COVID-19 (acute hepatitis, ascites in chronic ethylist and sars cov 2 infection) (seriousness criterion hospitalization). At the time of the report, ASCITES (acute hepatitis, ascites in chronic ethylist and sars cov 2 infection), HEPATITIS ACUTE (acute hepatitis, ascites in chronic ethylist and sars cov 2 infection) and COVID-19 (acute hepatitis, ascites in chronic ethylist and sars cov 2 infection) outcome was unknown. 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 provided. No treatment medications were reported. Company comment: This regulatory authority case concerns a 49-year-old male patient, with medical history of alcoholic, who experienced the unexpected events of hepatitis acute, COVID 19 and ascites, which required hospitalization. The events occurred after a dose of mRNA-1273. No information about dose number, vaccination schedule or administration date was provided. Temporal relation is unclear. As reported, acute hepatitis, ascites in chronic ethylist and sars cov 2 infection occurred. Patient's medical history provides alternative aetiology for events of hepatitis and ascites. The benefit-risk relationship of mRNA-1273 is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 04-Apr-2022: Follow up received on 04APR 2022 it contains NON-Significant information : No new information(NNI).

Case ID	Narrative (Complete)
[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] 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 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.

Case ID	Narrative (Complete)
[redacted]	This case was received via European Medicines Agency (Reference number: [redacted] on 04-Mar-2022 and was forwarded to Moderna on 04-Mar-2022. This regulatory authority case was reported by a consumer and describes the occurrence of LIVER INJURY (liver damage), SEPSIS (Sepsis), APPLICATION SITE ERYTHEMA (Application site erythema) and APPLICATION SITE SWELLING (Application site swelling) in a 50-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. Concurrent medical conditions included Overweight (overweight). On 04-Jun-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 09-Jun-2021, the patient experienced APPLICATION SITE ERYTHEMA (Application site erythema) (seriousness criterion hospitalization) and APPLICATION SITE SWELLING (Application site swelling) (seriousness criterion hospitalization). On an unknown date, the patient experienced LIVER INJURY (liver damage) (seriousness criterion hospitalization) and SEPSIS (Sepsis) (seriousness criterion hospitalization). At the time of the report, LIVER INJURY (liver damage) and SEPSIS (Sepsis) outcome was unknown and APPLICATION SITE ERYTHEMA (Application site erythema) and APPLICATION SITE SWELLING (Application site swelling) had not resolved. The action taken with mRNA-1273 (Spikevax) (Unknown) was unknown. Concomitant product use was not provided by the reporter. No treatment information was provided. Company comment: This regulatory authority case concerns a 50-year-old female patient with no relevant medical history, who experienced the unexpected serious (hospitalisation) events of Liver injury (AESI), Sepsis (AESI) unknown days and Application site erythema and application site swelling 4 days after the first dose of mRNA-1273 vaccine. The benefit-risk relationship of mRNA-1273 is not affected by this report. Seriousness of the events retained as per Regulatory Authority reporting.

Case ID	Narrative (Complete)
[redacted]	This spontaneous case was reported by a non-health professional and describes the occurrence of APLASTIC ANAEMIA (Severe aplastic anemia/severe bone marrow atrophy (severe aplastic anemia cellularity 5%)), FEBRILE NEUTROPENIA (Febrile neutropenia with Klebsiella pneumoniae septicemia), KLEBSIELLA SEPSIS (Febrile neutropenia with Klebsiella pneumoniae septicemia), CIRCULATORY COLLAPSE (Circulatory system failure), RENAL FAILURE (Kidney failure), HEPATIC FAILURE (Liver failure), WOUND HAEMORRHAGE (While working, she had bleeding that was difficult to stop from a wounded), HAEMOPTYSIS (Coughing up blood in the morning) and DECREASED IMMUNE RESPONSIVENESS (Persistent low immunity) in a 50-year-old female patient who received mRNA-1273 (COVID-19 Vaccine Moderna) (batch no. 049F21A) for COVID-19 vaccination. The patient had no underlying disease. Previously administered products included for COVID-19 vaccination: Sinovac (Sinovac) on 08-Apr-2021, Sinovac (Sinovac) on 06-May-2021 and Pfizer (Pfizer) on 09-Aug-2021. Past adverse reactions to the above products included No adverse reaction with Pfizer, Sinovac and Sinovac. On 27-Dec-2021, the patient received fourth dose of mRNA-1273 (COVID-19 Vaccine Moderna) (unknown route) 1 dosage form. On 28-Dec-2021, the patient experienced APLASTIC ANAEMIA (Severe aplastic anemia/severe bone marrow atrophy (severe aplastic anemia cellularity 5%)) (seriousness criteria death, hospitalization and medically significant). On an unknown date, the patient experienced FEBRILE NEUTROPENIA (Febrile neutropenia with Klebsiella pneumoniae septicemia) (seriousness criteria death, hospitalization and medically significant), KLEBSIELLA SEPSIS (Febrile neutropenia with Klebsiella pneumoniae septicemia) (seriousness criteria death, hospitalization and medically significant), CIRCULATORY COLLAPSE (Circulatory system failure) (seriousness criteria death, hospitalization and medically significant), RENAL FAILURE (Kidney failure) (seriousness criteria death, hospitalization and medically significant), HEPATIC FAILURE (Liver failure) (seriousness criteria death, hospitalization and medically significant), WOUND HAEMORRHAGE (While working, she had bleeding that was difficult to stop from a wounded) (seriousness criteria death and hospitalization), HAEMOPTYSIS (Coughing up blood in the morning) (seriousness criteria death and hospitalization) and DECREASED IMMUNE RESPONSIVENESS (Persistent low immunity) (seriousness criterion medically significant). The patient was hospitalized for 60 days due to APLASTIC ANAEMIA, CIRCULATORY COLLAPSE, FEBRILE NEUTROPENIA, HAEMOPTYSIS, HEPATIC FAILURE, KLEBSIELLA SEPSIS, RENAL FAILURE and WOUND HAEMORRHAGE. The patient was treated with DEXAMETHASONE at a dose of High dose. The patient died on 03-Mar-2022. The reported cause of death was febrile neutropenia with klebsiella pneumoniae septicemia, severe aplastic anemia/severe bone marrow atrophy (severe aplastic anemia cellularity 5%), circulatory system failure, Kidney failure, Liver failure, while working, she had bleeding that was difficult to stop from a wounded, coughing up blood in the morning and febrile neutropenia with klebsiella pneumoniae septicemia. It is unknown if an autopsy was performed. At the time of death, DECREASED IMMUNE RESPONSIVENESS (Persistent low immunity) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 07-Sep-2021, Full blood count: normal (normal) normal. On 28-Dec-2021, Body temperature: high (High) High Fever. On an unknown date, Biopsy bone marrow: severe bone marrow atropy (abnormal) Severe Bone marrow atropy(Severe aplastic anemia, cellularity 5%). On an unknown date, Full blood count: severe low blood count (Low) Severe Low blood count and severe low blood count Came to hospital again and Complete Blood count was checked, result: Severe low blood count. On an unknown date, Haemoglobin: 10.4 (Low) 10.4 g/dl and 9.2 (Low) 9.2 g/dl. On an unknown date, Platelet count: 3000 (Low) 3000 cells/mm3 and less than 1000 (Low) less than 1000. On an unknown date, White blood cell count: 2,170 (Low) 2,170 cell/mm3 and 2000 (Low) 2000 cell/mm3. For mRNA-1273 (COVID-19 Vaccine Moderna) (Unknown), the reporter did not provide any causality assessments. Concomitant product use was not provided by the reporter. The patient received Moderna vaccine as the fourth dose on 27-Dec-2021, after that she experienced fever and low platelet count. A physician diagnosed the patient with severe aplastic anemia caused by receiving the vaccine. The patient experienced persistent low immunity and severe infection. The patient had experienced headache, fever nausea, bruise on body, easy bruising without previous bumps, bruise on the body was not improving then she went to hospital. The symptoms had occurred 1 day after the fourth vaccination. She had received concentrated platelets and came back to work. Her condition was not improved then she came to the hospital again and then complete blood count was checked. She had a high fever and severe infection in the bloodstream. It had spread to circulatory system failure, kidney failure, liver failure and eventually death/passed away. Treatment for the event included treatment with the drug, the blood, and the blood product but condition was not improved, and the patient passed away on 03-Mar-2022 at 07.04 am. The vaccine recipient had received treatment for bruising. She had received concentrated platelets. She was treated with standard medication but was not responding. For the patient, the data had been collected and a joint meeting between a central post-vaccination adverse event expert panel and physicians who took care of the patient concluded that she had severe bone marrow atropy as a result, blood cells and platelets were very low. There was a potential for infection with K. pneumoniae bacteria in the bloodstream. For Acquired aplastic anemia, it could be caused by many reasons such as exposure to chemicals, radioactive substance or from the body's own immune dysfunction, cytotoxic T-cells were stimulated to destroy their own stem cells. Company comment: This case concerns a death of a 50-year-old female patient, with no medical history reported, who experienced the unexpected, serious (Hospitalization, Medically significant, Death) event of Aplastic anaemia, 01 day after and febrile neutropenia, klebsiella sepsis, circulatory collapse, hepatic failure, the events of wound haemorrhage, haemoptysis (Hospitalization, Death) and decreased immune responsiveness (Medically significant) on an unknown date after receiving the 4 dose of m RNA 1273 vaccine in the COVID-19 vaccination series. The patient was previously vaccinated with Sinovac vaccine (two doses) and the 3 dose with Pfizer vaccine about 4 months prior to the 4 dose, with no adverse reactions seen with Pfizer and Sinovac. Interchange of vaccine products was noted. As reported, after mRNA-1273 vaccination the patient experienced fever and low platelet count and a severe aplastic anemia was diagnosed. The patient experienced persistent low immunity and severe infection. On an unknown date, Biopsy bone marrow showed severe bone marrow atropy (abnormal) Severe Bone marrow atropy (Severe aplastic anemia, cellularity 5%), Severe Low blood counts(low Hb, WBC and platelets). Treatment for the event included

Case ID	Narrative (Complete)
	dexamethasone at high dose, blood and the blood products but condition was not improved, and the patient passed away 2 months after Moderna vaccine administration. The reported cause of death was febrile neutropenia with klebsiella pneumoniae septicemia, severe aplastic anemia/severe bone marrow atrophy, circulatory system failure, Kidney failure, Liver failure, wound haemorrhage, and haemoptysis. At the time of death, decreased immune responsiveness had not resolved. Decreased immune responsiveness and infection were likely related to concurrent aplastic anemia. The benefit-risk relationship of mRNA-1273 is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 07-Mar-2022: Follow-up information received contains no new info

Case ID	Narrative (Complete)
[redacted]	This case was initially received via [redacted] (Reference number: [redacted] on 03-Mar-2022. The most recent information was received on 29-Mar-2022 and was forwarded to Moderna on 06-Apr-2022. This case, initially reported to the [redacted] by a physician, was received via the [redacted] (Ref [redacted]). On 29-Mar-2022, follow-up information was received from a physician. The patient had reflux oesophagitis and visited a hospital once or twice a year and was occasionally prescribed a PPI. The patient had no regular oral medications. On an unknown date, body temperature before the vaccination: 36.4 degrees Celsius. On 13-Aug-2021, at 10:00, the patient received the 1st dose of this vaccine. On 25-Aug-2021, in the morning, the patient presented to a primary physician due to heartburn and acid reflux. Vonoprazan fumarate as needed was prescribed, and the symptoms improved. On 26-Aug-2021, at 10:00, acute hepatitis and hepatic function disorder developed. On 27-Aug-2021, general malaise and itching developed. On 31-Aug-2021, white stools and yellow urine were observed, and it was found that the patient had jaundice. On 03-Sep-2021, the patient went to see the family physician. Abdominal ultrasound showed enlarged gallbladder, and the patient visited another hospital with a referral for suspected cholecystitis. Abdominal ultrasound and abdominal CT showed that the enlarged gallbladder was not cholecystitis but suspected acute hepatitis, and the patient was hospitalized. Blood samples excluded hepatitis B, hepatitis C, autoimmune hepatitis, primary sclerosing cholangitis, and cytomegalovirus hepatitis from the causes of acute hepatitis. The patient had been previously infected with EB virus. On an unknown date, the patient placed on fasting, bed rest, and was followed up with administration of monoammonium glycyrrhizinate/glycine/aminoacetic acid/L-cysteine hydrochloride hydrate, which had no effect. On 16-Sep-2021, oral administration of ursodeoxycholic acid was started. On an unknown date, after starting oral administration, the patient continued to have jaundice and liver disorder. On 23-Sep-2021, the patient requested home healthcare and was discharged from the hospital. On 29-Sep-2021, the patient visited the outpatient department. Worsening trends were seen in the blood tests. On 01-Oct-2021, the patient was referred to and visited the reporting department with a request for detailed examination and treatment. On 05-Oct-2021, the patient was hospitalized in the reporting department. In liver biopsy, only findings of acute hepatitis were detected. On an unknown date, the patient tested negative for DLST for vonoprazan fumarate. In terms of exclusion, the only possible drug was this vaccine, and the patient was diagnosed with acute hepatitis. On 25-Oct-2021, shoulder joint pain developed. The patient's nearby orthopedic surgeon's examination indicated that hepatitis acute may have been a factor, but that collagen disease was also a possible differential diagnosis. Joints throughout the body ached here and there, both large and small joints, but the painful joints varied from time to time. There was no difference between the left and right sides, and no pain distal to the ankle joint. Joints from the wrist to the peripheral portion were painful. There was no back pain, but pain in the hip, shoulder, elbow, and knee joints was noted. RF and anti-CCP antibody tests performed to rule out the possibility of collagen disease were negative, and the ANA was mildly elevated, which was eightyfold higher, but was not considered significant. The joint pain disappeared within 2 days after the start of steroid pulse, and the patient was scheduled to consult immunology or other specialists at the time of recurrence, but during the hospitalization, there was no recurrence. On 26-Oct-2021, the patient was discharged from the hospital. The patient had persistent liver disorder as sequela. On 02-Nov-2021, the patient was hospitalized again. On an unknown date, suspected left adrenal adenoma, large intestinal papilloma, and low bone density of -1.8 SD were noted. On 03-Nov-2021, steroid pulse therapy 1,000 mg/day was performed for 3 days. On 04-Nov-2021, hepatobiliary enzymes and total bilirubin in blood tests improved over time. On 06-Nov-2021, the dose of prednisolone was reduced to 60 mg/day. On 08-Nov-2021, hepatobiliary enzymes were elevated again. On 10-Nov-2021, ALT increased to 1,005. There was no remarkable change in the general condition. On 11-Nov-2021, as the data worsened again, steroid pulse therapy was resumed with prednisolone 1,000 mg/day, and the therapy was performed at the same dose for 2 days. On 12-Nov-2021, ALT worsened to 1,061, but total bilirubin decreased, but PT did not decrease. The dose of prednisolone was then tapered. On 13-Nov-2021, the dose of prednisolone was tapered to 750 mg/day. Acne developed in the trunk and tended to enlarge, and pressure pain in the one on the back was noted. On 16-Nov-2021, the dose of prednisolone was tapered to 500 mg/day. On 17-Nov-2021, the use of ozenoxacin was started. The symptom extended to the neck, and the pain tended to intensify. On 19-Nov-2021, the dose of prednisolone was tapered to 250 mg/day. In the evening, oral administration of minocycline hydrochloride was started. The affected area tended to expand to the extremities with pressure pain. Although it would take some time for the symptoms to improve, the patient consulted the dermatology department again because the affected area had expanded and at the patient's request. On 22-Nov-2021, the dose of prednisolone was tapered to 125 mg/day. On 25-Nov-2021, the dose of prednisolone was tapered to 100 mg/day. On 28-Nov-2021, the dose of prednisolone was tapered to 80 mg/day. On 01-Dec-2021, the dose of prednisolone was tapered to 60 mg/day (oral). Since the application of benzoyl peroxide was ordered, the patient started using it. On 08-Dec-2021, the dose of prednisolone was tapered to 50 mg/day. On 13-Dec-2021, the patient visited a dermatologist. The use of petrolatum was discontinued, and ketoconazole was started. On 15-Dec-2021, the dose of prednisolone was tapered to 40 mg/day. On an unknown date, steroid diabetes developed, and blood glucose was high before noon. Around 20-Dec-2021, a similar skin eruption also appeared in the scrotum, and pruritus developed. On 22-Dec-2021, the dose of prednisolone was tapered to 35 mg/day. The patient was also seen by an endocrinologist and started on oral repaglinide 0.5 mg twice a day. On 23-Dec-2021, after the initiation of the second steroid pulse therapy on 11-Nov-2021, trans decreased over time, and ALT normalization was confirmed. On 28-Dec-2021, the patient visited the dermatologist. The use of hydrocortisone butyrate was started. On 29-Dec-2021, the dose of prednisolone was tapered to 30 mg/day. On 05-Jan-2022, the dose of prednisolone was tapered to 25 mg/day. On 12-Jan-2022, the dose of prednisolone was reduced to 20 mg/day as normal trans value had been maintained despite the dose tapering of prednisolone. The symptoms were resolving, and the patient discharged from the hospital. Data would be monitored on an outpatient basis after discharge from the hospital. The outcome of acute hepatitis and arthralgia was reported as resolving. No follow-up investigation will be made. Reporter comments continuation: Because vonoprazan fumarate was DLST negative, the occurrence of adverse events was not associated with concomitant drugs. Since the patient has no underlying disease, the occurrence of adverse events is not related to pathological factors including underlying diseases and complications. After the patient was discharged from the previous hospital, exacerbation of data was found in the outpatient department. After the data improved once at the reporting hospital and when it was time for discharge, the patient had exacerbation again, which has been continuing. Since the patient's general condition was good, the patient was discharged from the hospital once as in the previous hospital, and data for liver disorder would be f

Case ID	Narrative (Complete)
[redacted]	This case was received via [redacted] (Reference number: [redacted]) on 13-Mar-2022 and was forwarded to Moderna on 13-Mar-2022. This regulatory authority case was reported by a consumer and describes the occurrence of PALPITATIONS (Racing heart), MIGRAINE (Migraine), LIVER INJURY (Liver damage), DIZZINESS (Dizzy), the first episode of CHEST PAIN (Chest pain), FATIGUE (Fatigue/unusual tiredness), the second episode of CHEST PAIN (Chest pain), PYREXIA (Fever), DYSPNOEA (Shortness of breath) and TACHYCARDIA (Racing heart (tachycardia)) in a 26-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for an unknown indication. The patient's past medical history included Illness. On 30-Sep-2021, the patient received third dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 20-Jan-2022, the patient experienced the first episode of CHEST PAIN (Chest pain) (seriousness criterion medically significant). On 22-Jan-2022, the patient experienced MIGRAINE (Migraine) (seriousness criterion medically significant) and DIZZINESS (Dizzy) (seriousness criterion medically significant). On 24-Jan-2022, the patient experienced LIVER INJURY (Liver damage) (seriousness criterion medically significant). On an unknown date, the patient experienced PALPITATIONS (Racing heart) (seriousness criterion medically significant), FATIGUE (Fatigue/unusual tiredness) (seriousness criterion medically significant), the second episode of CHEST PAIN (Chest pain) (seriousness criterion medically significant), PYREXIA (Fever) (seriousness criterion medically significant), DYSPNOEA (Shortness of breath) (seriousness criterion medically significant) and TACHYCARDIA (Racing heart (tachycardia)) (seriousness criterion medically significant). At the time of the report, PALPITATIONS (Racing heart), MIGRAINE (Migraine), LIVER INJURY (Liver damage) and DIZZINESS (Dizzy) had not resolved and FATIGUE (Fatigue/unusual tiredness), the last episode of CHEST PAIN (Chest pain), PYREXIA (Fever), DYSPNOEA (Shortness of breath) and TACHYCARDIA (Racing heart (tachycardia)) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 23-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 dosage text reported as dose 3b. He took medication for Crohn's disease but was taken off. It was reported that the patient was light sensitive with dizzy and bad reaction times was getting black dots in vision. He took medication to stop migraine, but dose not work all the time and pain was not recovered. Patient planning to take MRI of brain on 18-Mar-2022. His troponin level was normal or raised. Patient relevant investigation included blood test. Patient was not tested positive for COVID-19 since he had the vaccine and not had symptoms associated with COVID-19. Patient was not enrolled in clinical trial. It was reported that the events were related to possible inflammation of the heart (myocarditis or pericarditis). Patient confirmed that there were no symptoms and not lead to a hospital stay. Patient took propanalo for the treatment. Company comment: This is a regulatory case concerning a 26 year-old, male patient with no relevant medical history, who experienced the serious (due to medically important condition) unexpected, events of Liver injury (AESI), palpitations, tachycardia, chest pain (two episodes reported), dyspnoea, migraine, dizziness, fatigue and pyrexia. The events of liver injury, chest pain (one episode), migraine and dizziness occurred approximately 3 months 21 days to 3 months 25 days after the third dose of mRNA-1273 vaccine and the rest of the events on an unknown date. The outcome of the event chest pain was reported as recovered with sequelae and for the event liver injury as not recovered. It was reported that the case could be related to possible inflammation of the heart (myocarditis or pericarditis), although no medical confirmation nor results for MRI and troponin performed were available. 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.

Case ID	Narrative (Complete)
[redacted]	This case was received via [redacted] (Reference number: [redacted] on 13-Mar-2022 and was forwarded to Moderna on 13-Mar-2022. This regulatory authority case was reported by a consumer and describes the occurrence of HEPATITIS A (hepatitis a) and AUTOIMMUNE HEPATITIS (Hepatitis autoimmune) in a 43-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for an unknown indication. The patient's past medical history included Suspected COVID-19 (Unsure when symptoms stopped) on 10-Oct-2021. On 13-Dec-2021, the patient received third dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 01-Jan-2022, the patient experienced AUTOIMMUNE HEPATITIS (Hepatitis autoimmune) (seriousness criterion hospitalization). On an unknown date, the patient experienced HEPATITIS A (hepatitis a) (seriousness criterion hospitalization). On 12-Mar-2022, AUTOIMMUNE HEPATITIS (Hepatitis autoimmune) was resolving. At the time of the report, HEPATITIS A (hepatitis a) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 10-Oct-2021, SARS-CoV-2 test: positive (Positive) Yes - Positive 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. The report did not related to possible inflammation of the heart (myocarditis or pericarditis). No concomitant medication details was provided. No treatment medication details was provided. Company comment: This regulatory authority case concerns a 43-year-old male patient, with no relevant medical history, who experienced the unexpected AESI of autoimmune hepatitis and unexpected event of hepatitis A, which were required hospitalization. The event of autoimmune hepatitis occurred approximately 19 days after the third dose of mRNA-1273, while hepatitis A occurred on unknown date. Autoimmune hepatitis was reported to be resolving, while outcome of hepatitis A was reported to be ongoing (not recovered). No information regarding diagnostic findings or clinical course of events was provided. No information regarding concomitant drugs or treatment provided were given. Very limited information is available. The benefit-risk relationship of mRNA-1273 is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 13-Mar-2022: Upon query received from business partner, non-significant correction was performed on 16-Mar-2022. The gender of patient was updated from female to male in company comment.

Case ID	Narrative (Complete)
[redacted]	This literature-non-study case was reported in a literature article and describes the occurrence of AUTOIMMUNE HEPATITIS (Autoimmune hepatitis (AIH)) in a 73-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. LITERATURE REFERENCE: Erard D, Villeret F, Lavrut P-M, Dumortie J. Autoimmune hepatitis developing after COVID 19 vaccine: Presumed guilty?. Clin Res Hepatol Gastroenterol. 2022;46:101841 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, after starting mRNA-1273 (Spikevax), the patient experienced AUTOIMMUNE HEPATITIS (Autoimmune hepatitis (AIH)) (seriousness criterion medically significant). At the time of the report, AUTOIMMUNE HEPATITIS (Autoimmune hepatitis (AIH)) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Alanine aminotransferase: 1027 1027 UI/L. On an unknown date, Alpha-1 anti-trypsin: normal (normal) normal. On an unknown date, Antimitochondrial antibody: negative (Negative) Specific liver autoantibodies anti mitochondrial was negative. On an unknown date, Antinuclear antibody: positive (Positive) Positive and negative (Negative) Specific liver autoantibodies Sp100 and anti gp210 was negative. On an unknown date, Aspartate aminotransferase: 1163 1163 UI/L. On an unknown date, Autoantibody test: negative (Negative) Specific liver autoantibodies anti SLA was negative. On an unknown date, Biopsy liver: abnormal (abnormal) diffuse acute hepatitis with lobular and portal intense lymphoplasmacytic infiltrate, with interface hepatitis and hepatocyte necrosis. On an unknown date, Blood bilirubin: 334 umol/l 334 umol/L. On an unknown date, Blood copper: normal (normal) normal and normal (normal) Normal. On an unknown date, Blood immunoglobulin G: 18 (High) 18 g/l. On an unknown date, Blood thyroid stimulating hormone: normal (normal) normal. On an unknown date, Ceruloplasmin: normal (normal) normal. On an unknown date, Hepatitis viral test: negative (Negative) Screening for viral hepatitis was negative (hepatitis A, B, C, E virus, CMV, HSV, EBV).. On an unknown date, International normalised ratio: normal (normal) normal. On an unknown date, Physical examination: normal (normal) Normal. On an unknown date, Smooth muscle antibody: negative (Negative) Specific liver autoantibodies anti-smooth muscle was negative. On an unknown date, Ultrasound abdomen: normal (normal) normal liver with no steatosis and no biliary dilation.. The action taken with mRNA-1273 (Spikevax) (Unknown) was unknown. For mRNA-1273 (Spikevax) (Unknown), the reporter considered AUTOIMMUNE HEPATITIS (Autoimmune hepatitis (AIH)) to be related. Company Comment: This literature non-study case concerns a 73-year-old, female patient with no reported medical history, who experienced the unexpected, serious (medically significant) adverse event of special interest Autoimmune hepatitis. The condition was diagnosed 21 days after receiving a single dose of mRNA-1273 vaccine. The patient was seen by a physician on an unspecified date after vaccination, presenting with asthenia, pruritus and jaundice. She is a non-alcoholic with no history of intravenous drugs or herbal supplements use. Physical examination was essentially normal. Initial blood tests showed severe acute hepatitis with increased total bilirubin and elevated hepatic transaminases. INR was within normal limits, so were ceruloplasmin, serum copper, alpha-1-antitrypsine and TSH. Screening for viral hepatitis (hepatitis A, B, C, E virus, CMV, HSV, EBV) was negative. The IgG level was noted to be elevated. The patient tested positive to anti-nuclear antibodies, although further testing for liver autoantibodies (anti-smooth muscle, anti-mitochondrial, anti-SLA, anti-Sp100, anti-gp210) yielded negative results. An abdominal ultrasound Doppler was performed which revealed a normal liver with no steatosis and no biliary dilation. Liver biopsy showed diffuse acute hepatitis with lobular and portal intense lymphoplasmacytic infiltrate, hepatocyte necrosis and features of interface hepatitis consistent with that of autoimmune hepatitis. The patient was then started on steroid therapy (1mg/kg) for 4 weeks with a rapid improvement of her condition. The benefit-risk relationship of mRNA-1273 is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 17-Mar-2022: Follow up received by safety on 18-Mar-2022 has Email with FTA received from SARA team and contains significant information: Author details, Lab data and event details updated.

Case ID	Narrative (Complete)
[redacted]	This case was received via European Medicines Agency (Reference number: [redacted] on 17-Mar-2022 and was forwarded to Moderna on 17-Mar-2022. This regulatory authority case was reported by a consumer and describes the occurrence of AUTOIMMUNE HEPATITIS (Greatly elevated liver tests, autoimmune liver disease triggered) in a 59-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 3002183) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 27-May-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) I dosage form. On 07-Jun-2021, the patient experienced AUTOIMMUNE HEPATITIS (Greatly elevated liver tests, autoimmune liver disease triggered) (seriousness criterion medically significant) and HEPATIC ENZYME INCREASED (Greatly elevated liver tests, autoimmune liver disease triggered). On 03-Jan-2022, AUTOIMMUNE HEPATITIS (Greatly elevated liver tests, autoimmune liver disease triggered) and HEPATIC ENZYME INCREASED (Greatly elevated liver tests, autoimmune liver disease triggered) had not resolved. The action taken with mRNA-1273 (Spikevax) (Unknown) was unknown. Concomitant medication was not provided. Information on risk factors or pre-existing conditions reported as none of the liver autoimmune disease caused by vaccination. After the second dose, the values increased even more. 6 months after vaccination, they drop slightly. Treatment information was not provided. Company comment: This is a regulatory authority case concerning a 59-year-old female patient with no medical history reported, who experienced serious, AESI, unexpected event of autoimmune hepatitis which occurred 11 days after the administration of mRNA-1273 vaccine (reported as the first dose of the COVID-19 vaccination schedule). Patient developed an increase in liver enzymes; after the second dose the values increased even more. Six months after vaccination values dropped slightly. No further details regarding clinical course, diagnostic tests or treatment performed were disclosed. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.

Case ID	Narrative (Complete)
[redacted]	This case was received via [redacted] (Reference number: [redacted]) on 23-Mar-2022 and was forwarded to Moderna on 23-Mar-2022. This regulatory authority case was reported by a consumer and describes the occurrence of AUTOIMMUNE HEPATITIS (Autoimmune hepatitis) in a patient of an unknown age and gender who received mRNA-1273 (Moderna CoviD-19 Vaccine) (batch no. 3002332) for an unknown indication. Concomitant products included mRNA-1273 (Moderna CoviD-19 Vaccine) for Vaccination. On 02-Jun-2021, the patient received first dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On an unknown date, the patient experienced AUTOIMMUNE HEPATITIS (Autoimmune hepatitis) (seriousness criterion medically significant). At the time of the report, AUTOIMMUNE HEPATITIS (Autoimmune hepatitis) 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 Medication use information was not provided by reporter. Patient was diagnosed with anti-smooth muscle antibody positive. After a collapse, Patient had blood tests, the GP diagnosed the above and notified to patient this was likely to be due to the covid vaccine. Patient await further scans and testing. Treatment Medication use information was not provided by reporter. Patient has not had symptoms associated with COVID-19. Patient had not tested positive for COVID-19 since having the vaccine. Patient was not enrolled in clinical trial. The report did not relate to possible inflammation of the heart (myocarditis or pericarditis). The relevant investigations or tests Liver scans and blood tests were conducted. Company Comment: This regulatory case concerns a patient of unknown age and gender, with no reported medical history, who experienced an unexpected, medically significant AESI Autoimmune hepatitis on an unknown date. The patient received two doses of mRNA-1273 COVID-19 vaccine (56 days Interval, with an Inappropriate schedule of vaccine administered noted in this case). Latency between vaccination and event cannot be established due to lack of information on onset date of the event. Reportedly, after collapsing, the patient had blood tests with positive anti-smooth muscle antibody. Liver scans were performed with pending result. GP diagnosed autoimmune hepatitis and notified the patient that it was likely to be due to the COVID vaccine. The benefit-risk relationship of mRNA-1273 is not affected by this report. Event's seriousness assessed per Regulatory Authority reporting.

Case ID	Narrative (Complete)
[redacted]	This case was received via Takeda Pharmaceuticals (Reference number [redacted] on 18-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]). The vaccine recipient did not take any oral regular medication and antipyretics with no history of eating raw meat and no overseas travel history. The patient had no appreciable history. On an unknown date, the patient received the 1st dose of the COVID-19 vaccine (product name unknown). On 11-Aug-2021, around 13:00, the patient received the 2nd vaccination with the vaccine. On 12-Aug-2021, during the daytime, the patient noticed malaise. In the early evening, the patient experienced pyrexia, followed by queasy. At 19:00, acute hepatic failure with hepatic coma and hepatic function disorder developed. On an unknown date, the patient experienced vomiting and the course of the condition was monitored, but it did not improve. On 15-Aug-2021, as the patient also complained of feeling of dyspnea, an emergency call was made, and the patient was transported to a medical institution. At the time of transportation, blood pressure was unable to be measured, and generalized livedo reticularis was noted. Blood test showed renal disorder (BUN: 39.3, Cre: 3.19), coagulation disorder (PT%: 17, PT-INR: 3.48), and metabolic acidosis (pH: 6.866, pCO2: 49.9, HCO3-: 8.6). CT inspection showed no significant findings that could be the cause, and the patient underwent tracheal intubation and received a continuous dose of vasopressor (noradrenalin) and was transported to the reporting hospital. Immediately after arrival at the hospital, the patient developed cardiopulmonary arrest, and at that time the livedo reticularis was purple-black color that was almost similar to postmortem lividity. The blood test was performed which showed hepatic disorder (AST: 432, ALT: 510), renal disorder (BUN: 30.1, Cre: 2.24), coagulation disorder (PT: 21%, 2.21), and acidosis (7.2). Subsequently, the patient was admitted into an intensive-care unit but suffered cardiopulmonary arrest several times, and circulatory dynamics was gradually exacerbated although continuous dose of adrenaline, large amounts of fluid replacement, blood transfusion, and continuous blood purification therapy were performed. The patient mainly had metabolic acidosis, renal disorder, and circulation failure with no known causes. On 16-Aug-2021, at 16:49, the patient was confirmed dead. On an unknown date, pathological anatomy was performed. The hepatic findings suggested suspected fulminant hepatitis, and findings of mild myocarditis was also noted. Hepatitis-associated viruses were not measured. The outcome of generalized livedo reticularis was unknown. The outcome of acute hepatic failure with hepatic coma, renal disorder, coagulation disorder, metabolic acidosis, cardiopulmonary arrest, circulation failure, suspected fulminant hepatitis, and myocarditis was reported as fatal. Follow-up investigation was tried, but it was not possible because of non-cooperation of the reporter. Reporter comments continuation: Although the symptoms did not apply to the diagnostic criteria for acute hepatic failure, there were fewer findings in the blood test compared to acidosis considering the time course; therefore, acute hepatic failure was suspected based on coma and coagulation abnormality. In addition, the diagnosis of myocarditis was made based on the findings of pathological anatomy, and during the clinical course, supportive treatments were mainly given as the patient mainly had metabolic acidosis, renal disorder, and circulation failure with no known causes. Although it is difficult to judge how strongly the association is suggested and to understand what kind of disease status was caused by the association, it must be suspected that there was an association because the patient who did not have a medical history experienced malaise and pyrexia after the vaccination, finally resulting in cardiac arrest. Thus, this case was reported. As a result of discuss with the physician who performed the autopsy, it was found that the findings of fulminant hepatitis and myocarditis were prominent and that other changes were mainly associated with circulation failure and resuscitation. There were no findings strongly suggestive of infection or other causative diseases. In terms of exclusion of other diseases, it is possible that the items of the specimen examination were not sufficient. Follow-up received on 12-APR-2022 Updated: Lab Data, Narrative 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 23-Mar-2022 and was forwarded to Moderna on 23-Mar-2022. This regulatory authority case was reported by a physician and describes the occurrence of COVID-19 IMMUNISATION (REVACCINATION WITH DIFFERENT COVID-19 VACCINE) and HEPATITIS ACUTE (HEPATITIS (ACUTE)) in a 42-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 214029) for COVID-19 vaccination. The patient's past medical history included COVID-19 immunisation (Vaxzevria dose 1) on 08-Mar-2021 and COVID-19 immunisation (Vaxzevria dose 2) on 12-May-2021. On 09-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 04-Jan-2022, after starting mRNA-1273 (Spikevax), the patient experienced HEPATITIS ACUTE (HEPATITIS (ACUTE)) (seriousness criterion medically significant). On an unknown date, the patient experienced COVID-19 IMMUNISATION (REVACCINATION WITH DIFFERENT COVID-19 VACCINE) (seriousness criterion medically significant). At the time of the report, COVID-19 IMMUNISATION (REVACCINATION WITH DIFFERENT COVID-19 VACCINE) and HEPATITIS ACUTE (HEPATITIS (ACUTE)) had not resolved. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. No concomitant information were reported by the reporter. No treatment information were reported by the reporter. Company comment: This regulatory case concerns a 42-year-old female patient with no reported medical history who experienced the unexpected serious (medically significant) event of Hepatitis acute. Revaccination with different COVID-19 vaccine was considered as an additional event. The event occurred approximately 26 days after a dose of mRNA-1273 vaccine administered as third dose for COVID 19 immunisation. Patient had received two doses of Vaxzevria COVID 19 vaccine prior to mRNA-1273 vaccine. The benefit-risk relationship of mRNA-1273 is not affected by this report. Seriousness of the event retained as per Regulatory Authority reporting.

Case ID	Narrative (Complete)
[redacted]	This case was received via European Medicines Agency (Reference number: [redacted] on 12-Apr-2022 and was forwarded to Moderna on 12-Apr-2022. This regulatory authority case was reported by a consumer and describes the occurrence of AUTOIMMUNE HEPATITIS (autoimmune hepatitis) in a 65-year-old female patient who received mRNA-1273 (Spikevax) (batch no. LOT 3004951) for COVID-19 vaccination. Information on risk factors or previous illnesses included breast cancer and rheumatism. On 09-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 22-Dec-2021, the patient experienced AUTOIMMUNE HEPATITIS (autoimmune hepatitis). At the time of the report, AUTOIMMUNE HEPATITIS (autoimmune hepatitis) had not resolved. Concomitant drugs were not reported. Treatment medications were not provided. Date of birth was reported as [redacted]1956. It was reported that blood collection, observation, rising liver values. Company Comment: This regulatory case concerns a 65-year-old female patient with the relevant medical history of rheumatism, who experienced the unexpected, non-serious adverse event of special interest of Autoimmune hepatitis, that occurred 13 days after a dose of mRNA-1273 vaccine, given as third dose. Patient reportedly had raised liver function values and the outcome of the event was reported as not resolved. Vaccination details of the primary series was not reported. Underlying rheumatism representing history of autoimmune disorder remains as confounder. The benefit-risk relationship of 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 26-Apr-2022 and was forwarded to Moderna on 26-Apr-2022. This regulatory authority case was reported by a physician and describes the occurrence of HEPATITIS ACUTE (Acute hepatitis) in a 24-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 214020) for COVID-19 vaccination. No Medical History information was reported. On 03-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On an unknown date, after starting mRNA-1273 (Spikevax), the patient experienced HEPATITIS ACUTE (Acute hepatitis) (seriousness criterion hospitalization). At the time of the report, HEPATITIS ACUTE (Acute hepatitis) had resolved. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. No relevant concomitant medications were reported. Dosage text mentioned as place of administration :Upper limb (not available injection side). No treatment information was provided. Company comment:This regulatory authority case concerns a 24 year old male patient with no reported medical history, who experienced the unexpected serious (hospitalization) event of Hepatitis acute, about 48 days after receiving the second dose of COVID -19 vaccination with mRNA-1273 vaccine. No further information on clinical course and management of the event was available in the report. The outcome of the event was 'resolved'. The benefit-risk relationship of mRNA-1273 is not affected by this report. Event's seriousness retained as per Regulatory Authority reporting.

Case ID	Narrative (Complete)
[redacted]	This spontaneous case was reported by a consumer and describes the occurrence of HEPATIC FAILURE (has liver failure and does not process stomach acids/ dyspepsia (heartburn), pain (heartburn pain), hepatic pain, liver disorder (liver discomfort), rash, rash macular) in a 39-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Seafood allergy (Allergy to Marisco) and Glucose intolerance (hereditary problems with glucose). Concomitant products included FLUTICASONE PROPIONATE (FLONASE [FLUTICASONE PROPIONATE]), HYOSCYAMINE, CALCIUM CARBONATE, MAGNESIUM CARBONATE, MAGNESIUM TRISILICATE (TUMS [CALCIUM CARBONATE;MAGNESIUM CARBONATE;MAGNESIUM TRISILICATE]), ALUMINIUM HYDROXIDE GEL, DRIED, MAGNESIUM CARBONATE (PEPCID [ALUMINIUM HYDROXIDE GEL, DRIED;MAGNESIUM CARBONATE]) and OMEPRAZOLE [redacted] [OMEPRAZOLE]) for an unknown indication. 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 an unknown date, the patient experienced HEPATIC FAILURE (has liver failure and does not process stomach acids/ dyspepsia (heartburn), pain (heartburn pain), hepatic pain, liver disorder (liver discomfort), rash, rash macular) (seriousness criterion medically significant) and HEPATIC STEATOSIS (Fatty liver). At the time of the report, HEPATIC FAILURE (has liver failure and does not process stomach acids/ dyspepsia (heartburn), pain (heartburn pain), hepatic pain, liver disorder (liver discomfort), rash, rash macular) and HEPATIC STEATOSIS (Fatty liver) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Hepatic enzyme: high (High) high. Patient reported that two weeks after getting the second dose of the Moderna covid19 vaccine got spot like chickenpox in their chest and stomach but no pain. 4 months later patient started getting heartburn pain, a rush on their wrist. He also had pain in the liver after vaccination, fatty liver and liver discomfort. Patient had liver failure and does not process stomach acids. Adverse event caused patient to have office visit, patient did not experienced a similar event in the past and patient stated that symptoms worsened. No treatment medication details provided. Company comment: This is a spontaneous case concerning a 39-year-old, male patient with relevant medical history of unspecified hereditary problems with glucose, who experienced the unexpected serious (medically significant) AESI event of hepatic failure and unexpected serious (medically significant) event of hepatic steatosis. The events exact occurrence was unknown but stated that the events occurred after the second dose of mRNA-1273 vaccine administration. Allegedly the events were described as, 2 weeks after the second dose of mRNA-1273 vaccine administration the patient experienced non painful spot like chickenpox lesion in his chest and stomach. 4 months later, patient started experiencing heartburn pain and a rash on his wrist. Patient had his unspecified studies done which revealed high unspecified hepatic enzyme values. On unknown date, after the second dose of mRNA-1273 vaccine administration patient had liver discomfort, pain in the liver, fatty liver and also he has liver failure and does not process stomach acids and at the time of the report his symptoms had worsened. The medical history of unspecified hereditary problems with glucose remain confounder for the events hepatic failure and hepatic steatosis. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. This case was linked to [redacted] (Patient Link).

Case ID	Narrative (Complete)
[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 AUTOIMMUNE HEPATITIS (Autoimmune hepatitis-like symptoms how jaundice) in a 52-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 000110A) for COVID-19 vaccination. Concurrent medical conditions included Hay fever. On 22-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 15-Feb-2022, the patient experienced AUTOIMMUNE HEPATITIS (Autoimmune hepatitis-like symptoms how jaundice) (seriousness criterion medically significant). On 03-Apr-2022, AUTOIMMUNE HEPATITIS (Autoimmune hepatitis-like symptoms how jaundice) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Blood immunoglobulin G: negative for hepatitis a, b, c (Negative) Negative for Hepatitis A, B, C. On an unknown date, Blood immunoglobulin M: negative for hepatitis a, b, c (Negative) Negative for Hepatitis A, B, C. On an unknown date, Liver function test: abnormal (abnormal) Abnormal. Concomitant product use was not provided by the reporter. No treatment information was provided. It was reported date of birth: [redacted]-1969, first symptoms mid-February 2022: jaundice, dark urine, colorless stools, fatigue, loss of appetite, nausea, itching, but also heartburn, consultation GP: blood count test for hep A B C E, all IgG IgM titers are negatively very high liver tests bsd. bilirubin. Company comment: This regulatory authority case concerns a 52-year-old male patient, with no relevant medical history, who experienced the serious (medically significant) unexpected AESI of autoimmune hepatitis (reported as autoimmune hepatitis-like symptoms), approximately 2.5 months after receiving a third dose of mRNA-1273. No information regarding previous COVID-19 vaccination schedule was provided. It is reported that patient experienced jaundice, dark urine, colorless stools, fatigue, loss of appetite, nausea, itching and heartburn. On consultation with general practitioner, tests were performed and IgG and IgM titers were negative for hepatitis A, B, C and E. Liver tests were mentioned as "very high". No information on autoantibody assays (antinuclear, anti-mitochondrial, anti-smooth muscle, amongst others), or hepatic images or liver biopsy was provided. No information on clinical course of the event was reported. The benefit-risk relationship of mRNA-1273 is not affected by this report.

Case ID	Narrative (Complete)
[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 ASCITES (Ascites, ultrasound and computed tomogram 2022 Januar) and AUTOIMMUNE HEPATITIS (Autoimmune Hepatitis, Laboratory Detected) in an 82-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 216044) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. pre-existing conditions gammopathy heart failure CRT pacemaker. The patient's past medical history included Heart failure (Information on risk factors or pre-existing conditions gammopathy heart failure CRT pacemaker) and Chemotherapy (Chemotherapy 8 x CHOP). Concurrent medical conditions included Gammopathy (Gammopathy for >10 years), CRT-P (Information on risk factors or pre-existing conditions gammopathy heart failure CRT pacemaker), Lymphoma (proven lymphoma since April 2019) since April 2019 and Myeloma (myeloma still exists). On 08-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 18-Jan-2022, the patient experienced ULTRASOUND SCAN ABNORMAL (Ascites, ultrasound and computed tomogram 2022 January), ASCITES (Ascites, ultrasound and computed tomogram 2022 Januar) (seriousness criterion medically significant) and COMPUTERISED TOMOGRAM ABNORMAL (Ascites, ultrasound and computed tomogram 2022 January). On 19-Jan-2022, the patient experienced LABORATORY TEST (Autoimmune Hepatitis, Laboratory Detected) and AUTOIMMUNE HEPATITIS (Autoimmune Hepatitis, Laboratory Detected) (seriousness criterion medically significant). At the time of the report, ULTRASOUND SCAN ABNORMAL (Ascites, ultrasound and computed tomogram 2022 January), ASCITES (Ascites, ultrasound and computed tomogram 2022 Januar) and COMPUTERISED TOMOGRAM ABNORMAL (Ascites, ultrasound and computed tomogram 2022 January) had not resolved and LABORATORY TEST (Autoimmune Hepatitis, Laboratory Detected) and AUTOIMMUNE HEPATITIS (Autoimmune Hepatitis, Laboratory Detected) had resolved with sequelae. Patient date of birth was reported as [redacted]1940. Information on risk factors or pre-existing conditions included gammopathy heart failure CRT pacemaker/hepatitis which was detected on Jan.2022 by laboratory, laboratory values were normal in November2021. CT of the abdomen in Jan.2022 because of lymphoma control showed ascites. Gammopathy for >10 years proven lymphoma since April 2019, chemotherapy 8 x CHOP, myeloma still exists. Concurrent conditions of gammopathy for more than 10 years, lymphoma since April 2019, myeloma and CRT pacemaker, and a historical condition of heart failure were reported. On an unknown date, chemotherapy with 8 cycles of CHOP (cyclophosphamide, doxorubicin hydrochloride, vincristine sulfate, prednisone) was given. In Nov 2021, lab values were normal. Vaccination with dose 3 of mRNA-1273 was done on 8 Dec 2021. On 18 Jan 2022, abdominal ultrasound & CT scan showed ascites, most likely due to lymphoma treatment. On 19 Jan 2021, autoimmune hepatitis was confirmed with unspecified laboratory. Details on clinical course, further diagnostics, and treatments were not reported. Company comment: This regulatory case concerns an 82-year-old, female patient, with the concurrent medical conditions of gammopathy, lymphoma & myeloma, and a history of heart failure & chemotherapy with 8 cycles of CHOP (cyclophosphamide, doxorubicin hydrochloride, vincristine sulfate, prednisone), who experienced the unexpected, medically significant events of an AESI Autoimmune hepatitis & Ascites in association with mRNA-1273 vaccine. Event ascites was confirmed with abdominal ultrasound and computed tomography scan approximately 1 month after the patient received her 3rd dose of mRNA-1273 vaccine. The following day, event autoimmune hepatitis was detected with an unspecified laboratory test. Event ascites has not resolved whereas event autoimmune hepatitis has resolved with sequela. Underlying lymphoma, myeloma & gammopathy, and history of chemotherapy with 8 cycles of CHOP – conditions that may have predisposed the patient to infections - could be considered contributory factors to the development of autoimmune hepatitis. History of heart failure and treatment with cyclophosphamide & prednisone could be confounders to the event ascites. The benefit-risk relationship of mRNA-1273 is not affected by this report. Events' seriousness assessed per Regulatory Authority reporting.

Case ID	Narrative (Complete)
[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 AUTOIMMUNE HEPATITIS (Autoimmune Hepatitis, Laboratory Detected) and ASCITES (Ascites, by ultrasound and by computer tomogram 2022 January) in an 82-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 216044) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included CRT-P since an unknown date and Chemotherapy. Concurrent medical conditions included Gammopathy (More than 10 years), Heart failure, Lymphoma in April 2019 and Myeloma. On 08-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 18-Jan-2022, the patient experienced COMPUTERISED TOMOGRAM ABNORMAL (Ascites, by ultrasound and by computer tomogram 2022 January), ASCITES (Ascites, by ultrasound and by computer tomogram 2022 January) (seriousness criterion medically significant) and ULTRASOUND SCAN ABNORMAL (Ascites, by ultrasound and by computer tomogram 2022 January). On 19-Jan-2022, the patient experienced LABORATORY TEST (Autoimmune Hepatitis, Laboratory Detected) and AUTOIMMUNE HEPATITIS (Autoimmune Hepatitis, Laboratory Detected) (seriousness criterion medically significant). At the time of the report, COMPUTERISED TOMOGRAM ABNORMAL (Ascites, by ultrasound and by computer tomogram 2022 January), ASCITES (Ascites, by ultrasound and by computer tomogram 2022 January) and ULTRASOUND SCAN ABNORMAL (Ascites, by ultrasound and by computer tomogram 2022 January) had not resolved and LABORATORY TEST (Autoimmune Hepatitis, Laboratory Detected) and AUTOIMMUNE HEPATITIS (Autoimmune Hepatitis, Laboratory Detected) had resolved with sequelae. The action taken with mRNA-1273 (Spikevax) (Unknown) was unknown. Concomitant medication list was not provided. Company comment. This regulatory case concerns an 82 – year – old, female patient with relevant medical history of lymphoma and myeloma, who experienced the unexpected, serious medically significant AESI of autoimmune hepatitis and the unexpected serious event of ascites. The events occurred approximately 42 days after the administration of a dose of mRNA-1273 vaccine, reported as third dose of her COVID – 19 immunization schedules. The report stated that the patient had a computerised tomogram and ultrasound of the abdomen where ascites was observed. Laboratory test detected autoimmune hepatitis (not provided for medical review). Patient´s mentioned medical history could be confounders for autoimmune hepatitis. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.

Case ID	Narrative (Complete)
[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 INFLUENZA (Frequently tired since 2nd vaccination and knocked off. Blood values ??no longer in Order especially the liver values. Diagnosis is based on an autoimmune hepatitis out. Further tests are pending.) and AUTOIMMUNE HEPATITIS (Frequently tired since 2nd vaccination and knocked off. Blood values ??no longer in Order especially the liver values. Diagnosis is based on an autoimmune hepatitis out. Further tests are pending.) in a 45-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. Co-suspect product included non-company product TOZINAMERAN (COMIRNATY) for Prophylactic vaccination. The patient's past medical history included Hypertension. On 02-Jul-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 09-Dec-2021, the patient received third dose of TOZINAMERAN (COMIRNATY) (unknown route) .3 milliliter. On an unknown date, the patient experienced INFLUENZA (Frequently tired since 2nd vaccination and knocked off. Blood values ??no longer in Order especially the liver values. Diagnosis is based on an autoimmune hepatitis out. Further tests are pending.) and AUTOIMMUNE HEPATITIS (Frequently tired since 2nd vaccination and knocked off. Blood values ??no longer in Order especially the liver values. Diagnosis is based on an autoimmune hepatitis out. Further tests are pending.). At the time of the report, INFLUENZA (Frequently tired since 2nd vaccination and knocked off. Blood values ??no longer in Order especially the liver values. Diagnosis is based on an autoimmune hepatitis out. Further tests are pending.) and AUTOIMMUNE HEPATITIS (Frequently tired since 2nd vaccination and knocked off. Blood values ??no longer in Order especially the liver values. Diagnosis is based on an autoimmune hepatitis out. Further tests are pending.) had resolved with sequelae. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In September 2021, Blood test: liver values increased heart in OK, blood values ??not. liver values increased.. In November 2021, Blood test: all on one indicate autoimmune hepatitis. with again increased values ??all on one indicate autoimmune hepatitis.. No concomitant medication were given. After the 2nd vaccination strong flu-like symptoms Side effects over 48 hours. Fever chills, body aches. Only with to endure painkillers. improvement of condition. From about 4 weeks after vaccination sudden flu symptoms to bedridden. September blood test General practitioner, visit to the cardiologist. heart in OK, blood values ??not. liver values increased. November 2nd blood test with again increased values ??all on one indicate autoimmune hepatitis. 3. Investigation ongoing. haven't been fit since the vaccination become. have 5x a week in the morning 30 minutes exercise and can do it not more. No treatment information were given. Company Comment: This is a Regulatory Authority case concerning a 45-year-old male patient, with no relevant medical history, who experienced the unexpected, non-serious, and AESI of Autoimmune hepatitis. The event started approximately 2 months after the second dose of mRNA-1273 vaccine, and at the time of the report it had recovered with sequel. Patient reported blood test showed liver values increased, which he repeated it 4 months approximately after vaccination, with increased values again, indicating autoimmune hepatitis. Investigation is ongoing. Third dose of Pfizer vaccine was administered 5 months after second dose, and remains as a co-suspect product. Interchange of vaccine products remains as a confounding factor for Autoimmune hepatitis.The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.

Case ID	Narrative (Complete)
[redacted]	This case was initially received via European Medicines Agency (Reference number: [redacted]) on 02-May-2022. The most recent information was received on 07-Jun-2022 and was forwarded to Moderna on 07-Jun-2022. This regulatory authority case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of HEPATOCELLULAR INJURY (Hepatocellular damage) in a 75-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Previously administered products included for Type II diabetes mellitus: metformin. Past adverse reactions to the above products included No adverse reaction with metformin. Concurrent medical conditions included Diabetes mellitus (Type II diabetes stabilized with metformin), Bipolar disorder and Hypercholesterolaemia. On 09-Nov-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 09-Nov-2021, the patient experienced ASTHENIA (Asthenia) and PYREXIA (Fever). On an unknown date, the patient experienced HEPATOCELLULAR INJURY (Hepatocellular damage) (seriousness criterion hospitalization). At the time of the report, HEPATOCELLULAR INJURY (Hepatocellular damage) and PYREXIA (Fever) had resolved and ASTHENIA (Asthenia) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 04-Feb-2022, SARS-CoV-2 test: negative (Negative) Negative. Concomitant medications was not provided by the reporter. Treatment information was not provided. Company comment: This regulatory case from EMA concerns a 75-year-old, female patient with concurrent conditions of Type II diabetes mellitus & hypercholesterolaemia, who experienced an unexpected, serious AESI Hepatocellular injury 87 days after receiving a 2nd dose of mRNA-1273 vaccine. Event hepatocellular damage resulted to the patient's hospitalization. Event outcome was resolved. Further details on the medical history, clinical course, diagnostics, and treatments were not reported. Type II diabetes mellitus and hypercholesterolaemia could increase the patient's risk of developing a hepatocellular damage. The benefit-risk relationship of mRNA-1273 is not affected by this report. Event's seriousness assessed per Regulatory Authority reporting. Most recent FOLLOW-UP information incorporated above includes: On 07-Jun-2022: Follow-up received wherein event EBV hepatitis deleted and new event added.

Case ID	Narrative (Complete)
[redacted]	This case was received via European Medicines Agency (Reference number: [redacted]) on 04-May-2022 and was forwarded to Moderna on 04-May-2022. This regulatory authority case was reported by a physician and describes the occurrence of RASH (RASHES), AUTOIMMUNE HEPATITIS (AUTOIMMUNE HEPATITIS) and COVID-19 IMMUNISATION (REVACCINATION WITH DIFFERENT COVID-19 VACCINE) in an 81-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 3006270) for COVID-19 vaccination. The patient's past medical history included COVID-19 immunisation (Comirnaty dos 3) on 21-Oct-2021, COVID-19 immunisation (Comirnaty dos 1) on 19-Feb-2021, Stroke and COVID-19 immunisation (Comirnaty dos 2) on 12-Mar-2021. Concurrent medical conditions included Atrial fibrillation and Hypertension. Concomitant products included ATORVASTATIN CALCIUM (LIPITOR) from 09-Oct-2018 to an unknown date, CALCIUM CARBONATE, COLECALCIFEROL (KALCIPOS-D) from 01-Jul-2020 to an unknown date, CYANOCOBALAMIN ZINC TANNATE (BETOLVEX [CYANOCOBALAMIN ZINC TANNATE]) from 01-Jul-2020 to an unknown date, ZOLEDRONIC ACID (ZOLEDRONIC ACID Z) from 20-May-2020 to an unknown date and WARFARIN SODIUM [redacted] from 21-Nov-2017 to an unknown date for an unknown indication. On 23-Feb-2022, the patient received fourth dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 09-Mar-2022, the patient experienced AUTOIMMUNE HEPATITIS (AUTOIMMUNE HEPATITIS) (seriousness criteria hospitalization and medically significant). On 23-Mar-2022, the patient experienced RASH (RASHES) (seriousness criteria hospitalization and medically significant). On an unknown date, the patient experienced COVID-19 IMMUNISATION (REVACCINATION WITH DIFFERENT COVID-19 VACCINE) (seriousness criteria hospitalization and medically significant). At the time of the report, RASH (RASHES), AUTOIMMUNE HEPATITIS (AUTOIMMUNE HEPATITIS) and COVID-19 IMMUNISATION (REVACCINATION WITH DIFFERENT COVID-19 VACCINE) had not resolved. 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 regulatory case concerns a 81-year-old female patient with no relevant medical history reported, who experienced the unexpected serious (medically significant/Hospitalization) events of Autoimmune hepatitis (AESI) and Rash after a dose (4th dose in vaccination schedule) of mRNA-1273 Vaccine administration. Additionally, COVID-19 immunization (Revaccination with different COVID-19 vaccine) was reported. She had received initial schedule of vaccination Dose 1, 2 and 3 with COMIRNATY. Patient experienced Autoimmune hepatitis 15 days after, and Rash 1 month after mRNA-1273 vaccine. No further details on clinical course, lab test results and treatment received were reported. At the time of the reporting, outcome of the events was not resolved. Concomitant drug ATORVASTATIN CALCIUM could be a confounder to the event Autoimmune hepatitis. Benefit risk relationship of mRNA-1273 Vaccine is not affected by this report. The case seriousness was assessed as per Regulatory Authority

Case ID	Narrative (Complete)
[redacted]	This case was initially received via [redacted] (Reference number: [redacted]) on 05-May-2022. The most recent information was received on 09-Jun-2022 and was forwarded to Moderna on 09-Jun-2022. This regulatory authority case was reported by a consumer and describes the occurrence of MALAISE (Unwell), CELLULITIS (Cellulitis), COVID-19 (SARS-CoV-2 infection), VOMITING (Vomiting), DIARRHOEA (Diarrhoea), ASTHENIA (Weakness), TREMOR (Shaking), RASH (Rash over arms), LIVER INJURY (Injury to liver), RENAL INJURY (Injury to kidney), FATIGUE (Fatigue), PAIN (Pain), HEPATIC FUNCTION ABNORMAL (Hepatic function abnormal), RENAL IMPAIRMENT (Renal impairment) and NAUSEA (Nausea) in a 49-year-old female patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) (batch no. 3005237) for COVID-19 vaccination. The patient's past medical history included Suspected COVID-19 from 08-Jan-2022 to 22-Jan-2022, Chronic kidney disease and Fatty liver. Concomitant products included COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (COVID-19 VACCINE ASTRAZENECA) from 05-Mar-2021 to an unknown date and COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (COVID-19 VACCINE ASTRAZENECA) from 21-May-2021 to an unknown date for COVID-19 vaccination, FENTANYL from 2014 to an unknown date for Pain. On 10-Dec-2021, the patient received third dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 10-Dec-2021, the patient experienced TREMOR (Shaking) (seriousness criteria hospitalization and medically significant) and PAIN (Pain) (seriousness criteria hospitalization and medically significant). 10-Dec-2021, the patient experienced NAUSEA (Nausea) (seriousness criteria hospitalization and medically significant). On 11-Dec-2021, the patient experienced VOMITING (Vomiting) (seriousness criteria hospitalization and medically significant), DIARRHOEA (Diarrhoea) (seriousness criteria hospitalization and medically significant), LIVER INJURY (Injury to liver) (seriousness criteria hospitalization and medically significant), RENAL INJURY (Injury to kidney) (seriousness criteria hospitalization and medically significant), FATIGUE (Fatigue) (seriousness criteria hospitalization and medically significant), HEPATIC FUNCTION ABNORMAL (Hepatic function abnormal) (seriousness criteria hospitalization and medically significant) and RENAL IMPAIRMENT (Renal impairment) (seriousness criteria hospitalization and medically significant). 11-Dec-2021, the patient experienced ASTHENIA (Weakness) (seriousness criteria hospitalization and medically significant). On 12-Dec-2021, the patient experienced RASH (Rash over arms) (seriousness criteria hospitalization and medically significant). On 10-Jan-2022, the patient experienced COVID-19 (SARS-CoV-2 infection) (seriousness criteria hospitalization and medically significant). On an unknown date, the patient experienced MALAISE (Unwell) (seriousness criteria hospitalization and medically significant) and CELLULITIS (Cellulitis) (seriousness criteria hospitalization and medically significant). The patient was hospitalized for 1 day due to DIARRHOEA and VOMITING. On 12-Dec-2021, VOMITING (Vomiting), DIARRHOEA (Diarrhoea) and TREMOR (Shaking) had resolved. On 14-Dec-2021, RASH (Rash over arms) had resolved. At the time of the report, MALAISE (Unwell), CELLULITIS (Cellulitis) and COVID-19 (SARS-CoV-2 infection) had resolved, ASTHENIA (Weakness) and RENAL INJURY (Injury to kidney) was resolving, LIVER INJURY (Injury to liver), FATIGUE (Fatigue), PAIN (Pain) and NAUSEA (Nausea) had not resolved and HEPATIC FUNCTION ABNORMAL (Hepatic function abnormal) and RENAL IMPAIRMENT (Renal impairment) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 11-Dec-2021, Blood test: showed reduction in kidney and liver function showed reduction in kidney and liver function. On 10-Jan-2022, SARS-CoV-2 test: positive (Positive) Yes - Positive COVID-19 test. In March 2022, Blood test: result not reported Result not reported and kidney function improvement but not liver function improvement in kidney function. No improvement in liver function. On an unknown date, Blood test: continue reduction in liver and kidney function Repeat blood test the following week concluded continue reduction in liver and kidney function. On an unknown date, Chest X-ray: results not provided Results not provided. On an unknown date, SARS-CoV-2 test: results not provided Results not provided. On an unknown date, Ultrasound abdomen: results not provided Results not provided. Company comment: This is a regulatory authority case reported by a consumer. A 49-year-old female patient, previously vaccinated with 2 doses of Astrazeneca, experienced medically significant events of malaise, cellulitis, COVID-19 (AESI), vomiting, diarrhoea, asthenia, tremor, rash, liver injury (AESI), renal injury, fatigue, pain, hepatic function abnormal, renal impairment (AESI) and nausea after receiving mRNA-1273 vaccine reported as the third dose of the COVID-19 vaccination schedule. According to the narrative, patient was fit and well the date of vaccine and felt slight nausea 45 minutes after vaccination. The following day she felt very unwell, was unable to get out of bed and due to vomiting and diarrhea she was admitted to the hospital and discharged the next day with instructions to repeat blood test as they showed reduction in kidney and liver function. Couple of days later the upper arm of the injection site became heavily inflamed, this was diagnosed initially as cellulitis in the upper arm, however it resolved itself within three days with no assistance. Blood tests performed in March 2022 showed improvement in kidney function, but no improvement in liver function. Abdominal ultrasound and chest X rays were also performed, but results were not provided. Other than monitoring and diagnostic test, patient have received no treatment. She changed her diet as was still suffering from bouts of nausea and fatigue. Relevant medical history included chronic kidney disease which could be a contributory factor for renal impairment, and fatty liver which could be a contributory factor for hepatic function abnormal. SARS-CoV-2 test was positive 31 days after vaccination; no further information was provided regarding this event. The benefit-risk relationship of mRNA-1273 is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 09-Jun-2022: Significant Follow-up received. Past medical history, Lab data, Dose details, Indication for concomitant drug was updated. Previous event Rash was deleted and new events: Hepatic function abnormal, Renal impairment and Nausea was added.

Case ID	Narrative (Complete)
[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 AUTOIMMUNE HEPATITIS (Autoimmune hepatitis) and CONDITION AGGRAVATED (Disease aggravation) in a 37-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. Concurrent medical conditions included Autoimmune hepatitis since 2003 and Disseminated lupus erythematosus since 2003. Concomitant products included TOZINAMERAN (COMIRNATY) from 28-Apr-2021 to 08-Jun-2021 for COVID-19 vaccination. On 16-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 20-Dec-2021, the patient experienced AUTOIMMUNE HEPATITIS (Autoimmune hepatitis) (seriousness criterion hospitalization). On an unknown date, the patient experienced CONDITION AGGRAVATED (Disease aggravation) (seriousness criterion hospitalization). At the time of the report, AUTOIMMUNE HEPATITIS (Autoimmune hepatitis) and CONDITION AGGRAVATED (Disease aggravation) was resolving. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Dosage text R1. Treatment information was not provided. Company comments This regulatory case concerns a 37-year-old, female patient, with history of having concurrent medical conditions Autoimmune hepatitis and Disseminated lupus erythematosus since 2003, who experienced the unexpected, serious (Hospitalization) AESI event of Auto Immune hepatitis, 4 days after receiving a dose of mRNA-1273 vaccine in the covid 19 vaccination series along with the unexpected, serious (Hospitalization) event of Condition Aggravated on an unknown date. Patient received her previous 2 doses with Comirnaty vaccines about 7 months and 6 months ago respectively, with no adverse events reported. Interchange of vaccine products was noted. Details on the clinical course, labs, diagnostics and treatments were not reported. Medical history of Autoimmune hepatitis and Disseminated lupus erythematosus remain as confounders for all the events. All the events are resolving. The benefit-risk relationship of mRNA-1273 is not affected by this report. Events' seriousness assessed per Regulatory Authority reporting.

Case ID	Narrative (Complete)
[redacted]	This spontaneous case was reported by a health care professional and describes the occurrence of AUTOIMMUNE HEPATITIS (Diagnosed with autoimmune hepatitis) in a 57-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 002F21A and 047621A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. There were no other vaccines given within 1 month prior to Moderna COVID-19 vaccine. It was unknown if patient ever had COVID positive test or diagnosis. Previously administered products included for Product used for unknown indication: shingrix vaccine (Reaction in either 2017 or 2018 shingrix vaccine). Past adverse reactions to the above products included Reaction to previous exposure to any vaccine with shingrix vaccine. Concurrent medical conditions included Hypertension, Seizure, Sulfonamide allergy and Atopic dermatitis. On 11-Aug-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 17-Sep-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 17-Sep-2021, after starting mRNA-1273 (Moderna COVID-19 Vaccine), the patient experienced INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (Date of 1st Moderna dose: 11Aug2021 Lot # 002F21A Date of 2nd Moderna dose: 17Sep2021 Lot # 047621A). In January 2022, the patient experienced AUTOIMMUNE HEPATITIS (Diagnosed with autoimmune hepatitis) (seriousness criterion medically significant). At the time of the report, AUTOIMMUNE HEPATITIS (Diagnosed with autoimmune hepatitis) had not resolved and INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (Date of 1st Moderna dose: 11Aug2021 Lot # 002F21A Date of 2nd Moderna dose: 17Sep2021 Lot # 047621A) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In October 2021, Alanine aminotransferase: 700-800 (High) Test Result: Liver enzymes AST, ALT 700-800. Diagnosed with autoimmune hepatitis.. In October 2021, Aspartate aminotransferase: 700-800 (High) Test Result: Liver enzymes AST, ALT 700-800. Diagnosed with autoimmune hepatitis.. In October 2021, Hepatic enzyme: 200-300 (High) Test Result: Liver enzymes elevated to 200-300. Diagnosed with autoimmune hepatitis.. On an unknown date, Antinuclear antibody: positive (Positive) Test Result: Positive ANA. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medication was reported. It was reported that there was ongoing waves of nausea, fatigue, right quadrant pain over liver. After 2 weeks of 2nd dose patient had severe nausea and was in bed for 2 weeks. In Oct-2021, patient went to doctor and liver enzymes went out the roof elevated to 200-300 then by end of Oct-2021 liver enzymes AST, ALT 700-800. It was diagnosed with autoimmune hepatitis around Jan-2022. States she had a positive ANA lab test and plans to see rheumatologist to determine cause of positive ANA , states liver enzymes were now back to normal. Patient had constant fatigue, waves of nausea and still had right quadrant pain says most likely from liver. No treatment medication information provided. Company comment: This spontaneous case concerns a 57-year-old, female patient with no relevant medical history reported, who experienced the unexpected, serious (medically significant) adverse event of special interest Autoimmune hepatitis, with symptoms of persistent nausea, fatigue and right quadrant pain. Inappropriate schedule of product administration was reported as an additional event wherein dosing interval of the mRNA-1273 primary series was 37 days - more than the recommended vaccination window. The event was diagnosed approximately 4 months after receiving the second dose of mRNA-1273. The patient initially presented with severe nausea 2 weeks post-vaccination. She sought medical consult wherein liver enzymes were reportedly elevated, AST and ALT at 700-800 values (unspecified unit), and positive ANA test. Treatment details were not provided in the case; but the liver enzymes reportedly went back to normal on an unspecified date. The patient is yet to schedule a rheumatologist consult for further etiologic investigations. The benefit-risk relationship of mRNA-1273 is not affected by this report.
[redacted]	This case was received via [redacted] (Reference number: [redacted] on 17-May-2022 and was forwarded to Moderna on 19-May-2022. This case was reported by a physician via a medical representative. On an unknown date, the patient received the 1st dose of this vaccine. On an unknown date, the patient received the 2nd dose of this vaccine. On an unknown date, the patient received the 3rd dose of this vaccine. On an unknown date, chills, pyrexia, liver disorder, and jaundice developed about one week later. Drug-induced hepatic disorder was suspected. On an unknown date, the patient was hospitalized. On an unknown date, the symptoms tended to be resolving. On an unknown date, the patient was discharged from the hospital. On an unknown date, the patient is currently being followed up in the hospital. The outcome of suspected drug-induced liver disorder was reported as resolving. Follow-up investigation will be made. Company Comment: The event developed after the administration of ELASOMERAN and there is temporal relationship.

Case ID	Narrative (Complete)
[redacted]	This regulatory authority case was reported by an other health care professional and describes the occurrence of NAUSEA (Nausea) and HEPATITIS ACUTE (Acute hepatitis) in a 24-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. On 29-Apr-2022, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 29-Apr-2022, the patient experienced NAUSEA (Nausea) (seriousness criterion hospitalization) and HEPATITIS ACUTE (Acute hepatitis) (seriousness criterion hospitalization). The patient was treated with SODIUM CHLORIDE (SODIUM CHLORIDE IV) (intravenous) at a dose of 0.9%, 500ml/bag ST IV and SILYMARIN [SILYBUM MARIANUM] (oral) at a dose of 150 milligram three times a day. At the time of the report, NAUSEA (Nausea) and HEPATITIS ACUTE (Acute hepatitis) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Alanine aminotransferase: 380 380. On an unknown date, Blood pressure measurement: 137/86 137/86 mmHg. On an unknown date, Body temperature: 36.4 36.4 C. On an unknown date, Heart rate: 100 100 beat/min. On an unknown date, Liver function test: abnormal (abnormal) PCR was negative. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Concomitant product was not provided. The patient received the third dose of COVID-19 vaccine (Moderna) on 29 April 2022. 05 May 2022 the patient complained that dark brown urine and nausea occurred after she received the third dose of Moderna vaccine. On 5th May 2022 patient visited hospital, the physician recommended the patient to hospitalize, but her family lived in city, so she returned for medical treatment. Test showed an abnormal liver index (PCR was negative), blood pressure 137/86 mmHg, pulsen100 beat/min, body temperature 36.4 C and prescribed medications. The Worldwide UID was reported as [redacted] Company Comment: This regulatory authority case concerns a 24-year-old female patient with no medical history reported, who experienced the unexpected serious (hospitalization) events of Nausea and Hepatitis acute which occurred on the same day after the third dose of mRNA-1273 vaccine. Its reported 6 days after the vaccination patient visited the hospital with complaints of dark brown urine and nausea. Liver function test reported as abnormal liver index (PCR was negative) and other investigations like Alanine aminotransferase: 380, Blood pressure measurement: 137/86 mmHg, Body temperature: 36.4 C, Heart rate:100 beat/min were reported on an unknown date at ED and treatment with Sodium chloride 0.9%, 500ml/bag ST IV and Silymarin 150 mg/cap 1# TID. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. The events were assessed as serious as per Regulatory Authority´s report.
[redacted]	This case was received via European Medicines Agency (Reference number: [redacted] on 23-May-2022 and was forwarded to Moderna on 23-May-2022. This regulatory authority case was reported by a physician and describes the occurrence of AUTOIMMUNE HEPATITIS (Autoimmune Hepatitis) in a 42-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 000125A) for COVID-19 vaccination. The patient's past medical history included Hemorrhage subarachnoid on 10-Jan-2022 and Adjustment disorder. Previously administered products included for Prophylactic vaccination: Comirnaty BNT162b2 on 22-Jun-2021 and Comirnaty BNT162b2 on 03-Aug-2021. Past adverse reactions to the above products included No adverse event with Comirnaty BNT162b2 and Comirnaty BNT162b2. Concurrent medical conditions included Hypothyreosis. On 19-Jan-2022, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 3 dosage form. On 07-Mar-2022, the patient experienced AUTOIMMUNE HEPATITIS (Autoimmune Hepatitis) (seriousness criterion hospitalization). At the time of the report, AUTOIMMUNE HEPATITIS (Autoimmune Hepatitis) 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 medications were reported. No treatment medications were reported. Company Comment: This regulatory case concerns a 42-year-old, female patient with no reported relevant medical history, who was hospitalized for the unexpected adverse event of special interest Autoimmune hepatitis. The patient also received 2 doses of Tozinameran COVID-19 vaccine approximately 5 months prior to mRNA-1273. The event occurred approximately 1.5 months after receiving mRNA-1273 as third COVID-19 vaccine dose. Clinical course and treatment details were not provided in the case. The patient reported hypothyroidism as concurrent condition but did not mention if this is an autoimmune type of thyroid disease. A pre-existing autoimmune disease is considered a risk factor to developing autoimmune hepatitis. The benefit-risk relationship of mRNA-1273 is not affected by this report. Event's seriousness was assessed as per Regulatory Authority's report.

Case ID	Narrative (Complete)
[redacted]	This spontaneous case was reported by a physician and describes the occurrence of HEPATOTOXICITY (hepatotoxicity) in a 69-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 056M21A, 033F21A, 032B21A and 048A21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Patient not had any allergies. The patient's past medical history included Tumour resection (Glioblastoma tumor in front right lobe was resected) in February 2021 and Chemotherapy (chemo drug 3 times in a row, like a Monday, Tuesday & Wednesday) since an unknown date. Concurrent medical conditions included Glioblastoma (Patient had glioblastoma. He had it for about a year.). On 11-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 08-Apr-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 05-Nov-2021, received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 14-May-2022, received fourth dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 14-May-2022, after starting mRNA-1273 (Moderna COVID-19 Vaccine), the patient experienced PAIN IN EXTREMITY (sore arm). In May 2022, the patient experienced HEPATOTOXICITY (hepatotoxicity) (seriousness criterion medically significant). At the time of the report, HEPATOTOXICITY (hepatotoxicity) outcome was unknown and PAIN IN EXTREMITY (sore arm) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 18-May-2022, Alanine aminotransferase: 329 (High) 329 (normal range is 54). On 18-May-2022, Aspartate aminotransferase: 103 (High) 103 (normal range is 30 or 40). On 23-May-2022, Alanine aminotransferase: 316 (High) 316 (normal range is 54). On 23-May-2022, Aspartate aminotransferase: 95 (High) 95 (normal range is 30 or 40). In 2022, AST/ALT ratio: showed 5 times more than normal elevation of ast/a (High) showed 5 times more than normal elevation of AST/ALT enzymes. In 2022, Blood alkaline phosphatase: 3 times the normal levels of the alkaline phosphat (High) 3 times the normal levels of the alkaline phosphatase enzyme. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter considered HEPATOTOXICITY (hepatotoxicity) to be related. No further causality assessment was provided for PAIN IN EXTREMITY (sore arm). Patient had been in a clinical trial for a brain tumor chemo medication with no side effects for more than 6 months. He got the chemo drug 3 times in a row, like a Monday, Tuesday & Wednesday. This would go on for about 4 weeks, & sometimes 5weeks if the month was longer. He had both doses of Moderna Covid-19 vaccine & 2 booster doses of Moderna Covid-19 vaccine during chemo clinical trials. After the second booster dose of Moderna vaccine received on 14-May-2022, the patient showed 5 times more than normal elevation of AST/ALT enzymes and 3 times the normal levels of the alkaline phosphatase enzyme. On 18-May-2022, ALT was 329 and AST was 103 which was 9-10 points higher. The blood work on 23-May-2022, showed that ALT was 316 (normal was 54) and AST was 95 (normal was 30 or 40). This AE caused patient to seek medical care from clinical trials team. He was always in the standard range. He was going to be kicked out of the clinical trials if these labs did not come back down. He was given a 2 week grace period. Currently he had only 1 week left. Patient had not received any new concomitant medication, he was followed up very closely and never showed before any hepatotoxicity related to the chemotherapy. T he HCP mentioned that he suspected that the patient might have hepatotoxicity related to the vaccine. No treatment information was provided. Company Comment: This spontaneous case concerns a 69-year-old male patient, with relevant medical history of Tumor resection for Glioblastoma and subsequent Chemotherapy, who experienced the unexpected serious(medically significant) AESI of Hepatotoxicity. The event occurred on the same month of receiving the fourth dose of mRNA-1273 Vaccine (Primary doses and 1 booster - Moderna). It was reported that the AST/ALT ratio was 5 times more than normal levels and the alkaline phosphatase was 3 times above normal values. The patient had both doses of Moderna Covid-19 vaccine & 2 booster doses of Moderna Covid-19 vaccine during chemo clinical trials. The patient would undergo chemotherapy 3 times a week that went on for 4 to 5 weeks. The outcome of the event was reported as unknown. The patient's medical history of chemotherapy remain as a confounder for the occurrence of the event. The reporter considered Hepatotoxicity to be related to the product. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 24-May-2022: Significant follow-up received: Case seriousness updated, reporter information added, patient details updated, event added, and 1-narrative updated.

Case ID	Narrative (Complete)
[redacted]	This literature-non-study case was reported in a literature article and describes the occurrence of DRUG-INDUCED LIVER INJURY (Possible (drug-vaccine interaction) moderna COVID-19 vaccine mediated enoxaparin-induced liver injury), PYREXIA (Lowgrade fever) and ASTHENIA (worsening weakness) in a 77-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. LITERATURE REFERENCE: Rafa O, Ostreni I, Basile EJ, Singh A. Potential role of the Moderna COVID-19 vaccine in enoxaparin's effects on liver functions.. Cureus. 2022;14(4) Co-suspect product included non-company product ENOXAPARIN for DVT prophylaxis. The patient's past medical history included Peripheral neuropathy. Previously administered products included for DVT prophylaxis: enoxaparin (3 years ago also taken with no adverse events noted). Past adverse reactions to the above products included No adverse event with enoxaparin. Concurrent medical conditions included Dementia, Knee osteoarthritis and Fall (recurrent history of mechanical falls). On an unknown date, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form and ENOXAPARIN (unknown route) 40 milligram. On an unknown date, the patient experienced DRUG-INDUCED LIVER INJURY (Possible (drug-vaccine interaction) moderna COVID-19 vaccine mediated enoxaparin-induced liver injury) (seriousness criteria hospitalization and medically significant), PYREXIA (Lowgrade fever) (seriousness criterion hospitalization), ASTHENIA (worsening weakness) (seriousness criterion hospitalization), DYSURIA (Intermittent dysuria), FALL (Fall) and DRUG INTERACTION (Possible (drug-vaccine interaction) moderna COVID-19 vaccine mediated enoxapaarin-induced liver injury). The patient was treated with ACETAMINOPHEN for Fever, at a dose of 975 milligram; ACETAMINOPHEN for Fever, at a dose of 650 milligram; NORMAL SALINE for Adverse event, at a dose of 1 liter bolus and HEPARIN for Adverse event, at a dose of 5000 units, q12h. At the time of the report, DRUG-INDUCED LIVER INJURY (Possible (drug-vaccine interaction) moderna COVID-19 vaccine mediated enoxaparin-induced liver injury) was resolving, PYREXIA (Lowgrade fever), ASTHENIA (worsening weakness) and DYSURIA (Intermittent dysuria) had resolved and FALL (Fall) and DRUG INTERACTION (Possible (drug-vaccine interaction) moderna COVID-19 vaccine mediated enoxapaarin-induced liver injury) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Alanine aminotransferase (7-56): 96 µ/l (High) 96 µ/L on Day 3, 24 µ/l (normal) 24 µ/L on Day 1, 138 µ/l (High) 138 µ/L on Day 5, 155 µ/l (High) 155 µ/L on Day 6, 196 µ/l (High) 196 µ/L on Day 7 and 99 µ/l (High) 99 µ/L on Day 8. On an unknown date, Aspartate aminotransferase (8-48): 99 µ/l (High) 99 µ/L on Day 3, 29 µ/l (normal) 29 µ/L on Day 1, 129 µ/l (High) 129 µ/L on Day 5, 171 µ/l (High) 171 µ/L on Day 6, 146 µ/l (High) 146 µ/L on Day 7 and 90 µ/l (High) 90 µ/L on Day 8. On an unknown date, Bacterial test: negative (Negative) rickettsia rickettsia, was negative. On an unknown date, Bartonella test: negative (Negative) Negative. On an unknown date, Blood albumin (3.4-5.4): 3.9 g/dl (normal) 3.9 g/dL on Day1, 3.6 g/dl (normal) 3.6 g/dL on Day3, 3.4 g/dl (normal) 3.4 g/dL on Day5, 3.1 g/dl (normal) 3.1 g/dL on Day6, 3.3 g/dl (normal) 3.3 g/dL on Day7 and 3.5 g/dl (normal) 3.5 g/dL on Day8. On an unknown date, Blood alkaline phosphatase (44-147): 190 µ/l (High) 190 µ/L on day3, 78 µ/l (normal) 78 µ/L on Day 1, 316 µ/l (High) 316 µ/L on Day 5, 399 µ/l (High) 399 µ/L on Day 6, 481 µ/l (High) 481 µ/L on Day 7 and 370 µ/l (High) 370 µ/L on Day 8. On an unknown date, Blood pressure measurement: 118/78 mm hg (normal) 118/78 mm Hg. On an unknown date, Body temperature (97-99): 100.7 degree f (High) found to be febrile at 100.7 degree F on day1 and again on day 5, 99.2 degree f, subsided (High) 99.2 degree F, subsided on day3, 100.7 degree f (High) elevated back up to 100.7 degree F on day5, 100.6 degree f (High) 100.6 degree F on day6, 98.9 degree f (normal) 98.9 degree F on day7 and 98.7 degree f (normal) 98.7 degree F on day8. On an unknown date, Borrelia test: negative (Negative) Negative. On an unknown date, Brucella test: negative (Negative) Negative. On an unknown date, COVID-19 screening: negative (Negative) Negative. On an unknown date, Chest X-ray: negative (Negative) Negative. On an unknown date, Computerised tomogram abdomen: no evidence of acute abnormalities (normal) showed no evidence of acute abnormalities and negative for acute pathology (Negative) CT abdomen with intravenous contrast for right upper quadrant was negative for acute pathology with regard to the liver and surrounding biliary structures. On an unknown date, Coxiella test: negative (Negative) Negative. On an unknown date, Cytomegalovirus test: negative (Negative) Negative. On an unknown date, Ehrlichia test: negative (Negative) Negative. On an unknown date, Electrocardiogram: negative (Negative) Negative. On an unknown date, Epstein-Barr virus test: negative (Negative) Negative. On an unknown date, Heart rate: 85 beats per minute (normal) heart rate of 85 beats per minute. On an unknown date, Hepatic enzyme: mildly elevated liver enzymes (High) mildly elevated liver enzymes 2 days after enoxaparin. On an unknown date, Hepatitis A virus test: negative (Negative) Negative. On an unknown date, Hepatitis B virus test: negative (Negative) Negative. On an unknown date, Hepatitis C virus test: negative (Negative) Negative. On an unknown date, Herpes simplex test: negative (Negative) HSV 1/2 Negative. On an unknown date, Influenza virus test: negative (Negative) Negative. On an unknown date, Magnetic resonance cholangiopancreatography: no acute pathology (normal) showed no acute pathology in the liver or biliary system. On an unknown date, Metabolic function test: no evidence of liver transaminitis. (normal) no evidence of liver transaminitis.. On an unknown date, Physical examination: supra-pubic tenderness Patient noted to have supra-pubic tenderness on physical examination. On an unknown date, Respiratory rate: 16 breaths per minute (normal) respiratory rate of 16 breaths per minute. On an unknown date, Ultrasound abdomen: normal (normal) abdominal ultrasound of the right upper quadrant that was negative for any acute abnormalities and showed normal hepatobiliary structures.. For mRNA-1273 (Spikevax) (Unknown), the reporter considered DRUG-INDUCED LIVER INJURY (Possible (drug-vaccine interaction) moderna COVID-19 vaccine mediated enoxaparin-induced liver injury), PYREXIA (Lowgrade fever), ASTHENIA (worsening weakness), DYSURIA (Intermittent dysuria), FALL (Fall) and DRUG INTERACTION (Possible (drug-vaccine interaction) moderna COVID-19 vaccine mediated enoxapaarin-induced liver injury) to be related.

Case ID	Narrative (Complete)
	No concomitant medications were reported. Patient had recurrent history of mechanical falls and presented to the emergency department (ED) with a complaint of mechanical fall four days prior. On the sixth day, patient complained of having chills overnight and some right upper quadrant abdominal tenderness, described as 4/10 at its worst. The seventh day, the patient reported abdominal pain and fever had resolved. The patient had no subjective complaints, and vitals were stable for the next 6 days when was discharged. Reporter stated that the vaccine's ability to stimulate such inflammatory states can potentially act as a mediator for enoxaparin's effects on the liver. Second, patient had no acute findings on his CT and MRCP of the abdomen. This could potentially support our former theory delineating how the vaccine itself does not cause the hepatic injury, but rather renders the liver vulnerable due to the body's inflammatory response to it, as evidenced by the patient's fever. It was the possibility of systemic inflammatory states causing direct damage to the liver via T-cells. COVID-19 vaccines primarily trigger T-cell-mediated immune reactions which can trigger such systemic inflammatory states. That mi

Appendix 11.21c Autoimmune Hepatitis: AIH confirmed case-Case listings

Case ID	Country	Report Type	ALL PT'S	Case Seriousness	Patient Age (Years)	Patient Gender	EASL	WHO	Confounders	Company Comment	Medical History	Concomitant Medications	WW Identifier	Batch/Lot Number	RP	Generic Name
[redacted]	[redacted]	Literature-Non-Study	Autoimmune hepatitis, Myalgia	Serious	36	Female	AIH (definite)	Possible	Ulcerative colitis; primary sclerosing cholangitis		Colitis ulcerative(C); Cholangitis sclerosing(C); Pruritus(C)	URSODEOXYCHOLIC ACID	[redacted]	0	Prior to Review Period	mRNA-1273
		Regulatory Authority	Autoimmune hepatitis, Product dose omission issue	Serious	62	Male	AIH	Possible	possible liver impact of the underlying diabetes and cardiomyopathy, although liver ultrasound did not show fatty liver.	AIH confirmed; WHO-UMC probable	Diabetes mellitus(C); Ischaemic cardiomyopathy(C)	CRESTOR; [redacted] ASA SANDOZ; ROSUVASTATIN		0	Prior to Review Period	mRNA-1273
		Literature-Non-Study	Autoimmune hepatitis, Herpes virus infection	Serious	76	Female	AIH	Possible	yes, prior COVID19 and other autoimmune disease (Hashimoto)	confirmed AIH, counfounder: COVID-19 3months prior. Context of other autoimmune disease (Hashimoto) WHO-UMC possible	COVID-19(H); Hypothyroidism(C); Transitional cell carcinoma(H); Hypotension(H)	MIDODRINE; ZOLPIDEM; LEVOTHYROXINE		300042460	Prior to Review Period	mRNA-1273
		Literature-Non-Study	Autoimmune hepatitis, Jaundice	Serious	71	Female	AIH	Possible	yes, paracetamol	confirmed AIH; WHO-UMC probable	Cholecystectomy; Hip arthroplasty; Osteoarthritis(H)	PARACETAMOL		0	Prior to Review Period	mRNA-1273
		Literature-Non-Study	Autoimmune hepatitis, Influenza like illness, Intentional dose omission, Malaise	Serious	56	Female	AIH	Possible	yes, statins	confirmed AIH; WHO-UMC probable	0	ROSUVASTATIN		0	Prior to Review Period	mRNA-1273
		Literature-Non-Study	Autoimmune hepatitis	Serious	52	Female	AIH	Conditional	none reported except no background of autoimmunity	confirmed AIH; WHO-UMC probable	0	0		0	Prior to Review Period	mRNA-1273
		Literature-Non-Study	Autoimmune hepatitis	Serious	65	Female	AIH	Possible	yes, polycythemia is involved in thrombosis Budd Chiari leading to liver failure which was not the clinical presentation here	confirmed AIH; WHO-UMC possible	Polycythaemia vera(H)	ACETYLSALICYLIC ACID; SERTRALINE; ESOMEPRAZOLE		0	Prior to Review Period	mRNA-1273
		Literature-Non-Study	Immune-mediated hepatitis, Inappropriate schedule of product administration	Serious	47	Male	AIH or DILI	Possible	No medical history reported - According to authors patient completely well	AIH or DILI; WHO-UMC possible	Alcohol use(C)	0		0	Prior to Review Period	mRNA-1273
		Literature-Non-Study	Autoimmune hepatitis	Serious	73	Female	AIH	Possible	No medical history reported; no information on any additional laboratory test including SARS-CoV-2	AIH; WHO-UMC possible	0	0		0	Review Period	mRNA-1273
		Literature-Non-Study	Autoimmune hepatitis	Serious	41	Female	AIH	Probable	No medical history reported	AIH confirmed; WHO-UMC probable	Premature menopause(C)	0		0	Prior to Review Period	mRNA-1273

Appendix 11.21d Autoimmune Hepatitis: AIH confirmed case-Case narratives

Case ID	Narrative (Complete)	WW Identifier
[redacted]	This literature-non-study case was reported in a literature article and describes the occurrence of AUTOIMMUNE HEPATITIS (Autoimmune hepatitis) in a 36-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. LITERATURE REFERENCE: Zhou T, Fronhoffs F, Dold L, Strassburg CP, Weismuller TJ. New-onset autoimmune hepatitis following mRNA COVID-19 vaccination in a 36-year-old woman with primary sclerosing cholangitis – should we be more vigilant?. J Hepatol. 2022;76(1):218–20 Concurrent medical conditions included Ulcerative colitis (was diagnosed at 33 years) since 2018, Primary sclerosing cholangitis (Due to recurrent episodes of purulent cholangitis and refractory strictures scheduled balloon dilatations had to be performed regularly every three months.) since 2018 and Pruritus. Concomitant products included URSODEOXYCHOLIC ACID for Ulcerative colitis and Primary sclerosing cholangitis. On 20-May-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 19-Jun-2021, received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. In 2021, the patient experienced AUTOIMMUNE HEPATITIS (Autoimmune hepatitis) (seriousness criteria hospitalization and medically significant) and MYALGIA (Minor muscle ache). The patient was hospitalized on 31-May-2021 due to AUTOIMMUNE HEPATITIS. The patient was treated with PREDNISONE on 10-Jun-2021 for Autoimmune hepatitis, at a dose of 50 mg and AZATHIOPRINE on 01-Jul-2021 for Autoimmune hepatitis, at an unspecified dose and frequency. At the time of the report, AUTOIMMUNE HEPATITIS (Autoimmune hepatitis) and MYALGIA (Minor muscle ache) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In 2021, Alanine aminotransferase: 588u/l (High) elevated (588U/l). In 2021, Antimitochondrial antibody: negative (Negative) negative. In 2021, Antineutrophil cytoplasmic antibody: negative (Negative) negative. In 2021, Antinuclear antibody: positive (Positive) 1:2560; homogeneous pattern was positive. In 2021, Aspartate aminotransferase: 581u/l (High) elevated (581U/l). In 2021, Blood alkaline phosphatase: slightly elevated (High) slightly elevated. In 2021, Blood bilirubin: normalization (normal) normalization and 1.4 mg/dl (High) rise (1.4 mg/dl). In 2021, Blood immunoglobulin G: elevated (High) elevated up to 24.75g/l (upper limit of normal: 16g/l) and normalization (14.6g/l) (normal) normalization (14.6g/l). In 2021, DNA antibody: positive (Positive) (186.8IU/l (ULN: 100 IU/l) were positive. In 2021, Gamma-glutamyltransferase: slightly elevated (High) slightly elevated. In 2021, Hepatic enzyme: rapidly decreasing (Low) rapidly decreasing. In 2021, Histology: dense lymphoplasmacellular portal infiltrate shows a dense lymphoplasmacellular portal infiltrate with involvement of the adjacent lobular parenchyma (interface hepatitis), which consists of lymphocytes, plasma cells and few eosinophils and abnormal showed a dense lymphoplasmacellular portal infiltrate with involvement of the adjacent lobular parenchyma (interface hepatitis) and discrete presence of rosette formation and apoptotic hepatocytes. Besides lymphocytes and plasma cells few eosinophils and small bile ducts with associated neutrophilic granulocytes (ductular reaction) were observed.. In 2021, International normalised ratio: 1.2 1.2 and rise (High) rise (1.2). In 2021, Serology test: negative (Negative) was negative for acute viral infections (hepatitis A, B, C, E, cytomegalovirus, Epstein-Barr-Virus, herpes virus). On an unknown date, Alanine aminotransferase: 193 u/l (High) 193 U/l and normalized (normal) normalized. On an unknown date, Aspartate aminotransferase: 117u/l (High) 117U/l and normalized (normal) normalized. On an unknown date, Blood alkaline phosphatase: 1077u/l (High) highly elevated (AP, 1077U/l). On an unknown date, Blood immunoglobulin G: 16.9g/l 16.9g/l and 16.9g/l (High) 16.9g/l. On an unknown date, Cholangiogram: abnormal Diagnosis was made after exclusion of viral or metabolic hepatopathy due to a typical cholangiogram. On an unknown date, Endoscopy biliary tract: decreased (Low) decreased. On an unknown date, Gamma-glutamyltransferase: 757u/l (High) 757U/l and decreased (Low) decreased. On an unknown date, Histology: abnormal (abnormal) Liver histology showed a dense lymphoplasmacellular portal infiltrate wit. On an unknown date, Red blood cell sedimentation rate: showed multiple highgrade showed multiple highgrade intra- and extrahepatic strictures. On an unknown date, Serology test: negative (Negative) Serology was negative for acute viral infections (hepatitis A, B, C, E, cytomegalovirus, Epstein-Barr-Virus, herpes virus and negative (Negative) Negative. On an unknown date, Transaminases: elevated (High) elevated but less than AP/GGT. The action taken with mRNA-1273 (Spikevax) (Unknown) was unknown. For mRNA-1273 (Spikevax) (Unknown), the reporter considered AUTOIMMUNE HEPATITIS (Autoimmune hepatitis) and MYALGIA (Minor muscle ache) to be possibly related. Diagnosis was made after exclusion of viral or metabolic hepatopathy due to a typical cholangiogram and highly elevated alkaline phosphatase (AP, 1077U/l) and gammaglutamyltransferase (GGT, 757U/l), while aspartate aminotransferase (AST, 117U/l), alanine aminotransferase (ALT, 193 U/l) and Immunoglobulin G (IgG, 16.9g/l) were only slightly elevated. Following treatment with ursodeoxycholic acid (1000mg/d) and endoscopic biliary intervention AP and gGT initially decreased and ALT and AST normalized. However, after one year, the patient presented with cholangitis and pruritus and ERC showed multiple highgrade intra- and extrahepatic strictures. Except for minor muscle aches the patient was without further symptoms after first dose of vaccine. On 31-May-2021 she was hospitalized for a scheduled endoscopic balloon dilatation of the strictures. Since the SARS-CoV2-antibody-titer two weeks after the 1st vaccination was only weak, we decided to vaccinate a 2nd time on 10-Jun-2021 while the patient was still treated with 50mg	[redacted]

Case ID	Narrative (Complete)	WW Identifier
	prednisone. Nonetheless, we recorded a further decline of liver enzymes. The SARS-CoV2-IgGantibody- response two weeks after the 2nd vaccination was sufficient with >384 BAU/ml. Author concluded that the question arises whether we should be more vigilant, at least in female patients with preexisting predisposition to autoimmune diseases, and routinely check aminotransferases 2-4 weeks after COVID-19-vaccination. Company comment: This case concerns a 36 year-old, female with a history of Primary sclerosing cholangitis and ulcerative colitis, who experienced the unexpected event of AUTOIMMUNE HEPATITIS. The event occurred within 11 days after the first dose of mRNA-1273 Moderna vaccine. Patients laboratory test showed elevated results Alanine aminotransferase, Aspartate aminotransferase, Blood alkaline, Blood immunoglobulin G, Gamma-glutamyltransferase; Postive for Antinuclear antibody, DNA antibody; Negative for Antimitochondrial antibody, Antineutrophil cytoplasmic antibody, Serology test; and Abnormal Histology results. The event was considered related to the product per the reporter´s assessment. The medical history could be a potentially confounder. The benefit-risk relationship of mRNA-1273 Moderna vaccine in not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 21-Sep-2021: Follow up received by safety on 22-Sep-2021 has Email with FTA received from SARA team and does not contain any new information. On 31-Mar-2022: Follow up received by safety on 31-Mar-2022 has Email with FTA received and contains significant information: Literature information updated (volume, issue, page number and year), start date of second dose updated and report type updated from Literature-Study to Literature-Non-Study as per current convention.	

Case ID	Narrative (Complete)	WW Identifier
[redacted]	This regulatory authority case was reported by a physician and describes the occurrence of AUTOIMMUNE HEPATITIS (Autoimmune hepatitis) in a 62-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Diabetes mellitus (Type 2 diabetes) and Ischemic cardiomyopathy (Ischemic heart disease). Concomitant products included METFORMIN HYDROCHLORIDE [redacted] ACETYLSALICYLIC ACID (ASA SANDOZ) and ROSUVASTATIN for Type 2 diabetes mellitus and Ischemic heart disease, ROSUVASTATIN CALCIUM (CRESTOR) for an unknown indication. On 04-May-2021, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form. On 11-May-2021, after starting mRNA-1273 (COVID-19 Vaccine Moderna), the patient experienced AUTOIMMUNE HEPATITIS (Autoimmune hepatitis) (seriousness criterion medically significant). On an unknown date, the patient experienced PRODUCT DOSE OMISSION ISSUE (Product dose omission issue). The patient was treated with PREDNISONE for Adverse event, at a dose of 40 mg once a day. At the time of the report, AUTOIMMUNE HEPATITIS (Autoimmune hepatitis) was resolving and PRODUCT DOSE OMISSION ISSUE (Product dose omission issue) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Alanine aminotransferase (Unknown-55): 1038 (abnormal) 1038 U/L (upper limit of normal (ULN) was reported as 55. On an unknown date, Alpha-1 anti-trypsin: normal (normal) Tested normal. On an unknown date, Antimitochondrial antibody: negative (Negative) Tested negative. On an unknown date, Antineutrophil cytoplasmic antibody: negative (Negative) Tested negative. On an unknown date, Aspartate aminotransferase (Unknown-34): 1127 (abnormal) 1127 U/L (upper limit of normal (ULN) 34 U/l. On an unknown date, Autoantibody test: positive (Positive) antibody (ANA) at a titer of 1:640 with fine speckled indirect immunofluorescence pattern on HEp2 cells, positive anti-gastric parietal cells antibody at a titer of 1:320. Anti-smooth muscle antibody (ASMA), anti neutrophil cytoplasmic antibody (ANCA), anti-soluble liver antigen (SLA) antibody, anti-liver kidney microsomal type 1 antibody (anti-LKM1), anti-liver cytosol type 1 (anti- LC1) antibody and anti mitochondrial antibody (AMA) were all negative. and positive (Positive) Autoimmune liver serology was repeated at 12 days after first testing. On an unknown date, Blood alkaline phosphatase (40-150): 192 (High) 192 U/L. On an unknown date, Blood bilirubin (Unknown-20.4): 204.8 (abnormal) 204.8 8 µmol/l (ULN 20.4 µmol/l). On an unknown date, Blood immunoglobulin G (5.4-18.22): 19.96 (High) 19.96 g/l. On an unknown date, Ceruloplasmin: normal (normal) Tested normal. On an unknown date, Gamma-glutamyltransferase (Unknown-55): 536 (normal) 536 U/l ULN 55 U/l. On an unknown date, Haemoglobin: 14.8 (normal) 14.8 g/dL. On an unknown date, Histology: abnormal (abnormal) Liver histology showed inflammatory portal infiltrate with interface hepatitis, lobular and centrilobular inflammation with centrilobular necrosis, in absence of fibrosis and steatosis.. On an unknown date, Immunology test: negative (Negative) Immunoblot for anti-SLA, anti-LC1, anti-LKM1, anti-sp100 and anti-gp210 (Alphadia), anti-transglutaminase IgA (Elisa, Thermofisher Scientific), ANCA, tested by indirect immunofluorescence on fixed human neutrophils (INOVA), anti-myeloperoxidase and anti-proteinase 3 (Elisa, Thermofisher Scientific) were all reported as negative. and positive (Positive) Indirect immunofluorescence on HEp2 and VSM47 cells (Euroimmun) showed positive nuclear staining with a speckled pattern and a faint rim-like pattern, coupled with positive cytoplasmic staining with a trabecular pattern.. On an unknown date, International normalised ratio: 1.16 (normal) 1.16 and 1.4 (normal) The patient did not develop signs of encephalopathy, and after a transient worsening of INR to 1.4, he showed spontaneous improvement of serum bilirubin, INR and transaminase levels.. On an unknown date, Physical examination: tender hepatomegaly tender hepatomegaly without ascites. On an unknown date, Platelet count: 309 (normal) 309 x 109/l. On an unknown date, Polymerase chain reaction: negative (Negative) Polymerase chain reaction for hepatitis B, C, E, anti hepatitis A virus and IgM were negative. On an unknown date, SARS-CoV-2 antibody test: 1392 Anti-SARS-Cov2 IgG spike 1 antibody 24 days after the first vaccine dose was positive (1392 AU/ml, positivity cut off: 50 AU/ml).. On an unknown date, Ultrasound abdomen: normal (normal) An abdominal ultrasound showed normal liver parenchyma, normal portal vein flow, no ascites, normal spleen size (11 cm).. On an unknown date, White blood cell count: 6.3 (normal) 6.3 x 109/l. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered AUTOIMMUNE HEPATITIS (Autoimmune hepatitis) to be possibly related. No further causality assessment was provided for PRODUCT DOSE OMISSION ISSUE (Product dose omission issue). The reporter stated that patient had presented to his general practitioner and did not take herbal remedies or other drugs, and his daily amount of alcohol consumption was 10g. Patient had no history of clinical apparent COVID-19. On examination,patient was jaundiced, and had tender hepatomegaly without ascites. The second vaccine dose was temporarily suspended. The lab test reported also included Anti-smooth muscle antibody (ASMA), anti-soluble liver antigen (SLA) antibody, anti-liver kidney microsomal type 1 antibody (anti-LKM1), anti-liver cytosol type 1 (anti- LC1) antibody and were reported as negative. Anti-SARS-Cov2 IgG spike 1 antibody was undergone 24 days after the first vaccine dose and reported as positive (1392 AU/ml, positivity cut-off: 50 AU/ml). Molecular-based assays for U1-snRNP, SSA/Ro, SSB/La, CENP-B, Scl-70, Jo-1, Sm, dsDNA, Fibrillarin, RNA Pol III, Rib-P, PM-Scl, PCNA, Mi2 were negative (CTD screen, Thermofisher Scientific). Anti-native pyruvate dehydrogenase complex E2 sudunit (PDC-E2), anti-recombinant PDC subunit E2, anti-2-oxoglutarate dehydrogenase complex E2 subunit (OGDC-E2) and anti-branched-chain 2-oxo acid dehydrogenase complex E2-subunit (BCOADC-E2) were negative (Alphadia). MIT-3 based Elisa (INOVA) was also negative.	[redacted]

Case ID	Narrative (Complete)	WW Identifier
	The reported lab results also included anti-cardiolipin IgG and IgM antibodies were negative IgA was positive (26.1 CU, positivity cut-off 20CU); similarly, anti-beta-2 glycoprotein IgA was positive (51.3 CU, positivity cut-off 20), with negative anti-beta-2 glycoprotein IgM and IgG. Human leukocyte antigen (HLA) testing showed DRB101:01 11:01, DQA1 01:01 05:01, and DQB1 03:01 05:01 The reporter also stated that the patient was on long term statin therapy. Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. Product dose omission issue is assessed as not applicable for causality.	

Case ID	Narrative (Complete)	WW Identifier
[redacted]	This literature-non-study case was reported in a literature article and describes the occurrence of AUTOIMMUNE HEPATITIS (Autoimmune hepatitis) in a 76-year-old female patient who received mRNA-1273 (COVID-19 Vaccine Moderna) (batch no. 300042460) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. LITERATURE REFERENCE: Vuille-Lessard E, Montani M, Bosch J, Semmo N. Autoimmune hepatitis triggered by SARS-CoV-2 vaccination. J Autoimmun. 2021;123:102710 The patient's past medical history included COVID-19 (Three months prior (mild disease not requiring hospitalization)) on 30-Oct-2020, Urothelial carcinoma in 2019 and Low blood pressure. Concurrent medical conditions included Hypothyroidism since 2016. Concomitant products included LEVOTHYROXINE for Hypothyroidism, MIDODRINE for Low blood pressure, ZOLPIDEM for Sleepy. On 02-Feb-2021 at 3:30 PM, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form. On 15-Feb-2021, the patient experienced AUTOIMMUNE HEPATITIS (Autoimmune hepatitis) (seriousness criterion medically significant). On an unknown date, the patient experienced HERPES VIRUS INFECTION (nasal herpes simplex virus infection). The patient was treated with PREDNISOLONE (oral) from 16-Mar-2021 to 25-May-2021 for Autoimmune hepatitis, at a dose of 40 mg and AZATHIOPRINE from 30-Mar-2021 to 19-Apr-2021 for Autoimmune hepatitis, at a dose of 50 mg. At the time of the report, AUTOIMMUNE HEPATITIS (Autoimmune hepatitis) had not resolved and HERPES VIRUS INFECTION (nasal herpes simplex virus infection) outcome was unknown. Possible DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 16-Mar-2021, Biopsy liver: positive (Positive) diagnosis of autoimmune hepatitis was suspected, with positive autoantibodies. The diagnosis was confirmed histologically on a liver biopsy performed on 16.03.2021. In 2021, Abdomen scan: normal (normal) Abdominal examination was remarkable for tender hepatomegaly. In 2021, Alanine aminotransferase: 579 (abnormal) Alanine transaminase of 579 U/L. In 2021, Anti-actin antibody: 84 (abnormal) anti-actin antibody 84 U (negativity cut-off less than 20 U). In 2021, Antimitochondrial antibody: negative (Negative) Anti-M2 antibody Negative. In 2021, Antineutrophil cytoplasmic antibody: positive (Positive) anti-neutrophil cytoplasmic antibodies (titer greater than 1:1280, perinuclear, MPO and PR3 negative) were strongly positive. In 2021, Antinuclear antibody: 1:1280 (Inconclusive) Anti-nuclear antibody (titer 1:1280, homogeneous, fine granular). In 2021, Aspartate aminotransferase: 811 (High) elevated aspartate transaminase of 811 U/L. In 2021, Biopsy liver: abnormal (abnormal) A liver biopsy showed a chronic markedly active hepatitis with interface hepatitis, plasma cells, feathery degeneration and pseudo rosettes typical findings of autoimmune hepatitis (AIH). The degree of fibrosis could not be assessed given the significant parenchymal collapse. Simplified AIH Score was 8 (definite diagnosis of AIH).. In 2021, Blood albumin: 28 (abnormal) albumin was 28 g/L. In 2021, Blood alkaline phosphatase: 124 (abnormal) Alkaline phosphatase of 124 U/L. In 2021, Blood bilirubin: 65 (abnormal) total bilirubin of 65 micro mol/L. In 2021, Blood creatinine: normal (normal) creatinine was normal. In 2021, Blood immunoglobulin G: 39.4 (abnormal) significantly increased (39.4 g/L). In 2021, Blood pressure measurement: low (Low) Low. In 2021, Full blood count: normal (normal) Complete blood count was normal. In 2021, Gamma-glutamyltransferase: 361 (abnormal) Gamma-glutamyltransferase of 361 U/L. In 2021, International normalised ratio: 1.23 (abnormal) INR was 1.23. In 2021, Liver function test: normal (normal) Liver enzymes were completely normal in a routine check-up three years prior, as well as two months after the COVID-19 infection, elevated (High) elevated liver enzymes when referred to Hepatology outpatient clinic and normal (normal) After four weeks of treatment, the liver enzymes had completely normalized and the patient's symptoms had significantly improved. In 2021, Ophthalmological examination: abnormal (abnormal) On examination, the patient had discrete scleral and sublingual icterus.. In 2021, Polymerase chain reaction: negative (Negative) PCR for hepatitis B and E viruses and for cytomegalovirus were negative. In 2021, Serology test: negative (Negative) Serologies for hepatitis A, B and C viruses were negative. In 2021, Ultrasound abdomen: abnormal (abnormal) Abdominal ultrasound showed a slightly enlarged and hyperechogenic liver without biliary duct dilatation. The action taken with mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) was unknown. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered AUTOIMMUNE HEPATITIS (Autoimmune hepatitis) to be possibly related. No further causality assessment was provided for HERPES VIRUS INFECTION (nasal herpes simplex virus infection). Patient was referred to Hepatology outpatient clinic with a 5-week history of dark urine, weight loss and fatigue, associated with elevated liver enzymes. Symptoms had begun two to three days after receiving the first dose of the mRNA-1273 SARS-CoV-2 vaccine. Laboratory test also included anti-smooth muscle antibody (titer 1:1280, against F-Actin, no specific immunofluorescence pattern observed), liver kidney microsome type 1 antibody and anti-soluble liver antigen antibody were negative. After four weeks of treatment, the liver enzymes had completely normalized and the patient's symptoms had significantly improved A decision was made to not administer the second dose of the vaccine.	[redacted]

Case ID	Narrative (Complete)	WW Identifier
	The patient discontinued azathioprine on her own after two months of therapy due to drug intolerance and development of a nasal herpes simplex virus infection. Six weeks after stopping therapy there were however no biochemical signs of an AIH relapse. Authors concluded that vaccination could lead to the development of autoimmune diseases, but proving such a relationship was challenging and given the close temporal relationship between the vaccination and onset of symptoms, they hypothesized that vaccination against COVID-19 could have triggered the development of Autoimmune hepatitis in their patient, with Hashimoto thyroiditis and prior COVID-19 infection acting as predisposing factors. Company Comment: Based on the current available information and temporal association between the use of the product, and the start date of the events, a causal relationship cannot be excluded. Concomitant autoimmune disease could be potentially confounder for the events. The prednisolone was stopped on 25.05.2021 after liver enzymes normalized. The patient had a relapse of the autoimmune hepatitis 3 months after the stop of therapy (in 08.2021), treated with prednisolone and mycophenolat mofetil. Most recent FOLLOW-UP information incorporated above includes: On 10-Aug-2021: Follow up received by safety on 12-Aug-2021 included an email with FTA received from SARA team and does not contain any new information. On 13-Sep-2021: Significant Follow up. Follow up received by safety 14-Sep-2021 included an Email with ADR form. Author details, patient details, history and onset date were updated.	

Case ID	Narrative (Complete)	WW Identifier
[redacted]	This literature-non-study case was reported in a literature article and describes the occurrence of AUTOIMMUNE HEPATITIS (Autoimmune Hepatitis) and JAUNDICE (jaundice) in a 71-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. LITERATURE REFERENCE: McShane C, Kiat C, Rigby J, Crosbie O. The mRNA COVID-19 vaccine - a rare trigger of autoimmune hepatitis?. J Hepatol. 2021:1-5 The patient's past medical history included Osteoarthritis knee, Cholecystectomy (20 years previously) and Hip replacement. Concomitant products included PARACETAMOL for an unknown indication. On 16-Apr-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On an unknown date, the patient experienced AUTOIMMUNE HEPATITIS (Autoimmune Hepatitis) (seriousness criteria hospitalization prolonged and medically significant). an unknown date, the patient experienced JAUNDICE (jaundice) (seriousness criterion hospitalization prolonged). The patient was hospitalized from sometime in 2021 to sometime in 2021 due to AUTOIMMUNE HEPATITIS and JAUNDICE. The patient was treated with PREDNISOLONE for Adverse event, at a dose of 1 dosage form. At the time of the report, AUTOIMMUNE HEPATITIS (Autoimmune Hepatitis) and JAUNDICE (jaundice) was resolving. Possible DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In April 2021, Alanine aminotransferase: high (High) 1067U/L, 1143U/L. In April 2021, Aspartate aminotransferase: high (High) 1469U/L. In April 2021, Biopsy liver: abnormal (abnormal) Up to 20 portal tracts were present, each expanded with a marked polymorphous inflammatory cell infiltrate of plasma cells, lymphocytes, eosinophils, neutrophils and PASD positive ceroid laden macrophages; interface hepatitis was present and continuous in most tracts, with portal-portal and portal-central bridging necrosis. In April 2021, Blood alkaline phosphatase: high (High) 217U/L, 237U/L. In April 2021, Blood bilirubin: high (High) 270umol/L, 332umol/L. In April 2021, Blood immunoglobulin G: high (High) markedly raised at 21.77g/L. In April 2021, Computerised tomogram: abnormal (abnormal) showed distal common bile duct dilation of 1.4cm consistent with prior cholecystectomy. In April 2021, Hepatitis A antibody: positive (Positive) Hepatitis A IgG was positive with a negative IgM. In April 2021, International normalised ratio: high (High) 1.4. In April 2021, Magnetic resonance cholangiopancreatography: abnormal (abnormal) showed distal common bile duct dilation of 1.4cm consistent with prior cholecystectomy. In April 2021, Physical examination: abnormal (abnormal) jaundiced. In April 2021, Smooth muscle antibody: positive (Positive) strongly positive with a titre of 2560 and an anti-actin pattern. In April 2021, Ultrasound liver: abnormal (abnormal) showed distal common bile duct dilation of 1.4cm consistent with prior cholecystectomy. In April 2021, Viral test: negative (Negative) negative for hepatitis B, C, and E, Epstein-Barr virus, cytomegalovirus and HIV. The action taken with mRNA-1273 (Spikevax) (Intramuscular) was unknown. For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered AUTOIMMUNE HEPATITIS (Autoimmune Hepatitis) and JAUNDICE (jaundice) to be possibly related. Patient had no confounding risk factors for developing autoimmune liver disease such as other autoimmune conditions or recent pregnancy. Patient was on no regular medications or supplements. Treatment medication included steroids Company Comment: Although a temporal association exist and the fact that vaccines have been known to be associated with reactivation of autoimmune disorder, the reported event is strongly confounded by the patient's underlying autoimmune conditions medical history. Hence, causal relationship with Spikevax cannot be confirmed. Most recent FOLLOW-UP information incorporated above includes: On 10-Aug-2021: Follow up received by safety on 12-Aug-2021 included an Email with FTA received from SARA team and does not contain any new information.	[redacted]

Case ID	Narrative (Complete)	WW Identifier
[redacted]	This literature-non-study case was reported in a literature article and describes the occurrence of AUTOIMMUNE HEPATITIS (autoimmune hepatitis) in a 56-year-old female patient who received mRNA-1273 (COVID 19 Vaccine Moderna) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. LITERATURE REFERENCE: Tan CK, Wong YJ, Wang LM, Ang TL, Kumar R. Autoimmune hepatitis following COVID-19 vaccination: True causality or mere association?. J Hepatol. 2021;75:1239-60 Concomitant products included ROSUVASTATIN for an unknown indication. On 14-Apr-2021, the patient received first dose of mRNA-1273 (COVID 19 Vaccine Moderna) (unknown route) 1 dosage form. On 15-Apr-2021, the patient experienced INFLUENZA LIKE ILLNESS (flu-like symptoms) and MALAISE (malaise). On an unknown date, the patient experienced AUTOIMMUNE HEPATITIS (autoimmune hepatitis) (seriousness criterion medically significant) and INTENTIONAL DOSE OMISSION (she later decided against receiving the recommended second dose). The patient was treated with BUDESONIDE for Autoimmune hepatitis, at an unspecified dose and frequency. At the time of the report, AUTOIMMUNE HEPATITIS (autoimmune hepatitis) was resolving, INFLUENZA LIKE ILLNESS (flu-like symptoms) and MALAISE (malaise) outcome was unknown and INTENTIONAL DOSE OMISSION (she later decided against receiving the recommended second dose) had resolved. Possible DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In 2019, Liver function test: normal (normal) normal. On an unknown date, Alanine aminotransferase: 1,701 u/l 1,701 U/L. On an unknown date, Antinuclear antibody: positive (Positive) Positive. On an unknown date, Aspartate aminotransferase: 1,124 u/l 1,124 U/L. On an unknown date, Biopsy liver: liver biopsy demonstrated portal inflammation with Liver biopsy demonstrated portal inflammation with interface hepatitis, accompanied by conspicuous lobular inflammation with the presence of plasma cell aggregates, rosette formation and apoptotic hepatocytes. The histological features are in-keeping with an AIH-type pattern. Eosinophils were also identified, raising the possibility of drug association. Early young fibrosis is noted in the portal regions and would be compatible with recent subacute injury.. On an unknown date, Blood albumin: 46 g/l 46 g/L. On an unknown date, Blood alkaline phosphatase: 298 u/l 298 U/L. On an unknown date, Blood bilirubin: 102 lmol/l 102 lmol/L. On an unknown date, Blood immunoglobulin G: 32.6 g/l serum IgG level was raised (32.6 G/L).. On an unknown date, Cytomegalovirus test: negative (Negative) Negative. On an unknown date, Eosinophil count: present Eosinophils were also identified, raising the possibility of drug association. On an unknown date, Epstein-Barr virus test: negative (Negative) Negative. On an unknown date, Hepatitis A virus test: negative (Negative) Negative. On an unknown date, Hepatitis B virus test: negative (Negative) Negative. On an unknown date, Hepatitis C virus test: negative (Negative) Negative. On an unknown date, Hepatitis E virus test: negative (Negative) Negative. On an unknown date, Herpes simplex test: negative (Negative) Negative. On an unknown date, Histology: aih-type pattern The histological features are inkeeping with an AIH-type pattern. Early young fibrosis is noted in the portal regions and would be compatible with recent subacute injury.. On an unknown date, International normalised ratio: 1.0 1.0. On an unknown date, Laboratory test: the initial laboratory studies showed that she had The initial laboratory studies showed that she had hepatocellular injury. On an unknown date, Physical examination: physical examination was normal except for scleral physical examination was normal except for scleral icterus.. On an unknown date, Ultrasound abdomen: unremarkable unremarkable. The action taken with mRNA-1273 (COVID 19 Vaccine Moderna) (Unknown) was unknown. For mRNA-1273 (COVID 19 Vaccine Moderna) (Unknown), the reporter considered AUTOIMMUNE HEPATITIS (autoimmune hepatitis), INFLUENZA LIKE ILLNESS (flu-like symptoms) and MALAISE (malaise) to be possibly related and INTENTIONAL DOSE OMISSION (she later decided against receiving the recommended second dose) to be not applicable. Six weeks after vaccination, she presented with a 1-week history of jaundice, feeling unwell and persistent anorexia. Apart from her regular medication (rosuvastatin 10 mg daily) started 9 years ago, she was not on any other prescription or traditional medication/supplements. cross-sectional abdominal imaging was unremarkable. anti-smooth muscle antibody was positive. The pre-treatment revised original AIH score was 16. Patient is still undergoing steroid therapy. Company Comment: This case concerns a 56-year-old female with no details on medical history, who experienced the unexpected serious event/AESI of Autoimmune hepatitis after mRNA- 1273 Moderna vaccine (Moderna COVID-19 Vaccine). Additionally. The onset of the event occurred approximately 6 weeks after the first dose of mRNA- 1273 vaccine. Clinical manifestations included jaundice, malaise and persistent anorexia. The rechallenge is not applicable since only information about the one dose was disclosed. The benefit-risk relationship of mRNA- 1273 vaccine / Moderna COVID-19 Vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 03-Nov-2021: Follow up received by safety 03-Nov-2021 included an Email with FTA received from SARA team and lab data, product details and events were updated.	[redacted]

Case ID	Narrative (Complete)	WW Identifier
[redacted]	This literature-non-study case was reported in a literature article and describes the occurrence of AUTOIMMUNE HEPATITIS (Autoimmune hepatitis) in a 52-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. LITERATURE REFERENCE: Goulas A, Kafiri G,Kranidiot H,Manolakopoulos S,et al. A typical autoimmune hepatitis (AIH) case following Covid-19 mRNA vaccination. More than a coincidence?. Liver Int. 2021 No Medical History information was reported. On 11-May-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On an unknown date, the patient experienced AUTOIMMUNE HEPATITIS (Autoimmune hepatitis) (seriousness criterion medically significant). The patient was treated with PREDNISOLONE for Malaise, Jaundice and Autoimmune hepatitis, at a dose of 50 mg once a day and AZATHIOPRINE for Malaise, Jaundice and Autoimmune hepatitis, at a dose of 50 mg once a day. At the time of the report, AUTOIMMUNE HEPATITIS (Autoimmune hepatitis) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Alanine aminotransferase (0-55): 936 u/l ALT: 936 U/L (0- 55 U/L). On an unknown date, Antinuclear antibody: positive (Positive) Antinuclear antibodies (1/320) and anti-smooth muscle antibody (ASMA) were positive.. On an unknown date, Aspartate aminotransferase (5-34): 350 u/l AST: 350 U/L (5-34 U/L),\. On an unknown date, Bilirubin conjugated (0-0.5): 5,5mg/dl D.Bil: 5,5mg/dL (0-0,5 mg/dL). On an unknown date, Blood alkaline phosphatase (40-150): 169 u/l ALP: 169 U/L (40-150 U/L). On an unknown date, Blood bilirubin (0.2-1.2): 9,06mg/dl T.Bil: 9,06mg/dL (0,2-1,2 mg/dL). On an unknown date, Blood immunoglobulin G (700-1600): elevated (High) IgG levels were elevated at 2396mg/dL (700-1600mg/dL). On an unknown date, Blood test: normal liver blood tests during previous periodica normal liver blood tests during previous periodical checkup. On an unknown date, C-reactive protein (<0.1-Unknown): 1,25mg/dl CRP: 1,25mg/dL (<1.0 mg/dL). On an unknown date, Cytomegalovirus test: negative (Negative) Serology for hepatitis A, B, C, E virus, CMV and EBV were negative.. On an unknown date, Epstein-Barr virus antibody: negative (Negative) Serology for hepatitis A, B, C, E virus, CMV and EBV were negative.. On an unknown date, Gamma-glutamyltransferase (9-36): 810 u/l 810 U/L (9-36 U/L). On an unknown date, Hepatitis A antibody: negative (Negative) Serology for hepatitis A, B, C, E virus, CMV and EBV were negative.. On an unknown date, Hepatitis B antibody: negative (Negative) Serology for hepatitis A, B, C, E virus, CMV and EBV were negative.. On an unknown date, Hepatitis C antibody: negative (Negative) Serology for hepatitis A, B, C, E virus, CMV and EBV were negative.. On an unknown date, Hepatitis E antibody: negative (Negative) Serology for hepatitis A, B, C, E virus, CMV and EBV were negative.. On an unknown date, Histology: liver histology (9 portal tracks) showed moderate Liver histology (9 portal tracks) showed moderate to severe inflammatory infiltration consisting of lymphocytes, plasmatocytes, histiocytes, few eosinophiles and neutrophiles with the presence of mild periportal hepatitis. Mild lobular inflammation, apoptotic bodies, hepatocytes with feathery degeneration of the cytoplasm and rosette formation were observed (Image. On an unknown date, Magnetic resonance cholangiopancreatography: normal (normal) MRCP was normal. and Abdominal ultrasound and MRCP were normal.. On an unknown date, Red blood cell sedimentation rate: 25 mm/h ESR: 25 mm/h. On an unknown date, Smooth muscle antibody: Antinuclear antibodies (1/320) and anti-smooth muscle antibody (ASMA) were positive.. On an unknown date, Ultrasound abdomen: normal (normal) Abdominal ultrasound was normal.. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown) was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter considered AUTOIMMUNE HEPATITIS (Autoimmune hepatitis) to be possibly related. No relevant concomitant medications were reported. No treatment information was provided. Patient with no medication history or alcohol abuse and normal liver blood tests during previous periodical checkup presented histologically confirmed AIH after 1st dose of the Moderna vaccine This is a literature case concerning a 52 years old, female patient with no clinical history who experienced the unexpected event of Autoimmune hepatitis. The event occurred following first dose of mRNA-1273 vaccine. Two weeks after receiving first dose the patient presented with malaise, jaundice and abnormal liver blood tests. Antinuclear antibodies (1/320) and anti-smooth muscle antibody (ASMA) were positive. Liver histology (9 portal tracks) showed moderate to severe inflammatory infiltration consisting of lymphocytes, plasmatocytes, histiocytes, few eosinophiles and neutrophiles with the presence of mild periportal hepatitis. The rechallenge was not applicable since only information about the second dose was disclosed. The patient started prednisolone per os daily followed by azathioprine, with gradual improvement of the symptoms and the laboratory tests. The benefit-risk relationship of Moderna Covid 19 vaccine is not affected by this report..	[redacted]

Case ID	Narrative (Complete)	WW Identifier
	The patient started prednisolone 50mg per os daily followed by azathioprine 50mg daily, with gradual improvement of the symptoms and the laboratory tests. The patient did not have any known background of autoimmunity. The clinical and laboratory data were compatible with typical AIH while the simplified AIH score proved a definite AIH case. Most recent FOLLOW-UP information incorporated above includes: On 11-Nov-2021: Follow up received by safety 11-Nov-2021 included an Email with FTA received from SARA team contain significant information in which lab data , Treatment Medications and Drug start date were added.	

Case ID	Narrative (Complete)	WW Identifier
[redacted]	This literature-non-study case was reported in a literature article and describes the occurrence of AUTOIMMUNE HEPATITIS (acute severe autoimmune hepatitis) in a 65-year-old female patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for COVID-19 vaccination. LITERATURE REFERENCE: Garrido I, Lopes S, Simoes MS, Liberal R, Lopes J, Carneiro F et al.. Autoimmune hepatitis after COVID-19 vaccine - more than a coincidence. J Autoimmun. 2021;125:102741 The patient's past medical history included Polycythemia vera (JAK2 V617F positive polycythemia vera under pegylated interferon since 2019). Concomitant products included ACETYLSALICYLIC ACID, SERTRALINE and ESOMEPRAZOLE for an unknown indication. 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, after starting mRNA-1273 (Moderna CoviD-19 Vaccine), the patient experienced AUTOIMMUNE HEPATITIS (acute severe autoimmune hepatitis) (seriousness criterion hospitalization). The patient was treated with PREDNISOLONE for Autoimmune hepatitis, at a dose of 60 milligram once a day. At the time of the report, AUTOIMMUNE HEPATITIS (acute severe autoimmune hepatitis) outcome was unknown. Possible DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Alanine aminotransferase: 24u/l 24U/L and 1092u/l 1092U/L - Two weeks after first dose. On an unknown date, Alpha-1 anti-trypsin: normal (normal) normal. On an unknown date, Antibody test: negative (Negative) antineutrophil cytoplasmic antibodies were negative. On an unknown date, Antimitochondrial antibody: negative (Negative) Negative. On an unknown date, Antineutrophil cytoplasmic antibody: negative (Negative) Negative. On an unknown date, Antinuclear antibody: positive (Positive) 1:100, speckled pattern. On an unknown date, Aspartate aminotransferase: 28u/l 28U/L and 1056u/l 1056U/L - Two weeks after first dose. On an unknown date, Autoantibody test: negative (Negative) Negative. On an unknown date, Biopsy liver: abnormal (abnormal) A percutaneous liver biopsy was performed, revealing a marked expansion of the portal tracts due to dense inflammatory infiltrate, with aggregates of plasma cells; severe interface hepatitis and multiple confluent foci of lobular necrosis were also observed.. On an unknown date, Blood alkaline phosphatase: 108u/l 108U/L and 24u/l 24U/L - Two weeks after first dose. On an unknown date, Blood bilirubin: 0.72 mg/dl 0.72 mg/dL and 1.14 mg/dl 1.14 mg/dL - Two weeks after first dose. On an unknown date, Blood immunoglobulin A: normal (normal) normal. On an unknown date, Blood immunoglobulin G: normal (normal) Normal after two weeks from vaccination and elevated (High) Elevated after five weeks from vaccination. On an unknown date, Blood immunoglobulin M: normal (normal) Normal. On an unknown date, Blood iron: normal (normal) Normal. On an unknown date, Ceruloplasmin: normal (normal) Normal. On an unknown date, Full blood count: normal (normal) Normal. On an unknown date, Gamma-glutamyltransferase: 24u/l 24U/L and 329u/l 329U/L - Two weeks after first dose. On an unknown date, International normalised ratio: normal (normal) Normal. On an unknown date, Investigation: negative (Negative) anti-soluble liver antigen was negative. On an unknown date, Polymerase chain reaction: negative (Negative) Polymerase chain reaction for hepatitis B, C and E viruses were negative.. On an unknown date, Serology test: negative (Negative) serology for hepatitis A virus, human immunodeficiency virus, cytomegalovirus, Epstein-Barr virus and herpes simplex virus type 1 and 2 were all negative.. On an unknown date, Smooth muscle antibody: negative (Negative) Negative. On an unknown date, Thyroid function test: normal (normal) Normal. On an unknown date, Ultrasound abdomen: normal (normal) hepatomegaly without cirrhotic morphology, and no biliary dilation or thrombosis.. The action taken with mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown) was unknown. For mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown), the reporter considered AUTOIMMUNE HEPATITIS (acute severe autoimmune hepatitis) to be possibly related. Patient reported that five weeks after vaccination, patient was presented with jaundice and choluria. The patient was admitted for clinical management. Patient symptoms include mild abdominal pain, jaundice and choluria. Treatment with prednisolone was started with a quick improvement of liver function tests and normalization of IgG levels. One month after initial diagnosis, the patient remains well on a tapering course of corticosteroids. Most recent FOLLOW-UP information incorporated above includes: On 11-Nov-2021: Upon review performed on 10-Feb-2021, Symptoms Abdominal pain, Jaundice and Choluria was removed and only the diagnosis 'acute severe autoimmune hepatitis' coded to LLT 'Autoimmune hepatitis' would be retained.	[redacted]

Case ID	Narrative (Complete)	WW Identifier
[redacted]	This literature-non-study case was reported in a literature article and describes the occurrence of IMMUNE-MEDIATED HEPATITIS (Immune-mediated hepatitis) in a 47-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. LITERATURE REFERENCE: Tun GSZ, Gleeson D, Dube A, Al-Joudeh A. Immune-mediated hepatitis with the moderna vaccine, no longer a coincidence but confirmed. J Hepatol. 2021 Concurrent medical conditions included Alcohol use (reported minimal alcohol intake). On 26-Apr-2021, the patient received first dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 06-Jul-2021, received second dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 29-Apr-2021, after starting mRNA-1273 (Moderna CoviD-19 Vaccine), the patient experienced IMMUNE-MEDIATED HEPATITIS (Immune-mediated hepatitis) (seriousness criterion medically significant). On 06-Jul-2021, the patient experienced INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (Inappropriate schedule of vaccine administered). The patient was treated with PREDNISOLONE on 21-Jul-2021 for Autoimmune hepatitis, at a dose of 40 milligram once a day. At the time of the report, IMMUNE-MEDIATED HEPATITIS (Immune-mediated hepatitis) was resolving and INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (Inappropriate schedule of vaccine administered) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In 2017, Liver function test: normal (normal) Liver function tests (LFTs) last checked 4 years previously were normal. On 30-Apr-2021, Alanine aminotransferase (10-49): 1048 u/l (High) ALT 1048 U/L. On 30-Apr-2021, Blood albumin (35-50): 41 g/l (normal) albumin 41 g/L. On 30-Apr-2021, Blood alkaline phosphatase (30-130): 229 u/l (High) ALP 229 U/L. On 30-Apr-2021, Blood bilirubin (0-20): 190 µmol/l (High) showed serum bilirubin 190 µmol/L. On 30-Apr-2021, Full blood count: normal (normal) normal. On 30-Apr-2021, International normalised ratio: normal (normal) normal. On 30-Apr-2021, Renal function test: normal (normal) normal. On 25-Jun-2021, Alanine aminotransferase (10-49): 332 u/l (High) ALT falling to 332 U/L. On 25-Jun-2021, Blood bilirubin (0-20): 69 µmol/l (High) bilirubin falling on 25th June to 69 µmol/L. On 20-Jul-2021, Alanine aminotransferase (10-49): 1084 u/l (High) ALT 1084 U/L. On 20-Jul-2021, Blood bilirubin (0-20): 355 µmol/l (High) bilirubin 355 µmol/L. On 20-Jul-2021, Prothrombin time: 18.4 seconds raised PT 18.4 seconds.. On an unknown date, Antinuclear antibody: positive (Positive) serum was positive for Anti-Nuclear Antibody. On an unknown date, Biopsy liver: abnormal (abnormal) Review of the liver biopsy showed acute active hepatitis: widespread areas of bridging necrosis, marked interface hepatitis, lymphoplasmatic inflammation including eosinophils, ballooned hepatocytes, multi-nucleated giant cells, and emperipolesis. There was minimal fibrosis, Ishak stage 1. The pattern of injury on histology was consistent with acute hepatitis, with features of autoimmune hepatitis or possible drug-induced liver injury (DILI), triggering an autoimmune-like hepatitis.. On an unknown date, Blood immunoglobulin G (6-16): 25.1 g/l (High) Serum IgG was raised at 25.1 g/L. On an unknown date, Blood immunoglobulin M (0.5-2): 2.2 g/l (High) 2.2 g/L. On an unknown date, Blood test: improve Prednisolone 40 mg/ day was continued and blood tests continue to improve. On an unknown date, Computerised tomogram abdomen: no significant findings showed no significant findings. On an unknown date, Computerised tomogram pelvis: no significant findings showed no significant findings. On an unknown date, Computerised tomogram thorax: no significant findings showed no significant findings. On an unknown date, Cytomegalovirus test: negative (Negative) Negative. On an unknown date, Epstein-Barr virus test: negative (Negative) Negative. On an unknown date, Hepatitis A virus test: negative (Negative) Negative. On an unknown date, Hepatitis B virus test: negative (Negative) Negative. On an unknown date, Hepatitis C virus test: negative (Negative) Negative. On an unknown date, Hepatitis E virus test: negative (Negative) Negative. On an unknown date, Liver function test: improved Prednisolone 40 mg/ day was continued and LFTs improved. On an unknown date, Magnetic resonance imaging: no significant findings MRI pancreas performed to exclude malignancy, showed no significant findings. On an unknown date, Physical examination: abnormal (abnormal) On examination, patient was alert, deeply jaundiced, with hepatomegaly but no ascites. On an unknown date, Prothrombin time: normalised (normal) On follow-up, PT normalised within 2 weeks.. On an unknown date, Ultrasound abdomen: abnormal (abnormal) Repeat abdominal ultrasound showed a mildly fatty liver, patent portal and hepatic vein flow, with no ascites.. On an unknown date, Ultrasound scan: no significant findings showed no significant findings. For mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown), the reporter considered IMMUNE-MEDIATED HEPATITIS (Immune-mediated hepatitis) and INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (Inappropriate schedule of vaccine administered) to be possibly related. Patient noted malaise and jaundice three days after receiving the 1st Moderna vaccine dose. Patient denied paracetamol use. Patient's jaundice faded and Liver function tests improved. The patient received his 2nd Moderna vaccine dose despite reporting the jaundice to the vaccination centre and the jaundice returned a few days after.	[redacted]

Case ID	Narrative (Complete)	WW Identifier
	After liver biopsy on the 21st July 2021 he was commenced onto Prednisolone Prednisolone was continued and LFTs improved. Patient was discharged on Prednisolone and on follow-up, blood tests continue to improve Author concluded that long-term follow up of identified individuals will be essential in determining the prognosis of this immune-mediated liver injury. Company Comment: This literature-non-study case concerns a 47-year-old male patient, with no relevant medical history, who experienced the unexpected events of Immune-mediated hepatitis and Inappropriate schedule of product administration. The event Immune-mediated hepatitis occurred approximately 3 days after receiving the first dose of mRNA-1273 Vaccine. Several lab and imaging tests were done and showed increased results for liver function tests, while Ultrasound, CT scan (Thorax and Abdomen) and MRI. (Pancreas) had no significant findings. A few days after receiving the second dose of the mRNA 1273 vaccine, the patients' jaundice returned. LFT's were again increased and liver biopsy showed acute active hepatitis with features of autoimmune hepatitis or possible drug-induced liver injury. Patient was treated with Prednisolone with subsequent improvement of LFTs. At the time of the report the outcome of the events was unknown. The rechallenge is positive since the event recurred upon readministration of the vaccine. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 11-Nov-2021: Upon review performed on 10-Feb-2022, laboratory tests, dose 1 and dose 2 information, event outcome, addition event were updated	

Case ID	Narrative (Complete)	WW Identifier
[redacted]	This literature-non-study case was reported in a literature article and describes the occurrence of AUTOIMMUNE HEPATITIS (Autoimmune hepatitis (AIH)) in a 73-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. LITERATURE REFERENCE: Erard D, Villeret F, Lavrut P-M, Dumortie J. Autoimmune hepatitis developing after COVID 19 vaccine: Presumed guilty?. Clin Res Hepatol Gastroenterol. 2022;46:101841 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, after starting mRNA-1273 (Spikevax), the patient experienced AUTOIMMUNE HEPATITIS (Autoimmune hepatitis (AIH)) (seriousness criterion medically significant). At the time of the report, AUTOIMMUNE HEPATITIS (Autoimmune hepatitis (AIH)) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Alanine aminotransferase: 1027 1027 UI/L. On an unknown date, Alpha-1 anti-trypsin: normal (normal) normal. On an unknown date, Antimitochondrial antibody: negative (Negative) Specific liver autoantibodies anti mitochondrial was negative. On an unknown date, Antinuclear antibody: positive (Positive) Positive and negative (Negative) Specific liver autoantibodies Sp100 and anti gp210 was negative. On an unknown date, Aspartate aminotransferase: 1163 1163 UI/L. On an unknown date, Autoantibody test: negative (Negative) Specific liver autoantibodies anti SLA was negative. On an unknown date, Biopsy liver: abnormal (abnormal) diffuse acute hepatitis with lobular and portal intense lymphoplasmacytic infiltrate, with interface hepatitis and hepatocyte necrosis. On an unknown date, Blood bilirubin: 334 umol/l 334 umol/L. On an unknown date, Blood copper: normal (normal) normal and normal (normal) Normal. On an unknown date, Blood immunoglobulin G: 18 (High) 18 g/l. On an unknown date, Blood thyroid stimulating hormone: normal (normal) normal. On an unknown date, Ceruloplasmin: normal (normal) normal. On an unknown date, Hepatitis viral test: negative (Negative) Screening for viral hepatitis was negative (hepatitis A, B, C, E virus, CMV, HSV, EBV).. On an unknown date, International normalised ratio: normal (normal) normal. On an unknown date, Physical examination: normal (normal) Normal. On an unknown date, Smooth muscle antibody: negative (Negative) Specific liver autoantibodies anti-smooth muscle was negative. On an unknown date, Ultrasound abdomen: normal (normal) normal liver with no steatosis and no biliary dilation.. The action taken with mRNA-1273 (Spikevax) (Unknown) was unknown. For mRNA-1273 (Spikevax) (Unknown), the reporter considered AUTOIMMUNE HEPATITIS (Autoimmune hepatitis (AIH)) to be related. Company Comment: This literature non-study case concerns a 73-year-old, female patient with no reported medical history, who experienced the unexpected, serious (medically significant) adverse event of special interest Autoimmune hepatitis. The condition was diagnosed 21 days after receiving a single dose of mRNA-1273 vaccine. The patient was seen by a physician on an unspecified date after vaccination, presenting with asthenia, pruritus and jaundice. She is a non-alcoholic with no history of intravenous drugs or herbal supplements use. Physical examination was essentially normal. Initial blood tests showed severe acute hepatitis with increased total bilirubin and elevated hepatic transaminases. INR was within normal limits, so were ceruloplasmin, serum copper, alpha-1-antitrypsine and TSH. Screening for viral hepatitis (hepatitis A, B, C, E virus, CMV, HSV, EBV) was negative. The IgG level was noted to be elevated. The patient tested positive to anti-nuclear antibodies, although further testing for liver autoantibodies (anti-smooth muscle, anti-mitochondrial, anti-SLA, anti-Sp100, anti-gp210) yielded negative results. An abdominal ultrasound Doppler was performed which revealed a normal liver with no steatosis and no biliary dilation. Liver biopsy showed diffuse acute hepatitis with lobular and portal intense lymphoplasmacytic infiltrate, hepatocyte necrosis and features of interface hepatitis consistent with that of autoimmune hepatitis. The patient was then started on steroid therapy (1mg/kg) for 4 weeks with a rapid improvement of her condition. The benefit-risk relationship of mRNA-1273 is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 17-Mar-2022: Follow up received by safety on 18-Mar-2022 has Email with FTA received from SARA team and contains significant information: Author details, Lab data and event details updated.	[redacted]

Case ID	Narrative (Complete)	WW Identifier
[redacted]	This literature-non-study case was reported in a literature article and describes the occurrence of AUTOIMMUNE HEPATITIS (SARS-CoV-2 vaccine induced-AIH) in a 41-year-old female patient who received mRNA-1273 (COVID 19 Vaccine Moderna) for COVID-19 vaccination. LITERATURE REFERENCE: Londono MC, Gines JG, Penataro JS. Another case of autoimmune hepatitis after SARS-CoV-2 vaccination - still casualty?. J Hepatol. 2021;75(5):1248-9 Concurrent medical conditions included Premature ovarian failure (undergoing substitutive hormonal therapy with no side effect.). 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 an unknown date, the patient experienced AUTOIMMUNE HEPATITIS (SARS-CoV-2 vaccine induced-AIH) (seriousness criterion medically significant). The patient was treated with PREDNISONE for Autoimmune hepatitis, at a dose of 1 milligram/kilogram. At the time of the report, AUTOIMMUNE HEPATITIS (SARS-CoV-2 vaccine induced-AIH) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In 2021, Alanine aminotransferase: 1,312 iu/l 1,312 IU/L. In 2021, Antinuclear antibody: positive (Positive) Positive. In 2021, Aspartate aminotransferase: 993 iu/l 993 IU/L. In 2021, Biopsy liver: abnormal (abnormal) The liver biopsy (2.5 cm, 19 portal tracts) showed a marked expansion of the portal tracts with a dense inflammatory infiltrate composed by lymphocytes and plasma cells, severe interface hepatitis and lobular inflammation with disperse necro inflammatory foci, apoptotic bodies and hepatocyte ballooning.. In 2021, Blood alkaline phosphatase: 190 iu/l 190 IU/L. In 2021, Blood bilirubin: 2.3 mg/dl 2.3 mg/dl (peak of 8.5 mg/dl). In 2021, Blood immunoglobulin G: 20.8 g/l (High) IgG levels were elevated (20.8 g/L).. In 2021, Cytomegalovirus test: negative (Negative) Negative. In 2021, Epstein-Barr virus test: negative (Negative) Negative. In 2021, Gamma-glutamyltransferase: 209 iu/l 209 IU/L. In 2021, Hepatitis A virus test: negative (Negative) Negative. In 2021, Hepatitis B virus test: negative (Negative) Negative. In 2021, Hepatitis C virus test: negative (Negative) Negative. In 2021, Hepatitis E virus test: negative (Negative) Negative. In 2021, Herpes simplex test: negative (Negative) herpes simplex virus type 1 and 2 and herpes 6 virus were negative. In 2021, Histology: no signs of parenchymal or perisinusoidal fibrosis Masson's trichrome staining showed no signs of parenchymal or perisinusoidal fibrosis.. In 2021, Smooth muscle antibody: positive (Positive) Positive. In 2021, Ultrasound liver: normal (normal) normal. For mRNA-1273 (COVID 19 Vaccine Moderna) (Unknown), the reporter considered AUTOIMMUNE HEPATITIS (SARS-CoV-2 vaccine induced-AIH) to be possibly related. After receiving the first dose of SARS-CoV-2 Moderna vaccine (mRNA-1273) the patient presented epigastric pain, nausea and vomiting. These symptoms lasted for 3 weeks and then decreased in intensity. Seven days after the second dose, symptoms reappeared with higher intensity and were associated with choluria and jaundice. Laboratory tests also included anti-soluble liver antigen (anti-SLA) and anti-liver cytosol tests which were positive The score of simplified diagnostic criteria of the International Autoimmune Hepatitis Group was 8 (definite diagnosis of AIH) and the patient was diagnosed with SARS-CoV-2 vaccine induced-AIH. Corticosteroid treatment with high-dose prednisone (1 mg/kg) was started with rapid normalization of liver enzymes. Authors stated that they believe that more than casualty, the association between SARS-CoV-2 vaccines and AIH is causality. Author concluded that the benefits of vaccination are far higher than the potential risks of the vaccines and therefore the report of these 2 cases should not be used as an argument against vaccination. It should be noted that these reports illustrate a rare adverse event that has only been detected after the administration of millions of doses of mRNA vaccines in a "real-world" setting. Most recent FOLLOW-UP information incorporated above includes: On 22-Jun-2021: Upon review performed on 10-Feb-2022, literature reference details, author contact information, laboratory tests, outcome of event were updated, dose 1 and dose 2 cases were merged On 22-Jun-2021: Upon internal review on 17-Feb-2022, a non-significant amendment was performed in the case: Company Comment corrected. On 23-Jun-2021: Follow up received by safety 23-JUN-2021 has Email with FTA received and does not contain any new information. On 25-Nov-2021: Follow up received by safety 25-NOV-2021 has Email with FTA received from SARA team and does not contain any new information. Company comment: This literature case describes the occurrence of serious AESI of Autoimmune hepatitis (SARS-CoV-2 vaccine induced-AIH) in a 41-year-old female patient with relevant medical history of premature ovarian failure with undergoing substitutive hormonal therapy. On unknown date patient received the first dose of mRNA-1273 and then presented (latency unknown) epigastric pain, nausea and vomiting. These symptoms lasted for 3 weeks and then decreased in intensity. Seven days after the second dose of mRNA-1273 symptoms reappeared with higher intensity and were associated with choluria and jaundice. Based on available tests results (very well documented) patient was diagnosed with SARS-CoV-2 vaccine induced-AIH. Corticosteroid treatment with high-dose prednisone (1 mg/kg) was started with rapid normalization of liver enzymes. Author of article believes that is the more than	[redacted]

Case ID	Narrative (Complete)	WW Identifier
	causality between the mRNA-1273 and reported event, however author is also stating that his article describes rare adverse event and only 2 such cases were documented so far after the millions of doses of mRNA-1273. Patient's medical history of premature ovarian failure with undergoing substitutive hormonal therapy seems to be confounding factor. The benefit-risk relationship of the Moderna mRNA-1273 vaccine is not affected by this report.	

Appendix 11.21e Autoimmune Hepatitis: Summary of Fatal Cases

Appendix 5: Summaries for Fatal Cases From US

[redacted] is a report from a consumer concerning a 39-year-old female patient. The patient's medical history included Sjogren's syndrome, Hashimoto's, inflammatory joint disease, osteoporosis, osteoarthritis and history of fractured tail bone and leg in three places. Concomitant medications included D3 2 pills a day, folic acid, B12, and calcium citrate. She was allergic to 15 different antibiotics, from two of which she had anaphylaxis; had "huge autoimmune issues"; had had reaction to Pneumovax vaccine. Approximately three days of receiving the second dose of Spikevax, the patient experienced "heart racing" and went to the emergency room. The patient started vomiting and developed kidney and liver failure, and she died the next day. Autopsy not available at the time of report.

[redacted] involves a 74-year-old male with end stage renal disease, hypertension and atrial septal defect, without reported medications. He developed COVID-19 pneumonia nine days after a dose of Spikevax. He developed dyspnea, encephalopathy, a GI disorder, liver injury not further specified, supraventricular tachycardia, tachycardia, thrombocytopenia and shock and died 21 days after vaccination.

[redacted] involves a 48-year-old female without reported medical history but who was taking VENLAFAXINE; DIVIGEL; PANTOPRAZOLE; ADDERALL. Two days after Spikevax dose 2 she was reported to experience hepatic and renal failure, and she died 15 days after vaccination, with no other relevant information provided.

[redacted] involves an 82-year-old female with a history of COPD, atrial fibrillation, and drug hypersensitivity. Medications were not reported. Patient complained of "heart pain" (angina pectoris) 17 days after the first dose of Spikevax and was transferred to the emergency room. Within 2 days, liver and kidney functions failed. Patient was also reported with acute respiratory failure and cardiogenic shock. No further relevant details reported. Patient died 21 days after vaccination.

[redacted] involves a 65-year-old male with a history of renal disorder not otherwise specified, without reported medications. On the day of vaccination, he was hospitalized and reported to experience heart inflammation, confusion, slurred speech, liver failure and loss of use of limbs, without further details. He died 84 days after vaccination.

[redacted] involves a 58-year-old male with a history of anxiety and rheumatoid arthritis, taking ASA, citalopram, prednisone and furosemide. The day following second dose of Spikevax, the patient was reported to have experienced Acute hepatic failure, Acute myocardial infarction, Aortic stenosis, Brain hypoxia, Cardiac arrest, Cardiogenic shock, Cardiomyopathy, Condition aggravated, Dyspnoea, Lactic acidosis, Malaise, Pulmonary embolism, Rash erythematous, Renal failure and Rheumatoid arthritis. The patient died eight days after vaccination. Further details were not reported.

[redacted] involved an 85-year-old female with hypertension and diabetes mellitus

who developed portal vein thrombosis at an unknown interval after her second dose. This was followed by hepatic failure and death with unknown interval.

[redacted] involves a 64-year-old female with prior history of breast cancer and mastectomy, taking hormone replacement therapy. Four or five months after "completing immunization series" the patient developed Cerebral venous thrombosis, Mesenteric venous occlusion, Superior mesenteric artery syndrome (with evidence of chronic occlusion) and was hospitalized. The patient was treated with TPA and developed acute liver failure. The patient died 13 days after hospitalization. The reported cause of death was Acute liver failure, Cerebral venous thrombosis and Superior mesenteric artery syndrome.

[redacted] involves a 68-year-old male with history of COPD, hypertension and leukemia. Six and a half months after dose 2 of Spikevax, the patient experienced a myocardial infarction, COVID pneumonia diagnosis and died. He also experienced on that day pneumothorax, seizure-like phenomena, hypoxia, hepatic failure, shock, ventricular tachycardia.

[redacted] involves a 31-year-old female with a history of type 1 diabetes (treated with Levemir), hypothyroidism, endometriosis, and drug allergy to clindamycin and penicillin. Four days after the first dose, the patient experienced acute hepatic failure, which was also the cause of death that occurred 8 days after vaccination. No other relevant details were reported.

[redacted] Involves a 55-year-old overweight female with depression and rheumatoid arthritis treated with hydroxychloroquine (recently discontinued and started taking an imported supplement: RT King) and bupropion. At 137 days after dose 2 of Spikevax she experienced atelectasis, cyanosis, disseminated intravascular coagulation, enterococcal bacteraemia, hepatic failure, renal failure, respiratory failure, pneumonia, pseudomonal bacteraemia, respiratory arrest, influenza, COVID-19 and thrombotic thrombocytopenia purpura, among other serious events. The events occurred approximately 137 days after the second dose of mRNA-1273.

[redacted] Involves a 63-year-old male. One day after dose 1, he "started to lose control of his nerves. He was constantly shaking. Patient could not hold a glass with water without it flying out of his hand accidentally and he needed someone behind him to walk anywhere because he would faint. After second dose the symptoms got worse. Patient was not able to walk without a walker, which quickly led him to a wheelchair. There was one day that the patient felt too confident and tried to sit at the counter barstool. The patient's legs gave out, or he fainted and landed on the ground and hit his head so hard, he was unconscious. Patient did not leave the hospital and his kidneys failed, then his liver and then his heart. He died 37 days after vaccination."

[redacted] involves a 73-year-old male with diabetes treated with "diabetes medication." Symptoms began two days after dose 1, and the patient died seven months and 24 days later. "Patient had vertigo, dizziness, hearing loss progressing to kidney and liver failure and death." Details were not provided.

[redacted] "Reporter stated that a girl [unknown age] with chronic liver disease went into liver failure and had jaundice and also died in hospital after [time not specified] receiving two shots of the booster." No other relevant information provided.

Appendix 11.21f Autoimmune Hepatitis: tabular Overview of Fatal cases with WHO Causality-Case listings

Case ID	Country	Report Type	Patient Age (Years)	Patient Gender	ALL PT'S	Primary Cause of Death	Confounders	WHO	EASL	Medical History	WW Identifier	RP
[redacted]	UNITED STATES	Spontaneous	39	Female	Hepatic failure, Palpitations, Renal failure, Vomiting	Renal failure	autoimmune underlying background (Sjogren, Hashimoto)	Unlikely	not AIH	No adverse event(H)	[redacted]	Prior to Review Period
	UNITED STATES	Regulatory Authority	74	Male	COVID-19, COVID-19 pneumonia, Death, Dyspnoea, Encephalopathy, Gastrointestinal disorder, Haemodynamic instability, Liver injury, Shock, Supraventricular tachycardia, Tachycardia, Thrombocytopenia	unknown cause of death	yes, end stage renal failure	Unlikely	not AIH	End stage renal disease(H); Hypertension(H); Atrial septal defect(H)		Prior to Review Period
	POLAND	Regulatory Authority	72	Male	Acute kidney injury, Dyspnoea, Embolism, Escherichia sepsis, Gallbladder enlargement, General physical health deterioration, Hyperuricaemia, Left ventricular hypertrophy, Leukopenia, Liver injury, Pyrexia, Renal cyst, Respiratory failure	unknown cause of death	COPD, cardiac & vascular disorders, diabetes	Unlikely	not AIH	Cystitis(C); Tobacco abuse(H); Lung neoplasm(H); Type 2 diabetes mellitus(C); Chronic obstructive pulmonary disease(C); Aortic valve calcification(H); Arteriosclerosis(C); Aortic valve calcification(H); Benign prostatic hyperplasia(H); Left ventricular hypertrophy(H); Mediastinum neoplasm(H)		Prior to Review Period
	UNITED STATES	Regulatory Authority	48	Female	Death, Hepatic failure, Renal failure	Unknown cause of death	renal failure, medications	Possible	not AIH	0		Prior to Review Period
	UNITED STATES	Regulatory Authority	82	Female	Acute respiratory failure, Angina pectoris, Cardiogenic shock, Death, Hepatic failure, Renal failure	Acute hypoxic respiratory failure	cardiogenic shock, renal failure	Unassessable	not AIH	Drug hypersensitivity; Drug hypersensitivity; Chronic obstructive pulmonary disease(C); Atrial fibrillation(C)		Prior to Review Period
	GERMANY	Regulatory Authority	63	Female	Acute hepatic failure, Haemorrhagic ascites, Shock haemorrhagic, Truncus coeliacus thrombosis	Hemorrhagic shock	Thrombosis, shock hemorrhagic	Unlikely	not AIH	0		Prior to Review Period
	UNITED STATES	Regulatory Authority	65	Male	Carditis, Confusional state, Dysarthria, Hepatic failure, Mobility decreased	unknown cause of death	oone reported	Possible	not AIH	Renal disorder(H)		Prior to Review Period
	UNITED STATES	Regulatory Authority	58	Male	Acute hepatic failure, Acute myocardial infarction, Aortic stenosis, Brain hypoxia, Cardiac arrest, Cardiogenic shock, Cardiomyopathy, Condition aggravated, Dyspnoea, General physical health deterioration, Lactic acidosis, Malaise, Pulmonary embolism, Rash, Rash erythematous, Renal failure, Rheumatoid arthritis	Unknown Cause of Death	MI, RA, multiorgan failure	Unlikely	not AIH	Anxiety(H); Rheumatoid arthritis(H)		Prior to Review Period
	UNITED STATES	Spontaneous	85	Female	Hepatic failure, Portal vein thrombosis	Liver failure	Portal thrombosis	Unlikely	not AIH	Hypertension(C); Diabetes mellitus(C)		Prior to Review Period
	UNITED STATES	Regulatory Authority	64	Female	Acute hepatic failure, Cerebral venous thrombosis, Mesenteric venous occlusion, Superior mesenteric artery syndrome	Acute liver failure	Breast cancer, CVA, thrombosis	Unassessable	not AIH	Breast cancer(H); Mastectomy		Prior to Review Period
	TAIWAN, PROVINCE OF CHINA	Regulatory Authority	71	Female	Acute hepatitis B, Altered state of consciousness, Asthenia, Bandaemia, Biliary tract disorder, Biliary tract infection, Cellulitis, Chills, Decubitus ulcer, Delirium, Hepatic failure, Hypokalaemia, Pyrexia, Sepsis	bepatitis B with acute liver failure	Hep B, sepsis	Unlikely	not AIH	Hepatitis B(C); Hepatic encephalopathy(C)		Prior to Review Period
	UNITED STATES	Regulatory Authority	68	Male	Acute myocardial infarction, COVID-19 pneumonia, Hepatic failure, Hypoxia, Pneumothorax, Respiratory failure, Seizure like phenomena, Shock, Ventricular tachycardia, Vomiting	unknown	COVID19, MI, shock	Unlikely	not AIH	Chronic obstructive pulmonary disease(H); Hypertension(H); Leukaemia(H)		Prior to Review Period
	UNITED STATES	Regulatory Authority	31	Female	Acute hepatic failure	Acute hepatic failure	diabetes type 1?	Unassessable	not AIH	Drug hypersensitivity; Drug hypersensitivity; Type 1 diabetes mellitus(C); Endometriosis(C); Hypothyroidism(C)		Prior to Review Period
	ITALY	Regulatory Authority	69	Male	Acute kidney injury, Cough, Disseminated intravascular coagulation, Hepatitis acute, Pyrexia, Systemic inflammatory response syndrome	Fever and cough. Hospitalized for acute bepatitis on Sep 2019. Rapid onset of acute kidney failure until dialysis treatment. Signs of hyperacute inflammatory syndrome. CID	DIC, renal failure	Unlikely	not AIH	0		Prior to Review Period
	UNITED STATES	Regulatory Authority	55	Female	Asthenia, Atelectasis, Back pain, Chest pain, Condition aggravated, COVID-19, Cyanosis, Disseminated intravascular coagulation, Dyspnoea, Dysstasia, Enterococcal bacteraemia, Fluid intake reduced, Hepatic failure, Hyperventilation, Illness, Immunisation reaction, Impaired self-care, Influenza, Lung infiltration, Oropharyngeal pain, Pain, Painful respiration, Pneumonia, Pseudomonal bacteraemia, Pyrexia, Renal failure, Respiratory arrest, Respiratory failure, Respiratory tract congestion, Thrombotic thrombocytopenic purpura	abrupt discontinuation of hydroxychloroquine for rheumatoid arthritis	COVID19, DIC, multi organ failure	Unlikely	not AIH	Depression(C); Rheumatoid arthritis(C); Overweight(H)		Prior to Review Period
	GERMANY	Regulatory Authority	77	Male	Autoimmune bepatitis	Autoimmune hepatitis with fatal outcome	None reported	Unlikely	not AIH	0		Prior to Review Period
	UNITED STATES	Regulatory Authority	63	Male	Arthropathy, Cardiac failure, Death, Pall, Gait disturbance, Head injury, Hepatic failure, Loss of consciousness, Renal failure, Syncope, Walking aid user, Wheelchair user	Arthropathy	Multiorgan failure	Unlikely	not AIH	0		Prior to Review Period
	UNITED STATES	Regulatory Authority	73	Male	Deafness, Death, Dizziness, Hepatic failure, Laboratory test, Renal failure, Vertigo	Deafness	reanl failure	Unassessable	not AIH	Diabetes mellitus(H)		Prior to Review Period
	GERMANY	Regulatory Authority	77	Male	Autoimmune hepatitis	Autoimmune hepatitis	None reported	Unlikely	not AIH	Dementia(H); Lipid metabolism disorder(H); Hypertonia(H)		Prior to Review Period
	TAIWAN, PROVINCE OF CHINA	Regulatory Authority	65	Male	Abdominal pain, Hepatic failure	Hepatic failure	sepsis, MI, chronic liver disease	Unlikely	not AIH	0		Prior to Review Period
	JAPAN	Regulatory Authority	41	Male	Acute hepatic failure, Cardio-respiratory arrest, Circulatory collapse, Hepatic function abnormal, Pyrexia, Upper gastrointestinal haemorrhage	Hepatic function disorder	digestive hemorrhagia	Possible	not AIH	Hepatic function abnormal(C); Diabetes mellitus(C); Lymphoma(C)		Prior to Review Period
	UNITED STATES	Spontaneous	0.00	Female	Extra dose administered, Hepatic failure	Liver failure	No	Unassessable	not AIH	Liver disorder(C)		Prior to Review Period

Case ID	Country	Report Type	Patient Age (Years)	Patient Gender	ALL PT'S	Primary Cause of Death	Confounders	WHO	EASL	Medical History	WW Identifier	RP
[redacted]	GERMANY	Regulatory Authority	69	Female	Coagulopathy, COVID-19, Hepatic failure, Multiple organ dysfunction syndrome, Shock haemorrhagic, Thrombocytopenia	Multi-organ failure	Multiple types of prior covid vaccines; SARS-COV-2 infection	Unlikely	not AIH	COVID-19(C); VAXZEVRIA; COMIRNATY	[redacted]	Review Period
	THAILAND	Spontaneous	50	Female	Aplastic anaemia, Circulatory collapse, Decreased immune responsiveness, Febrile neutropenia, Haemoptysis, Hepatic failure, Klebsiella sepsis, Renal failure, Wound haemorrhage	unknown cause of death	Prior immunization with Sinovac x2 and Pfizer	Conditional	not AIH	CORONAVAC; CORONAVAC; PFIZER BIONTECH COVID-19 VACCINE		Review Period
	JAPAN	Spontaneous	63	Male	Acute hepatic failure, Cardio-respiratory arrest, Circulatory collapse, Coagulopathy, Hepatitis fulminant, Livedo reticularis, Metabolic acidosis, Myocarditis, Renal disorder	unknown cause of death	No	Probable	not AIH	0		Review Period

Appendix 11.21g Autoimmune Hepatitis: tabular Overview of Fatal cases with WHO Causality-Case narratives

Case ID	Narrative (Complete)	MAH Comment	WW Identifier
[redacted]	A spontaneous report (United States) was received from a consumer concerning a 39-year-old, female patient, who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced heart racing, kidney failure, liver failure,vomiting and death. The patient's medical history included Sjogren's syndrome, Hashimoto's, inflammatory joint disease, osteoporosis, osteoarthritis. She has history of fractured tail bone and leg in three places. Concomitant medications included D3 2 pills a day, folic acid, B12, and calcium citrate. She was allergic to 15 different antibiotics two of which she had anaphylaxis; had huge autoimmune issues; had had reaction to Pneumovax vaccine. On an unown date ,prior to the onset of the events, the patient received their second of two planned doses of mRNA-1273 intramuscularly for prophylaxis of COVID-19 infection. Approximately after three days of receiving second dose vaccine patient experienced heart racing and went to the emergency room .The patient started vomiting and developed a kidney and liver failure. And on the next day she died.Autopsy is doing and the results are not available at the time of report. Action taken with mRNA-1273 in response to the events was reported as not applicable. The events heart racing, kidney failure, liver failure and death were considered serious and medically significant. The outcome of the events renal failure,hepatic failure,palpitations and vomiting was considered as Fatal.	This is a case of death in a 39year-old female subject with unknown medical history of anaphylactic reactions, allergic reactions to pneumovax vaccine, Sjogren's syndrome, Hashimoto's, inflammatory joint disease, osteoporosis, osteoarthritis, who died 4 days after receiving second dose of vaccine. Very limited information has been provided at this time. Further information has been requested.	[redacted]

Case ID	Narrative (Complete)	MAH Comment	WW Identifier
[redacted]	This case was initially received via United States FDA VAERS (Reference number: [redacted] on 23-Mar-2021. The most recent information was received on 23-Mar-2021 and was forwarded to Moderna on an unknown date. This regulatory authority case was reported by an other health care professional and describes the occurrence of DEATH (Death), COVID-19 (COVID-19), COVID-19 PNEUMONIA (COVID-19 pneumonia), DYSPNOEA (Dyspnoea), ENCEPHALOPATHY (Encephalopathy), GASTROINTESTINAL DISORDER (Gastrointestinal disorder), HAEMODYNAMIC INSTABILITY (Haemodynamic instability), LIVER INJURY (Liver injury), SHOCK (Shock), SUPRAVENTRICULAR TACHYCARDIA (Supraventricular tachycardia), TACHYCARDIA (Tachycardia) and THROMBOCYTOPENIA (Thrombocytopenia) in a 74-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 031M20A) for COVID-19 vaccination. The patient's past medical history included End stage renal disease (On Hemodialysis) since an unknown date, Hypertension and Atrial septal defect. On 11-Feb-2021, the patient received dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 20-Feb-2021, the patient experienced COVID-19 (COVID-19) (seriousness criterion death), COVID-19 PNEUMONIA (COVID-19 pneumonia) (seriousness criterion death), DYSPNOEA (Dyspnoea) (seriousness criterion death), ENCEPHALOPATHY (Encephalopathy) (seriousness criterion death), GASTROINTESTINAL DISORDER (Gastrointestinal disorder) (seriousness criterion death), LIVER INJURY (Liver injury) (seriousness criterion death), SUPRAVENTRICULAR TACHYCARDIA (Supraventricular tachycardia) (seriousness criterion death), TACHYCARDIA (Tachycardia) (seriousness criterion death) and THROMBOCYTOPENIA (Thrombocytopenia) (seriousness criterion death). On 02-Mar-2021, the patient experienced HAEMODYNAMIC INSTABILITY (Haemodynamic instability) (seriousness criterion death) and SHOCK (Shock) (seriousness criterion death). The patient died on 02-Mar-2021. The cause of death was not reported. It is unknown if an autopsy was performed. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Treatment of these events included dexamethasone and convalescent plasma. This is a case of sudden death in a 74-year-old male patient with a history of End stage renal disease (On Hemodialysis) and Hypertension, who died 20 days after receiving first dose of vaccine. Very limited information has been provided at this time. Very limited information regarding these events has been provided at this time. No further follow-up information is expected. Patient's advances age along with prior medical history of End Stage Renal Disease, hypertension and an atrial septum defect may be contributory to the occurrence of the death. Most recent FOLLOW-UP information incorporated above includes: On 23-Mar-2021: Upon internal review on 04AUG2021, the event of Atrial septal defect was removed as an event and moved to medical history.	0	[redacted]

Case ID	Narrative (Complete)	MAH Comment	WW Identifier
[redacted]	This regulatory authority case was reported by a physician and describes the occurrence of ESCHERICHIA SEPSIS (Escherishia coli sepsis), EMBOLISM (Suspicion of embolism), RENAL CYST (Small kidney cysts), LIVER INJURY (Liver damage), RESPIRATORY FAILURE (Respiratory failure), GALLBLADDER ENLARGEMENT (Gallbladder enlargement), LEFT VENTRICULAR HYPERTROPHY (Left ventricular of heart hypertrophy), HYPERURICAEMIA (Hyperuricemia), LEUKOPENIA (Leukopenia), GENERAL PHYSICAL HEALTH DETERIORATION (Deterioration of general condition), DYSPNOEA (Dyspnoea), ACUTE KIDNEY INJURY (Acute renal failure) and PYREXIA (Fever) in a 72-year-old male patient who received mRNA-1273 (COVID 19 Vaccine Moderna) (batch no. 30004272L) for COVID-19 vaccination. The patient's past medical history included Tobacco abuse, Lung neoplasm, Aortic valve calcification, Aortic valve calcification, Prostatic hyperplasia, Left ventricular hypertrophy and Mediastinum neoplasm. Concurrent medical conditions included Chronic cystitis, Type 2 diabetes mellitus, Chronic obstructive pulmonary disease and Atherosclerosis generalised (High-grade). On 18-Feb-2021, the patient received first dose of mRNA-1273 (COVID 19 Vaccine Moderna) (Intramuscular) 1 dosage form. On 19-Feb-2021, the patient experienced ESCHERICHIA SEPSIS (Escherishia coli sepsis) (seriousness criterion death), EMBOLISM (Suspicion of embolism) (seriousness criterion death), RENAL CYST (Small kidney cysts) (seriousness criterion death), LIVER INJURY (Liver damage) (seriousness criterion death), RESPIRATORY FAILURE (Respiratory failure) (seriousness criterion death), GALLBLADDER ENLARGEMENT (Gallbladder enlargement) (seriousness criterion death), LEFT VENTRICULAR HYPERTROPHY (Left ventricular of heart hypertrophy) (seriousness criterion death), HYPERURICAEMIA (Hyperuricemia) (seriousness criterion death), LEUKOPENIA (Leukopenia) (seriousness criterion death), GENERAL PHYSICAL HEALTH DETERIORATION (Deterioration of general condition) (seriousness criterion death), DYSPNOEA (Dyspnoea) (seriousness criterion death), ACUTE KIDNEY INJURY (Acute renal failure) (seriousness criteria death and medically significant) and PYREXIA (Fever) (seriousness criterion death). The patient died on 22-Feb-2021. The cause of death was not reported. An autopsy was performed, but no results were provided. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 19-Feb-2021, Body temperature: upto 39 (Inconclusive) up to 39 Celsius degrees. On 20-Feb-2021, Activated partial thromboplastin time: 40 (Inconclusive) 40. On 20-Feb-2021, Alanine aminotransferase: 62.9 (Inconclusive) 62.9. On 20-Feb-2021, Aspartate aminotransferase: 62.6 (Inconclusive) 62.6. On 20-Feb-2021, Base excess: -7.9 (Inconclusive) -7.9 mmol/l. On 20-Feb-2021, Basophil percentage: 0 (Inconclusive) 0. On 20-Feb-2021, Blood bicarbonate: 16 (Inconclusive) 16. On 20-Feb-2021, Blood bilirubin: 0.6 (Inconclusive) 0.6. On 20-Feb-2021, Blood creatinine: 2.4 (Inconclusive) 2.4. On 20-Feb-2021, Blood glucose: 120 (Inconclusive) 120. On 20-Feb-2021, Blood osmolarity: 269 (Inconclusive) 269. On 20-Feb-2021, Blood potassium: 4.2 (Inconclusive) 4.2. On 20-Feb-2021, Blood sodium: 137 (Inconclusive) 137. On 20-Feb-2021, Blood thyroid stimulating hormone: 1.57 (Inconclusive) 1.57. On 20-Feb-2021, Blood urea: 91.6 (Inconclusive) 91.6. On 20-Feb-2021, Blood uric acid: 8.88 (Inconclusive) 8.88. On 20-Feb-2021, C-reactive protein: 439 (Inconclusive) 439. On 20-Feb-2021, Electrocardiogram: unknown (Inconclusive) sinus rhythm accompanied by tachycardia, single ventricular beats. On 20-Feb-2021, Eosinophil percentage: 0 (Inconclusive) 0. On 20-Feb-2021, Fibrin D dimer: 1731 (Inconclusive) 1731. On 20-Feb-2021, Haematocrit: 35.9 (Inconclusive) 35.9. On 20-Feb-2021, Haemoglobin: 12.1 (Inconclusive) 12.1. On 20-Feb-2021, International normalised ratio: 1.4 (Inconclusive) 1.4. On 20-Feb-2021, Lymphocyte percentage: 19.2 (Inconclusive) 19.2. On 20-Feb-2021, Mean cell haemoglobin: 31.7 (Inconclusive) 31.7. On 20-Feb-2021, Mean cell haemoglobin concentration: 33.7 (Inconclusive) 33.7. On 20-Feb-2021, Mean cell volume: 94 (Inconclusive) 94,m5. On 20-Feb-2021, Mean platelet volume: 10.8 (Inconclusive) 10.8.	0	[redacted]

Case ID	Narrative (Complete)	MAH Comment	WW Identifier
	On 20-Feb-2021, Monocyte percentage: 12 (Inconclusive) 12. On 20-Feb-2021, Neutrophil percentage: 68.8 (Inconclusive) 68.8. On 20-Feb-2021, Oxygen saturation: 88 (Inconclusive) 88. On 20-Feb-2021, PCO2: 28.4 (Inconclusive) 28.4. On 20-Feb-2021, PO2: 58.3 (Inconclusive) 58.3. On 20-Feb-2021, Physical examination: abnormal (Inconclusive) Acute alveolar respiratory murmur over the lung fields, rales in the interscapular region on both sides, more to the right.. On 20-Feb-2021, Platelet count: 225 (Inconclusive) 225. On 20-Feb-2021, Platelet distribution width: 12.7 (Inconclusive) 12.7. On 20-Feb-2021, Platelet-large cell ratio: 32.1 (Inconclusive) 32.1 %. On 20-Feb-2021, Procalcitonin: 0.2% (Inconclusive) 0.2 %. On 20-Feb-2021, Prothrombin time: 62% (Inconclusive) 62 %. On 20-Feb-2021, Red blood cell count: 3.82 (Inconclusive) 3.82. On 20-Feb-2021, Red cell distribution width: 47.4 (Inconclusive) RDW-SD 47.4 fl RDW-CV 13.6 %. On 20-Feb-2021, SARS-CoV-2 test: negative (Negative) negative. On 20-Feb-2021, Troponin T: 14.17 (Inconclusive) 14.17. On 20-Feb-2021, White blood cell count: 2.92 (Inconclusive) 2.92. On 20-Feb-2021, pH body fluid: 7.370 (Inconclusive) 7.370. On 21-Feb-2021, Blood culture: unknown (Inconclusive) Investigation was terminated on 24-Feb-2021. E. coli was grown in anaerobic culture Amoxicillin/clavulanic acid R (MIC >=32.0) Cefuroxime I (MIC4.0) Piperacillin / Tazobactam S (MIC <=4.0) Ceftazidime S (MIC <= 0.12) Cefotaxime S (MIC <= 0.25) Cefepim S (MIC <= 0.12) Imipenem S (MIC <= 0.25) Meropenem S (MIC <= 0.25) Gentamycyna S (MIC <= 1.0) Amikacin S (MIC <= 2.0) Ciprofloxacin S (MIC <= 0.25) Trimethoprim / Sulfamethoxazole S (MIC <= 20.0) and unknown (Inconclusive) Investigation was terminated on 24-Feb-2021. E. coli was grown in aerobic culture Amoxicillin/clavulanic acid R (MIC >=32.0) Cefuroxime I (MIC4.0) Piperacillin / Tazobactam S (MIC <=4.0) Ceftazidime S (MIC <= 0.12) Cefotaxime S (MIC <= 0.25) Cefepim S (MIC <= 0.12) Imipenem S (MIC <= 0.25) Meropenem S (MIC <= 0.25) Gentamycyna S (MIC <= 1.0) Amikacin S (MIC <= 2.0) Ciprofloxacin S (MIC <= 0.25) Trimethoprim / Sulfamethoxazole S (MIC <= 20.0). On 21-Feb-2021, Blood glucose: 107 (Inconclusive) 7 am: 107mg% 5 pm: 82 mg%. On 24-Feb-2021, Autopsy: abnormal (Inconclusive) Initial diagnosis: a lardaceous tumor of the hilus and lower lobe of the right lung, 7x70 cm in size and surrounded by satellite nodules of various sizes. Metastases to the lymph nodes of the right hilum of the lung and to the lymph nodes of the tracheal bifurcation. The entire right lung, except for the tumor, is gray, poppy and disintegrates when touched. Left lung with signs of hyperemia and emphysema. High-grade generalized atherosclerosis. Left ventricular hypertrophy. Aortic valve calcification. Significant enlargement of the gallbladder. Small cysts of the kidney cortex (0.5 cm in diameter). Chronic cystitis. Prostatic hypertrophy.. For mRNA-1273 (COVID 19 Vaccine Moderna) (Intramuscular), the reporter considered DYSPNOEA (Dyspnoea), ACUTE KIDNEY INJURY (Acute renal failure) and PYREXIA (Fever) to be probably related and ESCHERICHIA SEPSIS (Escherishia coli sepsis), EMBOLISM (Suspicion of embolism), RENAL CYST (Small kidney cysts), LIVER INJURY (Liver damage), RESPIRATORY FAILURE (Respiratory failure), GALLBLADDER ENLARGEMENT (Gallbladder enlargement), LEFT VENTRICULAR HYPERTROPHY (Left ventricular of heart hypertrophy), HYPERURICAEMIA (Hyperuricemia), LEUKOPENIA (Leukopenia) and GENERAL PHYSICAL HEALTH DETERIORATION (Deterioration of general condition) to be possibly related. Additional medical history details included a tumor of the mediastinum and hilum of the right lung - in an ambulatory chest CT scan with contrast (09-Feb-2021), pathological infiltrative-nodal mass, also described peripherally from the tumor in the upper lobe at the apex of the segment 6 GGO density of atelectatic-inflammatory nature with accompan		

Case ID	Narrative (Complete)	MAH Comment	WW Identifier
[redacted]	This case was received via United States FDA VAERS (Reference number: [redacted]) on 01-Jun-2021 and was forwarded to Moderna on 01-Jun-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of DEATH (Death), HEPATIC FAILURE (Hepatic failure) and RENAL FAILURE (Renal failure) in a 48-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 016C219) for COVID-19 vaccination. No medical history was provided by the reporter. Concomitant products included VENLAFAXINE, VENLAFAXINE, ESTRADIOL (DIVIGEL), PANTOPRAZOLE and AMFETAMINE ASPARTATE, AMFETAMINE SULFATE, DEXAMFETAMINE SACCHARATE, DEXAMFETAMINE SULFATE (ADDERALL) for an unknown indication. On 30-Apr-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 02-May-2021, the patient experienced HEPATIC FAILURE (Hepatic failure) (seriousness criteria death, hospitalization and medically significant) and RENAL FAILURE (Renal failure) (seriousness criteria death, hospitalization and medically significant). The patient died on 15-May-2021. The cause of death was not reported. An autopsy was performed, but no results were provided. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Treatment information was not provided. Action taken with mRNA-1273 (Moderna COVID-19 Vaccine) in response to the event was not applicable. Company Comment: Based on the current available information and temporal association between the use of mRNA-1273 and the start date of the events, a causal relationship cannot be excluded. Very limited information regarding this events has been provided at this time.	0	[redacted]

Case ID	Narrative (Complete)	MAH Comment	WW Identifier
[redacted]	This case was received via United States FDA VAERS (Reference number: [redacted]) on 08-Jun-2021 and was forwarded to Moderna on 08-Jun-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of DEATH (Death), ACUTE RESPIRATORY FAILURE (Acute respiratory failure), CARDIOGENIC SHOCK (Cardiogenic shock), RENAL FAILURE (Renal failure), ANGINA PECTORIS (Angina pectoris) and HEPATIC FAILURE (Hepatic failure) in an 82-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 042L20A) for COVID-19 vaccination. Concurrent medical conditions included Penicillin allergy, Sulfonamide allergy, COPD and AFib. On 10-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 19-Feb-2021, the patient experienced DEATH (Death) (seriousness criteria death, hospitalization, medically significant and life threatening), ACUTE RESPIRATORY FAILURE (Acute respiratory failure) (seriousness criteria death, hospitalization prolonged, medically significant and life threatening), CARDIOGENIC SHOCK (Cardiogenic shock) (seriousness criteria death, hospitalization prolonged, medically significant and life threatening), RENAL FAILURE (Renal failure) (seriousness criteria death, hospitalization prolonged, medically significant and life threatening), ANGINA PECTORIS (Angina pectoris) (seriousness criteria death, hospitalization, medically significant and life threatening) and HEPATIC FAILURE (Hepatic failure) (seriousness criteria death, hospitalization prolonged, medically significant and life threatening). The patient died on 03-Mar-2021. The reported cause of death was Acute hypoxic respiratory failure and Cardiogenic shock. It is unknown if an autopsy was performed. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. On 27-Feb-2021, the patient with complain of Heart pain was transferred to Emergency room 2 times in 2 days. Within two days their liver and kidney function failed. The cause of death listed were acute hypoxic respiratory failure and cardiogenic shock on 03-Mar-2021. No Concomitant product use was reported. No treatment information was provided. Action taken with mRNA-1273 in response to the event was not applicable. Company Comment: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Concomitant medical conditions could be potentially confounders/co-suspects for the events.	0	[redacted]

Case ID	Narrative (Complete)	MAH Comment	WW Identifier
[redacted]	This case was initially received via European Medicines Agency (Reference number: [redacted] on 21-Jun-2021. The most recent information was received on 25-Aug-2021 and was forwarded to Moderna on 25-Aug-2021. This regulatory authority case was reported by a physician and describes the occurrence of HAEMORRHAGIC ASCITES (Hemorrhagic ascites), SHOCK HAEMORRHAGIC (Haemorrhagic shock), TRUNCUS COELIACUS THROMBOSIS (Truncus coeliacus thrombosis) and ACUTE HEPATIC FAILURE (Acute hepatic failure) in a 63-year-old female patient who received mRNA-1273 (COVID 19 Vaccine Moderna) (batch no. 3002620) for Prophylactic vaccination. No Medical History information was reported. On 29-Apr-2021, the patient received first dose of mRNA-1273 (COVID 19 Vaccine Moderna) (unknown route) 1 dosage form. On 10-Jun-2021, received second dose of mRNA-1273 (COVID 19 Vaccine Moderna) (unknown route) dosage was changed to 1 dosage form. On 12-Jun-2021, the patient experienced HAEMORRHAGIC ASCITES (Hemorrhagic ascites) (seriousness criteria death, hospitalization, medically significant and life threatening), SHOCK HAEMORRHAGIC (Haemorrhagic shock) (seriousness criteria death, hospitalization, medically significant and life threatening), TRUNCUS COELIACUS THROMBOSIS (Truncus coeliacus thrombosis) (seriousness criteria death, hospitalization, medically significant and life threatening) and ACUTE HEPATIC FAILURE (Acute hepatic failure) (seriousness criteria death, hospitalization, medically significant and life threatening). The reported cause of death was Hemorrhagic shock. It is unknown if an autopsy was performed. For mRNA-1273 (COVID 19 Vaccine Moderna) (Unknown), the reporter considered HAEMORRHAGIC ASCITES (Hemorrhagic ascites), SHOCK HAEMORRHAGIC (Haemorrhagic shock), TRUNCUS COELIACUS THROMBOSIS (Truncus coeliacus thrombosis) and ACUTE HEPATIC FAILURE (Acute hepatic failure) to have an unknown relationship. Concomitant medications were not provided. Treatment information was not provided. This case refers to a 63-year-old female patient who experienced the serious unexpected events Haemorrhagic ascites, Haemorrhagic shock, Haemorrhagic shock and Acute hepatic failure events 2 days after receiving the mRNA vaccine. Very limited information regarding the events has been provided at this time. The events are probably related to the patient's comorbidities. Additional information required. Most recent FOLLOW-UP information incorporated above includes: On 21-Jun-2021: Seriousness criteria was changed to 'hospitalisation' and 'life threatening' from 'death' and outcome of the events changed to 'unknown' and 'not recovered' from fatal. On 25-Aug-2021: Follow up received contains no significant information. On 25-Aug-2021: Follow-up information received contain significant information. Updated event outcome and cause of the death.	0	[redacted]

Case ID	Narrative (Complete)	MAH Comment	WW Identifier
[redacted]	This case was received via United States FDA VAERS (Reference number: [redacted] on 22-Jun-2021 and was forwarded to Moderna on 22-Jun-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of CARDITIS (heart inflammation), CONFUSIONAL STATE (confusion), DYSARTHRIA (Slurred speech), HEPATIC FAILURE (liver failure) and MOBILITY DECREASED (loss of use of limbs) in a 65-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The patient's past medical history included Kidney disorder (Kidney disease.) since an unknown date. On 22-Feb-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 22-Feb-2021, the patient experienced CARDITIS (heart inflammation) (seriousness criteria death, hospitalization and medically significant), CONFUSIONAL STATE (confusion) (seriousness criteria death and hospitalization), DYSARTHRIA (Slurred speech) (seriousness criterion death), HEPATIC FAILURE (liver failure) (seriousness criteria death, hospitalization and medically significant) and MOBILITY DECREASED (loss of use of limbs) (seriousness criterion death). The patient was hospitalized on 22-Feb-2021 due to CARDITIS, CONFUSIONAL STATE and HEPATIC FAILURE. The patient died on 17-May-2021. It is unknown if an autopsy was performed. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. No concomitant medications were reported. Patient had lab done on 23-Feb-2021 -17-May-2021 but no results were reported. No treatment information was reported. Based on current available information and the temporal association between product use and the start date of the events a causal relationship cannot be excluded.	0	[redacted]

Case ID	Narrative (Complete)	MAH Comment	WW Identifier
[redacted]	This case was received via United States FDA VAERS (Reference number: [redacted]) on 03-Aug-2021 and was forwarded to Moderna on 03-Aug-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of ACUTE HEPATIC FAILURE (Acute hepatic failure), ACUTE MYOCARDIAL INFARCTION (Acute myocardial infarction), AORTIC STENOSIS (Aortic stenosis), BRAIN HYPOXIA (Brain hypoxia), CARDIAC ARREST (Cardiac arrest), CARDIOGENIC SHOCK (Cardiogenic shock), CARDIOMYOPATHY (Cardiomyopathy), CONDITION AGGRAVATED (Condition aggravated), DYSPNOEA (Dyspnoea), GENERAL PHYSICAL HEALTH DETERIORATION (General physical health deterioration), LACTIC ACIDOSIS (Lactic acidosis), MALAISE (Malaise), PULMONARY EMBOLISM (Pulmonary embolism), RASH (Rash), RASH ERYTHEMATOUS (Rash erythematous), RENAL FAILURE (Renal failure) and RHEUMATOID ARTHRITIS (Rheumatoid arthritis) in a 58-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The patient's past medical history included Anxiety and Rheumatoid arthritis. Concomitant products included ACETYLSALICYLIC ACID (ASPRIN), CITALOPRAM, PREDNISONE and FUROSEMIDE for an unknown indication. On 02-Jun-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 03-Jun-2021, the patient experienced ACUTE HEPATIC FAILURE (Acute hepatic failure) (seriousness criteria death and medically significant), ACUTE MYOCARDIAL INFARCTION (Acute myocardial infarction) (seriousness criteria death and medically significant), AORTIC STENOSIS (Aortic stenosis) (seriousness criteria death and medically significant), BRAIN HYPOXIA (Brain hypoxia) (seriousness criteria death and medically significant), CARDIAC ARREST (Cardiac arrest) (seriousness criteria death and medically significant), CARDIOGENIC SHOCK (Cardiogenic shock) (seriousness criteria death and medically significant), CARDIOMYOPATHY (Cardiomyopathy) (seriousness criteria death and medically significant), CONDITION AGGRAVATED (Condition aggravated) (seriousness criterion death), DYSPNOEA (Dyspnoea) (seriousness criterion death), GENERAL PHYSICAL HEALTH DETERIORATION (General physical health deterioration) (seriousness criterion death), LACTIC ACIDOSIS (Lactic acidosis) (seriousness criteria death and medically significant), MALAISE (Malaise) (seriousness criterion death), PULMONARY EMBOLISM (Pulmonary embolism) (seriousness criteria death and medically significant), RASH (Rash) (seriousness criterion death), RASH ERYTHEMATOUS (Rash erythematous) (seriousness criterion death), RENAL FAILURE (Renal failure) (seriousness criteria death and medically significant) and RHEUMATOID ARTHRITIS (Rheumatoid arthritis) (seriousness criteria death and medically significant). The patient died on 10-Jul-2021. The cause of death was not reported. It is unknown if an autopsy was performed. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No treatment drug information was provided. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was not applicable For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Company Comment Very limited information regarding these events has been provided at this time. No further follow up information is expected.	0	[redacted]

Case ID	Narrative (Complete)	MAH Comment	WW Identifier
[redacted]	This spontaneous case was reported by a consumer and describes the occurrence of PORTAL VEIN THROMBOSIS (developed a clot in her portal vein) and HEPATIC FAILURE (liver failure) in an 85-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 002A21A and 041L20A) for COVID-19 vaccination. Concurrent medical conditions included Hypertension and Diabetes. On 28-Jan-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 26-Feb-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient experienced PORTAL VEIN THROMBOSIS (developed a clot in her portal vein) (seriousness criteria death, hospitalization and medically significant) and HEPATIC FAILURE (liver failure) (seriousness criteria death, hospitalization and medically significant). The reported cause of death was Liver failure. It is unknown if an autopsy was performed. It was reported that the reporter believed that her mother passed away as a result of a complication with the vaccine. Patient's mother received first dose on 28-JAN-2021. Patient received second dose one 26-FEB-2021. The patient was 85-year-old with hypertension and diabetes and developed a clot in her portal vein. Patient was hospitalized. The clot made her go into liver failure which was the cause of death. The date of the reported events remained unknown at the time of the report. Treatment information were not provided by the reporter. Concomitant medications were not reported by reporter. Company Comment: This is the case of an 85-year-old female subject with a history of hypetension and diabetes who died due to hepatic falure. Reportedly, the patient initially developed thrombosis in portal vein (a clot in her portal vein), however a temporal association between the use of the product and the start date of the event was not reported. The patient subsequently developed liver failure and died due to liver failure, as reported, however, the date of death was not provided. It is unknown if an autopsy was performed. Very limited information regarding these events has been provided at this time. Causality is confounded with the patient's advanced age, hypertension and diabetes.	0	[redacted]

Case ID	Narrative (Complete)	MAH Comment	WW Identifier
[redacted]	This case was received via United States FDA VAERS (Reference number: [redacted] on 07-Sep-2021 and was forwarded to Moderna on 07-Sep-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of ACUTE HEPATIC FAILURE (Acute hepatic failure), CEREBRAL VENOUS THROMBOSIS (Cerebral venous thrombosis), MESENTERIC VENOUS OCCLUSION (Mesenteric venous occlusion) and SUPERIOR MESENTERIC ARTERY SYNDROME (Superior mesenteric artery syndrome) in a 64-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The patient's past medical history included Breast cancer and Mastectomy NOS (Breast Ca s/p resection). On 08-Mar-2021, the patient received dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 10-Aug-2021, the patient experienced ACUTE HEPATIC FAILURE (Acute hepatic failure) (seriousness criteria death, hospitalization and medically significant), CEREBRAL VENOUS THROMBOSIS (Cerebral venous thrombosis) (seriousness criteria death, hospitalization and medically significant), MESENTERIC VENOUS OCCLUSION (Mesenteric venous occlusion) (seriousness criteria death and hospitalization) and SUPERIOR MESENTERIC ARTERY SYNDROME (Superior mesenteric artery syndrome) (seriousness criteria death, hospitalization and medically significant). The patient was treated with TPA for Superior mesenteric artery syndrome, at an unspecified dose and frequency. The patient died on 23-Aug-2021. The reported cause of death was Acute liver failure, Cerebral venous thrombosis and Superior mesenteric artery syndrome. It is unknown if an autopsy was performed. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Patient other medication was reported as HRT (hormonal replacement therapy) since 2016. It was reported that 4 months after completing immunization series patient was noted with SMA, SMV, and cerebral venous thrombus. Report from outside hospital show that the SMA had collateralization in August suggestive of a chronic occlusion s/p thrombectomy with TPA infusion the patient developed ALF and died on 23-Aug-2021. Patient treatment information was also reported as Anticoagulant therapy from 10-Aug-2021. Action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown) was Not applicable. Very limited information regarding this event/s has been provided at this time. Further information has been requested. Further information is not expected.	0	[redacted]

Case ID	Narrative (Complete)	MAH Comment	WW Identifier
[redacted]	This regulatory authority case was reported by a pharmacist and describes the occurrence of ACUTE HEPATITIS B (Acute hepatitis B), HEPATIC FAILURE (Hepatitis B with acute liver failure), SEPSIS (Sepsis), CELLULITIS (Right forearm cellulitis), BILIARY TRACT DISORDER (Delirium suspected biliary tract problem), HYPOKALAEMIA (Hypokalemia), ASTHENIA (generalized asthenia/weakness), ALTERED STATE OF CONSCIOUSNESS (altered state of consciousness), CHILLS (chills), PYREXIA (Fever), DELIRIUM (Delirium suspected biliary tract problem), DECUBITUS ULCER (r/o pressure sore), BILIARY TRACT INFECTION (biliary tract infection) and BANDAEMIA (bandemia) in a 71-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. Concurrent medical conditions included Hepatitis B (Hepatitis B with liver failure) and Hepatic encephalopathy (hepatic encephalopathy (grade 3 – 4), suspected to be induced by liver failure). On 07-Jul-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 07-Jul-2021, the patient experienced ACUTE HEPATITIS B (Acute hepatitis B) (seriousness criteria death, hospitalization and medically significant). On 14-Jul-2021, the patient experienced HEPATIC FAILURE (Hepatitis B with acute liver failure) (seriousness criteria death, hospitalization and medically significant), SEPSIS (Sepsis) (seriousness criteria death, hospitalization and medically significant), HYPOKALAEMIA (Hypokalemia) (seriousness criteria death, hospitalization and medically significant), ALTERED STATE OF CONSCIOUSNESS (altered state of consciousness) (seriousness criteria death, hospitalization and medically significant), CHILLS (chills) (seriousness criteria death and hospitalization), PYREXIA (Fever) (seriousness criteria death and hospitalization), DECUBITUS ULCER (r/o pressure sore) (seriousness criteria death and hospitalization), BILIARY TRACT INFECTION (biliary tract infection) (seriousness criteria death, hospitalization and medically significant) and BANDAEMIA (bandemia) (seriousness criteria death and medically significant). On 02-Aug-2021, the patient experienced CELLULITIS (Right forearm cellulitis) (seriousness criteria death, hospitalization and medically significant), BILIARY TRACT DISORDER (Delirium suspected biliary tract problem) (seriousness criteria death and hospitalization), ASTHENIA (generalized asthenia/weakness) (seriousness criteria death and hospitalization) and DELIRIUM (Delirium suspected biliary tract problem) (seriousness criteria death, hospitalization and medically significant). The patient was hospitalized from 14-Jul-2021 to 31-Jul-2021 due to ALTERED STATE OF CONSCIOUSNESS, BILIARY TRACT INFECTION, CELLULITIS, CHILLS, DECUBITUS ULCER, HYPOKALAEMIA, PYREXIA and SEPSIS. The patient died on 26-Aug-2021. The reported cause of death was hepatitis b with acute liver failure. It is unknown if an autopsy was performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 14-Jul-2021, Ammonia: 112 (Inconclusive) 112. On 14-Jul-2021, Blood pressure measurement: 134/93 (Inconclusive) 134/93 mmHg. On 14-Jul-2021, Body temperature: 39.1°C (Inconclusive) 39.1°C. On 14-Jul-2021, Heart rate: 107 (Inconclusive) 107 beats per minute. On 14-Jul-2021, Hypokalaemia: k 3.0 -> 3.1 (Inconclusive) K 3.0 -> 3.1. On 14-Jul-2021, Respiratory rate: 20 (Inconclusive) 20 breaths per minute. On 02-Aug-2021, Blood bilirubin: 5.9 => 8.7 (High) 5.9 => 8.7. On 02-Aug-2021, Blood pressure measurement: 146/103 (Inconclusive) 146/103 mmHg. On 02-Aug-2021, Body temperature: 37°C (Inconclusive) 37°C. On 02-Aug-2021, Heart rate: 65 (Inconclusive) 65 beats per minute. On 02-Aug-2021, Respiratory rate: 18 (Inconclusive) 18 breaths per minute. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. No concomitant medication reported. Treatment information not provided. Company Comment: This case concerns a 71-year-old, female patient with relevant medical history of hepatitis B with liver failure and Hepatic encephalopathy, who experienced the unexpected events of acute hepatitis Hepatic failure, cellulitis, biliary tract disorder, hypokalemia, asthenia, altered state of consciousness, chills, pyrexia, delirium, decubitus ulcer, biliary tract infection and bandaemia. The events occurred approximately between 1 and 8 days after the first dose of mRNA-1273 and had a fatal	0	[redacted]

Case ID	Narrative (Complete)	MAH Comment	WW Identifier
	outcome 12 days after. The rechallenge was not applicable, as the events happened after the first dose. The medical history of T hepatitis B with liver failure and Hepatic encephalopathy remains a cofounder. he benefit-risk relationship of mRNA-1273 is not affected by this report.		

Case ID	Narrative (Complete)	MAH Comment	WW Identifier
[redacted]	This case was received via United States FDA VAERS (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 ACUTE MYOCARDIAL INFARCTION (Acute myocardial infarction), COVID-19 PNEUMONIA (COVID-19 pneumonia), HEPATIC FAILURE (Hepatic failure), HYPOXIA (Hypoxia), PNEUMOTHORAX (Pneumothorax), RESPIRATORY FAILURE (Respiratory failure), SEIZURE LIKE PHENOMENA (Seizure like phenomena), SHOCK (Shock), VENTRICULAR TACHYCARDIA (Ventricular tachycardia) and VOMITING (Vomiting) in a 68-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The patient's past medical history included COPD, Hypertension and Leukemia. On 19-Mar-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 05-Oct-2021, the patient experienced ACUTE MYOCARDIAL INFARCTION (Acute myocardial infarction) (seriousness criteria death, hospitalization and medically significant), COVID-19 PNEUMONIA (COVID-19 pneumonia) (seriousness criteria death, hospitalization and medically significant), HEPATIC FAILURE (Hepatic failure) (seriousness criteria death, hospitalization and medically significant), HYPOXIA (Hypoxia) (seriousness criteria death, hospitalization and medically significant), PNEUMOTHORAX (Pneumothorax) (seriousness criteria death, hospitalization and medically significant), RESPIRATORY FAILURE (Respiratory failure) (seriousness criteria death, hospitalization and medically significant), SEIZURE LIKE PHENOMENA (Seizure like phenomena) (seriousness criteria death, hospitalization and medically significant), SHOCK (Shock) (seriousness criteria death, hospitalization and medically significant), VENTRICULAR TACHYCARDIA (Ventricular tachycardia) (seriousness criteria death, hospitalization and medically significant) and VOMITING (Vomiting) (seriousness criteria death and hospitalization). The patient was treated with DEXAMETHASONE at an unspecified dose and frequency; REMDESIVIR for COVID-19 pneumonia, at an unspecified dose and frequency; NOREPINEPHRINE BITARTRATE (LEVOPHED BITARTRAT) at an unspecified dose and frequency and PROPOFOL at an unspecified dose and frequency. The patient died on 05-Oct-2021. The cause of death was not reported. It is unknown if an autopsy was performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 05-Oct-2021, Electrocardiogram: st segment elevation (abnormal) ST segment elevation. On 05-Oct-2021, Oxygen saturation: 80 (Low) 80. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. The patients has gone through procedures like Cardioversion, Endotracheal intubation, Haemofiltration, Mechanical ventilation, Resuscitation on 5th oct 2021. Also it has been described that the patient has been Transfer from clinic where patient was attempting to receive monoclonal antibody infusion when found to be hypoxic with SPO2 in low 80s. Upon arrival to our hospital vomited and underwent seizure like activity and lost pulse. CPR initiated with v tach. Defibrillated, intubated, started on amiodarone drip. Developed shock and started on levophed and propofol drips. STAT EKG showed ST elevation, code STEMI was called. Ejection fraction 15%. Started on remdesevir for covid pneumonia but stopped due to liver failure. Given dexamethasone. Developed right sided pneumothorax and developed renal failure requiring CRRT. Increasing respiratory failure with max vent settings and flolan. Family decided to transition to comfort care.	0	[redacted]

Case ID	Narrative (Complete)	MAH Comment	WW Identifier
[redacted]	This case was received via United States FDA VAERS (Reference number: [redacted] on 26-Oct-2021 and was forwarded to Moderna on 26-Oct-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of ACUTE HEPATIC FAILURE (Acute hepatic failure) in a 31-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 048F21A) for COVID-19 vaccination. Concurrent medical conditions included Drug allergy (Clindamycin), Penicillin allergy, Type 1 diabetes mellitus, Endometriosis and Hypothyroidism. Concomitant products included INSULIN DETEMIR (LEVEMIR) for an unknown indication. On 30-Sep-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 04-Oct-2021, the patient experienced ACUTE HEPATIC FAILURE (Acute hepatic failure) (seriousness criteria death, hospitalization and medically significant). The patient died on 08-Oct-2021. The reported cause of death was Acute hepatic failure. It is unknown if an autopsy was performed. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No treatment medications provided by the reporter. This case concerns a 31-year-old, female patient with medical history of type 2 diabetes mellitus, who experienced the unexpected serious adverse event of special interest of acute hepatic failure. The event occurred approximately 4 days after the first dose of Spikevax (Moderna COVID-19 vaccine) and had a fatal outcome, with death occurring 4 days after the event on set. It is not known if an autopsy was performed to the patient. The rechallenge was not applicable since the event occurred after the first dose and the patient died. The medical history diabetes mellitus could remain as a confounding factor. The benefit-risk relationship of Spikevax (Moderna COVID-19 vaccine) is not affected by this report.	0	[redacted]

Case ID	Narrative (Complete)	MAH Comment	WW Identifier
[redacted]	This case was received via European Medicines Agency (Reference number: [redacted] on 28-Oct-2021 and was forwarded to Moderna on 28-Oct-2021. This regulatory authority case was reported by a physician and describes the occurrence of HEPATITIS ACUTE (Fever and cough. Hospitalized for acute hepatitis on Sep 2019. Rapid onset of acute kidney failure until dialysis treatment. Signs of hyperacute inflammatory syndrome. CID), PYREXIA (Fever and cough. Hospitalized for acute hepatitis on Sep 2019. Rapid onset of acute kidney failure until dialysis treatment. Signs of hyperacute inflammatory syndrome. CID), DISSEMINATED INTRAVASCULAR COAGULATION (Fever and cough. Hospitalized for acute hepatitis on Sep 2019. Rapid onset of acute kidney failure until dialysis treatment. Signs of hyperacute inflammatory syndrome. CID), COUGH (Fever and cough. Hospitalized for acute hepatitis on Sep 2019. Rapid onset of acute kidney failure until dialysis treatment. Signs of hyperacute inflammatory syndrome. CID), ACUTE KIDNEY INJURY (Fever and cough. Hospitalized for acute hepatitis on Sep 2019. Rapid onset of acute kidney failure until dialysis treatment. Signs of hyperacute inflammatory syndrome. CID) and SYSTEMIC INFLAMMATORY RESPONSE SYNDROME (Fever and cough. Hospitalized for acute hepatitis on Sep 2019. Rapid onset of acute kidney failure until dialysis treatment. Signs of hyperacute inflammatory syndrome. CID) in a 69-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 214019) for COVID-19 vaccination. No medical history was reported. Concomitant products included CLARITHROMYCIN for an unknown indication. On 08-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 10-Sep-2021, the patient experienced HEPATITIS ACUTE (Fever and cough. Hospitalized for acute hepatitis on Sep 2019. Rapid onset of acute kidney failure until dialysis treatment. Signs of hyperacute inflammatory syndrome. CID) (seriousness criteria death and medically significant), PYREXIA (Fever and cough. Hospitalized for acute hepatitis on Sep 2019. Rapid onset of acute kidney failure until dialysis treatment. Signs of hyperacute inflammatory syndrome. CID) (seriousness criterion death), DISSEMINATED INTRAVASCULAR COAGULATION (Fever and cough. Hospitalized for acute hepatitis on Sep 2019. Rapid onset of acute kidney failure until dialysis treatment. Signs of hyperacute inflammatory syndrome. CID) (seriousness criteria death and medically significant), COUGH (Fever and cough. Hospitalized for acute hepatitis on Sep 2019. Rapid onset of acute kidney failure until dialysis treatment. Signs of hyperacute inflammatory syndrome. CID) (seriousness criterion death), ACUTE KIDNEY INJURY (Fever and cough. Hospitalized for acute hepatitis on Sep 2019. Rapid onset of acute kidney failure until dialysis treatment. Signs of hyperacute inflammatory syndrome. CID) (seriousness criteria death and medically significant) and SYSTEMIC INFLAMMATORY RESPONSE SYNDROME (Fever and cough. Hospitalized for acute hepatitis on Sep 2019. Rapid onset of acute kidney failure until dialysis treatment. Signs of hyperacute inflammatory syndrome. CID) (seriousness criteria death and medically significant). The patient died on 27-Sep-2021. The reported cause of death was fever and cough. hospitalized for acute hepatitis on sep 2019. rapid onset of acute kidney failure until dialysis treatment. signs of hyperacute inflammatory syndrome. cid, fever and cough. hospitalized for acute hepatitis on sep 2019. rapid onset of acute kidney failure until dialysis treatment. signs of hyperacute inflammatory syndrome. cid, fever and cough. hospitalized for acute hepatitis on sep 2019. rapid onset of acute kidney failure until dialysis treatment. signs of hyperacute inflammatory syndrome. cid, fever and cough. hospitalized for acute hepatitis on sep 2019. rapid onset of acute kidney failure until dialysis treatment. signs of hyperacute inflammatory syndrome. cid, fever and cough. hospitalized for acute hepatitis on sep 2019. rapid onset of acute kidney failure until dialysis treatment. signs of hyperacute inflammatory syndrome. cid and fever and cough. hospitalized for acute hepatitis on sep 2019. rapid onset of acute kidney failure until dialysis treatment. signs of hyperacute inflammatory syndrome. cid. It is unknown if an autopsy was performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 27-Sep-2021, Blood bilirubin:. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. No treatment information mentioned. The patient received the 1st dose of the Spikevax (ex Moderna) vaccine on 04-Aug-2021 at 1:28 pm lot 3004730. Received the 2nd dose on 08-Sep-2021 at 09:45 am lot 214019. Company Comment	0	[redacted]

Case ID	Narrative (Complete)	MAH Comment	WW Identifier
	This case concerns a 69-year-old male patient with no relevant medical history reported, who experienced the unexpected, serious (fatal) events of hepatitis acute, pyrexia, disseminated intravascular coagulation, cough, acute kidney injury and systemic inflammatory response syndrome. The events occurred 2 days after the second dose of mRNA-1273. The rechallenge was not applicable since information about the first dose was not disclosed. The benefit-risk relationship of mRNA-1273 is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 28-Oct-2021: Signficant Translation received on 29-Oct-2021 for initial SD: Time of vaccination, dose details updated. On 29-Oct-2021: Significant followup received: newevent added. On 19-Nov-2021: Follow-up information included no new information.		

Case ID	Narrative (Complete)	MAH Comment	WW Identifier
[redacted]	This case was received via United States FDA VAERS (Reference number: [redacted]) on 02-Nov-2021 and was forwarded to Moderna on 02-Nov-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of ASTHENIA (Asthenia), ATELECTASIS (Atelectasis), BACK PAIN (Back pain), CHEST PAIN (Chest pain), CONDITION AGGRAVATED (Condition aggravated), CYANOSIS (Cyanosis), DISSEMINATED INTRAVASCULAR COAGULATION (Disseminated intravascular coagulation), DYSPNOEA (Dyspnoea), DYSSTASIA (Dysstasia), ENTEROCOCCAL BACTERAEMIA (Enterococcal bacteraemia), FLUID INTAKE REDUCED (Fluid intake reduced), HEPATIC FAILURE (Hepatic failure), HYPERVENTILATION (Hyperventilation), ILLNESS (Illness), IMPAIRED SELF-CARE (Impaired self-care), LUNG INFILTRATION (Lung infiltration), VACCINATION COMPLICATION (Malaise), OROPHARYNGEAL PAIN (Oropharyngeal pain), PAIN (Pain), PAINFUL RESPIRATION (Painful respiration), PNEUMONIA (Pneumonia), PSEUDOMONAL BACTERAEMIA (Pseudomonal bacteraemia), PYREXIA (Pyrexia), RENAL FAILURE (Renal failure), RESPIRATORY ARREST (Respiratory arrest), RESPIRATORY FAILURE (Respiratory failure), RESPIRATORY TRACT CONGESTION (Respiratory tract congestion), THROMBOTIC THROMBOCYTOPENIC PURPURA (Thrombotic thrombocytopenic purpura), INFLUENZA (tested positive for flu) and COVID-19 (COVID-19) in a 55-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 003C21A) for COVID-19 vaccination. The patient's past medical history included Overweight. Concurrent medical conditions included Depression and Rheumatoid arthritis. Concomitant products included BUPROPION and HYDROXYCHLOROQUINE for an unknown indication. On 24-Apr-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 08-Sep-2021, the patient experienced ASTHENIA (Asthenia) (seriousness criteria death, hospitalization, disability and life threatening), ATELECTASIS (Atelectasis) (seriousness criteria death, hospitalization, disability and life threatening), BACK PAIN (Back pain) (seriousness criteria death, hospitalization, disability and life threatening), CHEST PAIN (Chest pain) (seriousness criteria death, hospitalization, disability and life threatening), CONDITION AGGRAVATED (Condition aggravated) (seriousness criteria death, hospitalization, disability and life threatening), CYANOSIS (Cyanosis) (seriousness criteria death, hospitalization, disability and life threatening), DISSEMINATED INTRAVASCULAR COAGULATION (Disseminated intravascular coagulation) (seriousness criteria death, hospitalization, disability, medically significant and life threatening), DYSPNOEA (Dyspnoea) (seriousness criteria death, hospitalization, disability and life threatening), DYSSTASIA (Dysstasia) (seriousness criteria death, hospitalization, disability and life threatening), ENTEROCOCCAL BACTERAEMIA (Enterococcal bacteraemia) (seriousness criteria death, hospitalization, disability, medically significant and life threatening), FLUID INTAKE REDUCED (Fluid intake reduced) (seriousness criteria death, hospitalization, disability and life threatening), HEPATIC FAILURE (Hepatic failure) (seriousness criteria death, hospitalization, disability, medically significant and life threatening), HYPERVENTILATION (Hyperventilation) (seriousness criteria death, hospitalization, disability and life threatening), IMPAIRED SELF-CARE (Impaired self-care) (seriousness criteria death, hospitalization, disability and life threatening), LUNG INFILTRATION (Lung infiltration) (seriousness criteria death, hospitalization, disability and life threatening), VACCINATION COMPLICATION (Malaise) (seriousness criteria death, hospitalization, disability and life threatening), OROPHARYNGEAL PAIN (Oropharyngeal pain) (seriousness criteria death, hospitalization, disability and life threatening), PAIN (Pain) (seriousness criteria death, hospitalization, disability and life threatening), PAINFUL RESPIRATION (Painful respiration) (seriousness criteria death, hospitalization, disability and life threatening), PNEUMONIA (Pneumonia) (seriousness criteria death, hospitalization, disability, medically significant and life threatening), PSEUDOMONAL BACTERAEMIA (Pseudomonal bacteraemia) (seriousness criteria death, hospitalization, disability, medically significant and life threatening), PYREXIA (Pyrexia) (seriousness criteria death, hospitalization, disability and life threatening), RENAL FAILURE (Renal failure) (seriousness criteria death, hospitalization, disability, medically significant and life threatening), RESPIRATORY ARREST (Respiratory arrest) (seriousness criteria death, hospitalization, disability, medically significant and life threatening), RESPIRATORY FAILURE (Respiratory failure) (seriousness criteria death, hospitalization, disability, medically significant and life threatening), RESPIRATORY TRACT CONGESTION (Respiratory tract congestion) (seriousness criteria death, hospitalization, disability and life threatening) and THROMBOTIC THROMBOCYTOPENIC PURPURA (Thrombotic thrombocytopenic purpura) (seriousness criteria death, hospitalization, disability, medically significant and life threatening). On 09-Sep-2021, the patient experienced ILLNESS (Illness) (seriousness criteria death, hospitalization, disability and life threatening). On 13-Sep-2021, the patient experienced COVID-19 (COVID-19) (seriousness criteria death, hospitalization, disability and life threatening). On an unknown date, the patient experienced INFLUENZA (tested positive for flu) (seriousness criteria death and hospitalization). The patient was hospitalized on 13-Sep-2021 due to ASTHENIA, ATELECTASIS, BACK PAIN, CHEST PAIN, CONDITION AGGRAVATED, COVID-19, CYANOSIS, DISSEMINATED INTRAVASCULAR COAGULATION, DYSPNOEA, DYSSTASIA, ENTEROCOCCAL	0	[redacted]

Case ID	Narrative (Complete)	MAH Comment	WW Identifier
	BACTERAEMIA, FLUID INTAKE REDUCED, HEPATIC FAILURE, HYPERVENTILATION, ILLNESS, IMPAIRED SELF-CARE, INFLUENZA, LUNG INFILTRATION, OROPHARYNGEAL PAIN, PAIN, PAINFUL RESPIRATION, PNEUMONIA, PSEUDOMONAL BACTERAEMIA, PYREXIA, RENAL FAILURE, RESPIRATORY ARREST, RESPIRATORY FAILURE, RESPIRATORY TRACT CONGESTION, THROMBOTIC THROMBOCYTOPENIC PURPURA and VACCINATION COMPLICATION. The patient was treated with GUAIFENESIN (MUCINEX) for Adverse event, at an unspecified dose and frequency; VITAMIN C [ASCORBIC ACID] for Adverse event, at an unspecified dose and frequency and HEPARIN for Adverse event, at an unspecified dose and frequency. The patient died on 09-Oct-2021. The reported cause of death was abrupt discontinuation of hydroxychloroquine for rheumatoid arthritis and antibody dependent enhancement of influenza due to covid vaccine.. It is unknown if an autopsy was performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 08-Sep-2021, Blood culture: positive (Positive) positive for streptoccocus pneumonia. On 08-Sep-2021, Influenza virus test positive: positive (Positive) Positive. On 08-Sep-2021, Oxygen saturation decreased: decreased (Low) decreased. On 08-Sep-2021, SARS-CoV-2 antibody test: positive (Positive) Positive IgG antibodies. On 08-Sep-2021, SARS-CoV-2 test: negative (Negative) negative and positive (Positive) positive IgG antibodies. On 08-Sep-2021, Sputum culture positive: positive (Positive) positive for streptoccocus pneumonia.. On 13-Sep-2021, Angiogram: abnormal (abnormal) No CT angiographic evidence of pulmonary embolus is seen. There are bilateral lower lung subsegmental atelectasis. Mild bilateral pulmonary infiltrates are seen.. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Patient stopped taking hydroxychloroquine and started taking a supplement from another country called RT King and reported improvement in arthritis symptoms.No concomitant product was provided. Patient was treated with maximal critical care management including broad spectrum antibiotics, ventilation, continuous renal replacement therapy, blood/platelet transfusions, chest tube, OG tube feedings, and anticoagulation initially that was later discontinued. Patient had minimal responsiveness to pain only after sedatio		

Case ID	Narrative (Complete)	MAH Comment	WW Identifier
[redacted]	This case was received via European Medicines Agency (Reference number: [redacted]) on 10-Nov-2021 and was forwarded to Moderna on 10-Nov-2021. This regulatory authority case was reported by a consumer and describes the occurrence of AUTOIMMUNE HEPATITIS (Autoimmune hepatitis with fatal outcome) in a 77-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3004217) for Prophylactic vaccination. No Medical History information was reported. On 30-Jul-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 04-Aug-2021, the patient experienced AUTOIMMUNE HEPATITIS (Autoimmune hepatitis with fatal outcome) (seriousness criteria death and medically significant). The reported cause of death was autoimmune hepatitis with fatal outcome. It is unknown if an autopsy was performed. Patient medical history mention as depression, dementia, arterial hypertension, hyperlipoproteinemia. On 09-AUG-2021 onset of jaundice and on 14-AUG-2021 hospitalization with initial diagnosis of hepatitis. Patient had Initially very high transaminases and very high bilirubin. Patient was start of therapy with prednisolone and azathioprine. Patient had developed of transient cytopenia, reduction of the azathioprine dose. Reporter comment mention as 05-Nov-2021 The deceased's autopsy took place on 09-Nov-2021 by the forensic medicine department. No relevant concomitant and treatment medications were reported. Company Comment - This is a fatal case that concerns a 77-year-old male patient, with no relevant medical history reported, who experienced the unexpected fatal event of AUTOIMMUNE HEPATITIS. The event occurred five days after the first dose of mRNA-1273, with death occurring tow months later. The rechallenge was not applicable as no additional dose is going to be administered. The benefit-risk relationship of mRNA-1273 is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 10-Nov-2021: Translation document received on 15-Nov-2021 included verbatim added, medical history, event information, general information added in the inarrative. On 12-Nov-2021: Non-Significant Follow up On 12-Nov-2021: Translation document received on 15-Nov-2021 included reporter comment added.	Do you or the person affected have any known allergies? If yes, which? No. Information on risk factors or pre-existingconditions: depression, dementia, arterial hypertension, hyperlipoproteinemia/ on 30-Jul-2021 1st Spikevax vaccination. On 04-Aug-2021, start of the performance status reduction with general weakness. On 09-Aug onset of jaundice and on 14-Aug hospitalization with initial diagnosis of hepatitis, which was subsequently classified as autoimmune hepatitis. Initially very high transaminases and very high bilirubin. Start of therapy with prednisolone and then azathioprine. Then development of transient cytopenia with improvement again except for persistent leukopenia (2.5) upon reduction of the azathioprine dose. Liver values incl. bilirubin showed a trend to improvement. Ultimately, however, progressive deterioration of the performance status, ultimately with lethal outcome on 10/11/2021. The doctor who performed the 2nd post-mortem examination also considered the Spikevax vaccination to be causative and subsequently reported it as an unnatural death.	[redacted]

Case ID	Narrative (Complete)	MAH Comment	WW Identifier
[redacted]	This case was received via United States FDA VAERS (Reference number: [redacted] on 16-Nov-2021 and was forwarded to Moderna on 16-Nov-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of CARDIAC FAILURE (Cardiac failure), DEATH (Death), HEPATIC FAILURE (Hepatic failure), LOSS OF CONSCIOUSNESS (Loss of consciousness), RENAL FAILURE (Renal failure), SYNCOPE (Syncope), ARTHROPATHY (Arthropathy), FALL (Fall), GAIT DISTURBANCE (Gait disturbance), HEAD INJURY (Head injury), WALKING AID USER (Walking aid user) and WHEELCHAIR USER (Wheelchair user) in a 63-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 012M20A and 029A21A) for COVID-19 vaccination. No Medical History information was reported. On 08-Mar-2021, the patient received dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 08-Mar-2021, received dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 09-Mar-2021, the patient experienced CARDIAC FAILURE (Cardiac failure) (seriousness criteria death, hospitalization and medically significant), DEATH (Death) (seriousness criteria death, hospitalization and medically significant), HEPATIC FAILURE (Hepatic failure) (seriousness criteria death, hospitalization and medically significant), LOSS OF CONSCIOUSNESS (Loss of consciousness) (seriousness criteria death, hospitalization and medically significant), RENAL FAILURE (Renal failure) (seriousness criteria death, hospitalization and medically significant), SYNCOPE (Syncope) (seriousness criteria death, hospitalization and medically significant), ARTHROPATHY (Arthropathy) (seriousness criteria death and hospitalization), FALL (Fall) (seriousness criteria death and hospitalization), GAIT DISTURBANCE (Gait disturbance) (seriousness criteria death and hospitalization), HEAD INJURY (Head injury) (seriousness criteria death and hospitalization), WALKING AID USER (Walking aid user) (seriousness criteria death and hospitalization) and WHEELCHAIR USER (Wheelchair user) (seriousness criteria death and hospitalization). The patient died on 14-May-2021. The reported cause of death was Arthropathy, Cardiac failure, Fall, Gait disturbance, Head injury, Hepatic failure, Loss of consciousness, Renal failure, Syncope, Walking aid user and Wheelchair user. 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 product use was not provided. Treatment information was not provided. It was stated that patient took first shot on 08-Feb-2021 and a day later he started to lose control of his nerves. He was constantly shaking. Patient could not hold a glass with water without it flying out of his hand accidentally and he needed someone behind him to walk anywhere because he would faint. The second shot was on 08-Mar-2021. The symptoms got worse. This case concerns a death of a 63-year-old, male patient with no relevant medical history, who experienced the unexpected events of cardiac failure, hepatic failure, loss of consciousness, renal failure, syncope, arthropathy, fall, gait disturbance, head injury, walking aid user and wheelchair user, which all required hospitalization and were reported with death as seriousness criteria. The events occurred approximately 1 day after the a dose of mRNA-1273. It was reported that two doses were administered on same day which seems unlikely. As reported a day after receiving first dose of mRNA-1273 the patient started to lose control of his nerves. He was constantly shaking and he needed someone behind him to walk anywhere because he would faint. After second dose the symptoms got worse. Patient was not able to walk without a walker, which quickly led him to a wheelchair. There was one day that the patient felt too confident and tried to sit at the counter barstool. The patient's legs gave out, or he fainted and landed on the ground and hit his head so hard, he was unconscious. Patient did not leave the hospital and his kidneys failed, then his liver and then his heart. He died 37 days after vaccination. The rechallenge was not applicable. The benefit-risk relationship of mRNA-1273 is not affected by this report. Event seriousness assessed as per Regulatory Authority reporting.	0	[redacted]

Case ID	Narrative (Complete)	MAH Comment	WW Identifier
[redacted]	This case was received via United States FDA VAERS (Reference number: [redacted] on 16-Nov-2021 and was forwarded to Moderna on 16-Nov-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of DEATH (Death), HEPATIC FAILURE (Hepatic failure), RENAL FAILURE (Renal failure), DEAFNESS (Deafness), DIZZINESS (Dizziness), VERTIGO (Vertigo) and LABORATORY TEST (Laboratory test) in a 73-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for an unknown indication. The patient's past medical history included Diabetes. On 03-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 05-Mar-2021, the patient experienced DEATH (Death) (seriousness criteria death and disability), HEPATIC FAILURE (Hepatic failure) (seriousness criteria death and disability), RENAL FAILURE (Renal failure) (seriousness criteria death and disability), DEAFNESS (Deafness) (seriousness criteria death and disability), DIZZINESS (Dizziness) (seriousness criteria death and disability), VERTIGO (Vertigo) (seriousness criteria death and disability) and LABORATORY TEST (Laboratory test) (seriousness criteria death and disability). The patient died on 27-Oct-2021. The reported cause of death was Deafness, Dizziness, Hepatic failure, Renal failure, Vertigo and Laboratory test. It is unknown if an autopsy was performed. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Concomitant medications included diabetes medication. No treatment medications were reported. Batch number of the suspect product was unknown. Action taken with the suspect product was not applicable. Multiple tests were done from 04-Apr-2021 to 10-Oct-2021. Patient had vertigo, dizziness, hearing loss progressing to kidney and liver failure and death. Company Comment: This case concerns a 73-year-old male patient with relevant medical history of Diabetes, who experienced the following serious unexpected events: Hepatic failure, Renal failure, Dizziness, Vertigo and Deafness. The outcome of all reported events was reported as fatal, and Death was also stated as separate event as per source document. In addition, Laboratory test was also reported as an event. The events occurred two days after the patient had received the first dose of the mRNA-1273 vaccine. Very limited information regarding the reported events was disclosed at the moment and details regarding tests which were performed were not provide. The patient died nearly 8 months after the administration of the vaccine. Although all events were reported with fatal outcome, the exact cause of death was not specified and it remained unknown whether the autopsy was performed. The re-challenge is not applicable having in mind that the patient died. The patient's elderly age and underlying Diabetes remain confounders for the reported events. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.	0	[redacted]

Case ID	Narrative (Complete)	MAH Comment	WW Identifier
[redacted]	This case was initially received via European Medicines Agency (Reference number: [redacted] on 19-Nov-2021. The most recent information was received 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 AUTOIMMUNE HEPATITIS (above all autoimmune hepatitis) in a 77-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3004217) for COVID-19 vaccination. The patient's past medical history included Dementia, Lipid metabolism disorder NOS and Hypertonus. On 30-Jul-2021, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 04-Aug-2021, the patient experienced AUTOIMMUNE HEPATITIS (above all autoimmune hepatitis) (seriousness criteria death and hospitalization). The patient died on 11-Oct-2021. The reported cause of death was Autoimmune hepatitis. It is unknown if an autopsy was performed. The action taken with mRNA-1273 (Spikevax) (Unknown) was unknown. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. Concomitant medications were not reported. It was reported that on 04-Aug-2021, patient had onset of symptoms with icterus and reduction in general state of health, on 17-Aug-2021, patient was hospitalized and diagnosis of (autoimmune) hepatitis was made. Patient had Treatment with Prednisolone and Azathioprine. Over the course slow improvement in liver values but clinical deterioration with fatal outcome on 11-Oct-2021. Company comment -This is a regulatory case concerning a 77 year- old male patient, with relevant medical history of Lipid metabolism disorders who experienced the serious unexpected event of autoimmune hepatitis with fatal outcome 4 days after receiving a dose of mRNA-1273 (seriousness criteria death, hospitalization). Patient was vaccinated on 30-Jul-2021 and it was reported the patient had onset of symptoms with icterus and reduction in general state of health, on 17-Aug-2021, patient was hospitalized and the diagnosis of autoimmune hepatitis was made; Patient had Treatment with Prednisolone and Azathioprine. Over the course slow improvement in liver values and died on 11-Oct-2021. The benefit-risk relationship of mRNA-1273 is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 19-Nov-2021: Translated document received on 19-Nov-2021 and included verbatim of the event was updated as per translation and Clinical course of events and treatment information was added in I narrative. On 04-Jan-2022: Due to incorrect follow-up receipt date, this case is amended to reflect the actual follow-up receipt date/Date FU Rcvd by Safety. This case was submitted on-time based on the actual follow-up receipt date. The actual follow-up receipt date/ Date FU Rcvd by Safety for this case is 04-Jan-2022 On 05-Jan-2022: Significant follow up information received on 05-Jan-2022, product indication was updated. history updated. Narrative updated.	Start of complaints with jaundice and AZ reduction on 04.08.2021, hospitalization and diagnosis (autoimmune) hepatitis. therapy with prednisolone and azathioprine. In the course of slow liver value improvement but clinical deterioration with exitus letalis on 11.10.2021.	[redacted]

Case ID	Narrative (Complete)	MAH Comment	WW Identifier
[redacted]	This regulatory authority case was reported by an other health care professional and describes the occurrence of HEPATIC FAILURE (Liver failure) and ABDOMINAL PAIN (Abdominal pain) in a 65-year-old male patient who received mRNA-1273 (COVID 19 Vaccine Moderna) for COVID-19 vaccination. No Medical History information was reported. On 22-Oct-2021, the patient received dose of mRNA-1273 (COVID 19 Vaccine Moderna) (unknown route) 1 dosage form. On 06-Nov-2021, the patient experienced HEPATIC FAILURE (Liver failure) (seriousness criteria death and medically significant) and ABDOMINAL PAIN (Abdominal pain) (seriousness criteria death and medically significant). The reported cause of death was Hepatic failure and Abdominal pain. It is unknown if an autopsy was performed. On 11/06/202, The patient went to the emergency room. Patient experienced generalized weakness/asthenia and acute weakness/inability to walk, and had a pain index [score of] 0 points, generalized weakness and sallow facial complexion. GCS: E4V5M6. Medical history included HTN, DM, hyperlipidemia, CKD, Borderline dilated pancreatic duct, high amlase [sic: amylase], lipase, Chronic liver Disease, Bil. renal parenchymal disease.(ECHO 1090330) CBD dilate (echo 1090706) CLD Mild to moderate fatty liver, uneven fat distribution r/o Left hydronephorsis [sic: hydronephrosis] (echo 1090706) Left renal multiple cysts and stones (echo 1090706),BPH Insomnia, bronchtiis [sic: bronchitis], Smoker. Laboratory data included BP 148 / 81 mmHg, HR: 137 beats/minute, RR: 18 breaths/minute, BT: 38.1°C, SpO2: 97%. WBC21.86x1000/uLRBC2.41x10^6/uL, Hgb7.2g/dL, PLT450x1000/uL, ALP931IU/L, Tropo-I3.244ng/mL, Lactate2.6m mol/L, PT(INR)2.05, Sugar279mg/dL, Bil (Total)19.5mg/dL Bil (Direct)>10mg/dL, GOT185IU/L, GPT169IU/L, Lipase32U/L, CRP193.48mg/L, Urea N40.8mg/dL, Creatinine1.78mg/dL Na131.7mmol/L K4.2m mol/L, Tropo-I1.876ng/mL, Ammonia141µg/dL. On 10/06, the patient's COVID-19 nucleic acid test was negative. Concomitant medications included Piperacillin 2g+Tazobactam 0.25g (Tazocin compound/Vial) 1 Vial Q6H IVD Acetylsalicylic acid (Bokey 100mg/Cap) 3 Cap PO ST 1 day Ticagrelor (Brilinta 90mg/Tab) 2 Tab PO ST 1 day Pantoprazole (Pantoloc 40mg/Vial) 1 Vial Q12H IVD Albumin (Plasbumin 25%, 12.5g/50mL/Bot) 1 Bot ST IVD 1 day Tranexamic acid (Tranexamic acid 250mg/5mL/Amp) 2 Amp ST IVD 1 day 11/7 ER-expired. The patient received the first dose of the Moderna [vaccine] at Kaohsiung Veterans General Hospital on 07/15/2021 The relevant diagnosis results were sepsis, myocardial infarction (NSTEMI), gastrointestinal bleeding, unconfirmed suspected jaundice, inflammatory liver disease, and chronic kidney disease. Treatment for the events were not provided Company comment:This case concerns a 65-year-old male patient, with medical history of hypertension, diabetes, hyperlipidemia, chronic liver disease and smoker (reported in SD narrative), who experienced the serious unexpected events of hepatic failure and abdominal pain with fatal outcome after second dose of mRNA-1273. The patient experienced after vaccination chills, jaundice, generalized weakness, asthenia, inability to walk, had pain and sallow facial complexion. As per SD narrative the patient´s relevant diagnosis results were sepsis, myocardial infarction (NSTEMI), gastrointestinal bleeding, unconfirmed suspected jaundice, inflammatory liver disease, and chronic kidney disease. The fatal outcome occurred 17 days after second dose. Patient´s medical history could be contributing factors. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.	0	[redacted]

Case ID	Narrative (Complete)	MAH Comment	WW Identifier
[redacted]	This case was initially received via Takeda Pharmaceuticals (Reference number [redacted] on 01-Dec-2021. The most recent information was received on 07-Feb-2022 and was forwarded to Moderna on 14-Feb-2022. This case, initially reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by a physician, was received via the PMDA (Ref, [redacted]). On 07-Feb-2022, follow-up information was received from a physician. On 04-Dec-2020, the patient already had hepatic function disorder in another hospital. Blood test showed AST of 112 and ALT of 146. On 02-Apr-2021, the patient already had hepatic function disorder in another hospital. Blood test showed AST of 80 and ALT of 100. Administration of metformin hydrochloride 500 mg was started for diabetes mellitus. On an unknown date, body temperature before the vaccination: 36.1 degrees Celsius. On 07-Sep-2021, at 13:55, the patient received the 1st dose of the vaccine. On 10-Sep-2021, blood test showed AST of 152 and ALT of 179. It was presumed that hepatic function disorder developed. On an unknown date, body temperature before the vaccination: 36.1 degrees Celsius. On 05-Oct-2021, at 13:44, the patient received the 2nd dose of the vaccine. On 27-Oct-2021, pyrexia developed. On 03-Nov-2021, jaundice developed. On 07-Nov-2021, at 01:00, respiratory discomfort developed, and an emergency call was made. The patient experienced cardiopulmonary arrest in the ambulance. After transportation to the hospital, the heartbeat resumed. On arrival at the reporting hospital, the patient had haematemesis and underwent emergency endoscopy, and there was no bleeding point. The cause of cardio-respiratory arrest was uncertain by CT examination, a diagnosis of acute hepatic failure was made. The patient entered the ICU. Multimodality therapy including massive transfusion was also difficult to control upper gastrointestinal bleeding. The patient was confirmed dead. The cause of the death was circulatory failure, and there were no significant findings in the macroscopic findings. The outcome of pyrexia and cardio-respiratory arrest was unknown. The outcome of hepatic function disorder worsens, acute hepatic failure, upper gastrointestinal hemorrhage, and circulatory failure was reported as fatal. No follow-up investigation will be made. Reporter comments continuation: The onset of adverse events is not related to concomitant drugs. Lymphoma, which was not indicated, is suspected. The onset of adverse events is related to pathological factors of suspected lymphoma if hepatic infiltration is noted. Autopsy is ongoing. Follow-up received on 07-FEB-2022 Updated: Other Relevant History, Lab Data, Product Information, Event Information, Narrative, Reporter Comments Company Comment: The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	It was not possible to identify the cause of acute progression of hepatic function disorder by examinations including viral testing, and it is also uncertain whether the event had a causal relationship with the vaccine. The association with adverse events cannot be assessed. Hepatic function disorder may have worsened after the administration, and the onset of adverse events is temporally related to the timing of administration of this vaccine. See "narrative" section	[redacted]

Case ID	Narrative (Complete)	MAH Comment	WW Identifier
[redacted]	This spontaneous case was reported by a consumer and describes the occurrence of HEPATIC FAILURE (liver failure, person died with liver disease) in a female patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Chronic liver disease (chronic liver disease). On an unknown date, the patient received fourth dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On an unknown date, 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 HEPATIC FAILURE (liver failure, person died with liver disease) (seriousness criteria death, hospitalization and medically significant) and EXTRA DOSE ADMINISTERED (receiving two shots of the booster.). The patient died on an unknown date. The reported cause of death was Liver failure. It is unknown if an autopsy was performed. At the time of death, EXTRA DOSE ADMINISTERED (receiving two shots of the booster.) had resolved. Concomitant medication information was not provided by the reporter. Treatment medication information was not provided by the reporter. Reporter stated that a girl with chronic liver disease went into liver failure and had jaundice and also died in hospital after receiving two shots of the booster. Company comment: This is a spontaneous case concerning a female patient of an unknown age with concurrent medical condition of Chronic liver disease who experienced serious, unexpected event of hepatic failure. Vaccination dates and start date of the event were not provided. Reporter stated that a girl with chronic liver disease went into liver failure and had jaundice and also died in hospital after receiving two shots of the booster. Date of death was not disclosed. It is unknown if an autopsy was performed. Very limited information regarding this event has been provided at this time. Further information has been requested. Concurrent medical condition of Chronic liver disease remains a confounder. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 07-Jan-2022: Non-significant follow up appended	0	[redacted]

Case ID	Narrative (Complete)	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 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.	0	[redacted]

Case ID	Narrative (Complete)	MAH Comment	WW Identifier
[redacted]	This spontaneous case was reported by a non-health professional and describes the occurrence of APLASTIC ANAEMIA (Severe aplastic anemia/severe bone marrow atrophy (severe aplastic anemia cellularity 5%)), FEBRILE NEUTROPENIA (Febrile neutropenia with Klebsiella pneumoniae septicemia), KLEBSIELLA SEPSIS (Febrile neutropenia with Klebsiella pneumoniae septicemia), CIRCULATORY COLLAPSE (Circulatory system failure), RENAL FAILURE (Kidney failure), HEPATIC FAILURE (Liver failure), WOUND HAEMORRHAGE (While working, she had bleeding that was difficult to stop from a wounded), HAEMOPTYSIS (Coughing up blood in the morning) and DECREASED IMMUNE RESPONSIVENESS (Persistent low immunity) in a 50-year-old female patient who received mRNA-1273 (COVID-19 Vaccine Moderna) (batch no. 049F21A) for COVID-19 vaccination. The patient had no underlying disease. Previously administered products included for COVID-19 vaccination: Sinovac (Sinovac) on 08-Apr-2021, Sinovac (Sinovac) on 06-May-2021 and Pfizer (Pfizer) on 09-Aug-2021. Past adverse reactions to the above products included No adverse reaction with Pfizer, Sinovac and Sinovac. On 27-Dec-2021, the patient received fourth dose of mRNA-1273 (COVID-19 Vaccine Moderna) (unknown route) 1 dosage form. On 28-Dec-2021, the patient experienced APLASTIC ANAEMIA (Severe aplastic anemia/severe bone marrow atrophy (severe aplastic anemia cellularity 5%)) (seriousness criteria death, hospitalization and medically significant). On an unknown date, the patient experienced FEBRILE NEUTROPENIA (Febrile neutropenia with Klebsiella pneumoniae septicemia) (seriousness criteria death, hospitalization and medically significant), KLEBSIELLA SEPSIS (Febrile neutropenia with Klebsiella pneumoniae septicemia) (seriousness criteria death, hospitalization and medically significant), CIRCULATORY COLLAPSE (Circulatory system failure) (seriousness criteria death, hospitalization and medically significant), RENAL FAILURE (Kidney failure) (seriousness criteria death, hospitalization and medically significant), HEPATIC FAILURE (Liver failure) (seriousness criteria death, hospitalization and medically significant), WOUND HAEMORRHAGE (While working, she had bleeding that was difficult to stop from a wounded) (seriousness criteria death and hospitalization), HAEMOPTYSIS (Coughing up blood in the morning) (seriousness criteria death and hospitalization) and DECREASED IMMUNE RESPONSIVENESS (Persistent low immunity) (seriousness criterion medically significant). The patient was hospitalized for 60 days due to APLASTIC ANAEMIA, CIRCULATORY COLLAPSE, FEBRILE NEUTROPENIA, HAEMOPTYSIS, HEPATIC FAILURE, KLEBSIELLA SEPSIS, RENAL FAILURE and WOUND HAEMORRHAGE. The patient was treated with DEXAMETHASONE at a dose of High dose. The patient died on 03-Mar-2022. The reported cause of death was febrile neutropenia with klebsiella pneumoniae septicemia, severe aplastic anemia/severe bone marrow atrophy (severe aplastic anemia cellularity 5%), circulatory system failure, Kidney failure, Liver failure, while working, she had bleeding that was difficult to stop from a wounded, coughing up blood in the morning and febrile neutropenia with klebsiella pneumoniae septicemia. It is unknown if an autopsy was performed. At the time of death, DECREASED IMMUNE RESPONSIVENESS (Persistent low immunity) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 07-Sep-2021, Full blood count: normal (normal) normal. On 28-Dec-2021, Body temperature: high (High) High Fever. On an unknown date, Biopsy bone marrow: severe bone marrow atropy (abnormal) Severe Bone marrow atropy(Severe aplastic anemia, cellularity 5%). On an unknown date, Full blood count: severe low blood count (Low) Severe Low blood count and severe low blood count Came to hospital again and Complete Blood count was checked, result: Severe low blood count. On an unknown date, Haemoglobin: 10.4 (Low) 10.4 g/dl and 9.2 (Low) 9.2 g/dl. On an unknown date, Platelet count: 3000 (Low) 3000 cells/mm3 and less than 1000 (Low) less than 1000. On an unknown date, White blood cell count: 2,170 (Low) 2,170 cell/mm3 and 2000 (Low) 2000 cell/mm3. For mRNA-1273 (COVID-19 Vaccine Moderna) (Unknown), the reporter did not provide any causality assessments. Concomitant product use was not provided by the reporter. The patient received Moderna vaccine as the fourth dose on 27-Dec-2021, after that she experienced fever and low platelet count. A physician diagnosed the patient with severe aplastic anemia caused by receiving the vaccine. The patient experienced persistent low immunity and severe infection.	0	[redacted]

Case ID	Narrative (Complete)	MAH Comment	WW Identifier
	The patient had experienced headache, fever nausea, bruise on body, easy bruising without previous bumps, bruise on the body was not improving then she went to hospital. The symptoms had occurred 1 day after the fourth vaccination. She had received concentrated platelets and came back to work. Her condition was not improved then she came to the hospital again and then complete blood count was checked. She had a high fever and severe infection in the bloodstream. It had spread to circulatory system failure, kidney failure, liver failure and eventually death/passed away. Treatment for the event included treatment with the drug, the blood, and the blood product but condition was not improved, and the patient passed away on 03-Mar-2022 at 07.04 am. The vaccine recipient had received treatment for bruising. She had received concentrated platelets. She was treated with standard medication but was not responding. For the patient, the data had been collected and a joint meeting between a central post-vaccination adverse event expert panel and physicians who took care of the patient concluded that she had severe bone marrow atropy as a result, blood cells and platelets were very low. There was a potential for infection with K. pneumoniae bacteria in the bloodstream. For Acquired aplastic anemia, it could be caused by many reasons such as exposure to chemicals, radioactive substance or from the body's own immune dysfunction, cytotoxic T-cells were stimulated to destroy their own stem cells. Company comment: This case concerns a death of a 50-year-old female patient, with no medical history reported, who experienced the unexpected, serious (Hospitalization, Medically significant, Death) event of Aplastic anaemia, 01 day after and febrile neutropenia, klebsiella sepsis, circulatory collapse, hepatic failure, the events of wound haemorrhage, haemoptysis (Hospitalization, Death) and decreased immune responsiveness (Medically significant) on an unknown date after receiving the 4 dose of m RNA 1273 vaccine in the COVID-19 vaccination series. The patient was previously vaccinated with Sinovac vaccine (two doses) and the 3 dose with Pfizer vaccine about 4 months prior to the 4 dose, with no adverse reactions seen with Pfizer and Sinovac. Interchange of vaccine products was noted. As reported, after mRNA-1273 vaccination the patient experienced fever and low platelet count and a severe aplastic anemia was diagnosed. The patient experienced persistent low immunity and severe infection. On an unknown date, Biopsy bone marrow showed severe bone marrow atropy (abnormal) Severe Bone marrow atropy (Severe aplastic anemia, cellularity 5%), Severe Low blood counts(low Hb, WBC and platelets). Treatment for the event included dexamethasone at high dose, blood and the blood products but condition was not improved, and the patient passed away 2 months after Moderna vaccine administration. The reported cause of death was febrile neutropenia with klebsiella pneumoniae septicemia, severe aplastic anemia/severe bone marrow atrophy, circulatory system failure, Kidney failure, Liver failure, wound haemorrhage, and haemoptysis. At the time of death, decreased immune responsiveness had not resolved. Decreased immune responsiveness and infection were likely related to concurrent aplastic anemia. The benefit-risk relationship of mRNA-1273 is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 07-Mar-2022: Follow-up information received contains no new info		

Case ID	Narrative (Complete)	MAH Comment	WW Identifier
[redacted]	This case was received via Takeda Pharmaceuticals (Reference number: [redacted] on 18-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]). The vaccine recipient did not take any oral regular medication and antipyretics with no history of eating raw meat and no overseas travel history. The patient had no appreciable history. On an unknown date, the patient received the 1st dose of the COVID-19 vaccine (product name unknown). On 11-Aug-2021, around 13:00, the patient received the 2nd vaccination with the vaccine. On 12-Aug-2021, during the daytime, the patient noticed malaise. In the early evening, the patient experienced pyrexia, followed by queasy. At 19:00, acute hepatic failure with hepatic coma and hepatic function disorder developed. On an unknown date, the patient experienced vomiting and the course of the condition was monitored, but it did not improve. On 15-Aug-2021, as the patient also complained of feeling of dyspnea, an emergency call was made, and the patient was transported to a medical institution. At the time of transportation, blood pressure was unable to be measured, and generalized livedo reticularis was noted. Blood test showed renal disorder (BUN: 39.3, Cre: 3.19), coagulation disorder (PT%: 17, PT-INR: 3.48), and metabolic acidosis (pH: 6.866, pCO2: 49.9, HCO3-: 8.6). CT inspection showed no significant findings that could be the cause, and the patient underwent tracheal intubation and received a continuous dose of vasopressor (noradrenalin) and was transported to the reporting hospital. Immediately after arrival at the hospital, the patient developed cardiopulmonary arrest, and at that time the livedo reticularis was purple-black color that was almost similar to postmortem lividity. The blood test was performed which showed hepatic disorder (AST: 432, ALT: 510), renal disorder (BUN: 30.1, Cre: 2.24), coagulation disorder (PT: 21%, 2.21), and acidosis (7.2). Subsequently, the patient was admitted into an intensive-care unit but suffered cardiopulmonary arrest several times, and circulatory dynamics was gradually exacerbated although continuous dose of adrenaline, large amounts of fluid replacement, blood transfusion, and continuous blood purification therapy were performed. The patient mainly had metabolic acidosis, renal disorder, and circulation failure with no known causes. On 16-Aug-2021, at 16:49, the patient was confirmed dead. On an unknown date, pathological anatomy was performed. The hepatic findings suggested suspected fulminant hepatitis, and findings of mild myocarditis was also noted. Hepatitis-associated viruses were not measured. The outcome of generalized livedo reticularis was unknown. The outcome of acute hepatic failure with hepatic coma, renal disorder, coagulation disorder, metabolic acidosis, cardiopulmonary arrest, circulation failure, suspected fulminant hepatitis, and myocarditis was reported as fatal. Follow-up investigation was tried, but it was not possible because of non-cooperation of the reporter. Reporter comments continuation: Although the symptoms did not apply to the diagnostic criteria for acute hepatic failure, there were fewer findings in the blood test compared to acidosis considering the time course; therefore, acute hepatic failure was suspected based on coma and coagulation abnormality. In addition, the diagnosis of myocarditis was made based on the findings of pathological anatomy, and during the clinical course, supportive treatments were mainly given as the patient mainly had metabolic acidosis, renal disorder, and circulation failure with no known causes. Although it is difficult to judge how strongly the association is suggested and to understand what kind of disease status was caused by the association, it must be suspected that there was an association because the patient who did not have a medical history experienced malaise and pyrexia after the vaccination, finally resulting in cardiac arrest. Thus, this case was reported. As a result of discuss with the physician who performed the autopsy, it was found that the findings of fulminant hepatitis and myocarditis were prominent and that other changes were mainly associated with circulation failure and resuscitation. There were no findings strongly suggestive of infection or other causative diseases. In terms of exclusion of other diseases, it is possible that the items of the specimen examination were not sufficient. Follow-up received on 12-APR-2022 Updated: Lab Data, Narrative Company Comment: The events developed after the administration of ELASOMERAN and there is temporal relationship.	The patient who had no appreciable medical history experienced worsening of the general condition from the following day of vaccination, leading to metabolic acidosis, renal disorder, and coagulation disorder in several days, eventually resulted in cardiopulmonary arrest. The events developed after the administration of ELASOMERAN and there is temporal relationship.	[redacted]

Appendix 11.21h Autoimmune Hepatitis: Literature Search Methodology

(Acute hepatic failure) OR (Autoimmune hepatitis)) OR (Drug-induced liver injury)) OR (Hepatic failure)) OR (Hepatitis acute)) OR (Hepatitis fulminant)) OR (Hepatitis toxic)) OR (Hepatocellular injury)) OR (Hepatotoxicity)) OR (Immune-mediated hepatic disorder)) OR (Immune-mediated hepatitis)) OR (Liver injury))) AND ("mrna vaccines"[MeSH Terms] OR "2019 ncov vaccine mrna 1273"[MeSH Terms] OR ("2019 ncov vaccine mrna 1273"[MeSH Terms] OR ("2019 ncov"[All Fields] AND "vaccine"[All Fields] AND "mRNA 1273"[All Fields]) OR "2019 ncov vaccine mrna 1273"[All Fields] OR "mRNA 1273"[All Fields] OR "mRNA 1273"[All Fields] OR ("2019 ncov vaccine mrna 1273"[MeSH Terms] OR ("2019 ncov"[All Fields] AND "vaccine"[All Fields] AND "mRNA 1273"[All Fields]) OR "2019 ncov vaccine mrna 1273"[All Fields] OR "mrna1273"[All Fields]) OR ("modernatx"[All Fields] AND "1273"[All Fields]) OR "1273"[All Fields] OR ("2019 ncov vaccine mrna 1273"[MeSH Terms] OR ("2019 ncov"[All Fields] AND "vaccine"[All Fields] AND "mRNA 1273"[All Fields]) OR "2019 ncov vaccine mrna 1273"[All Fields] OR "m 1273"[All Fields]) OR "m 1273"[All Fields] OR ("moderna"[All Fields] AND ("covid 19 vaccines"[MeSH Terms] OR ("covid 19"[All Fields] AND "vaccines"[All Fields]) OR "covid 19 vaccines"[All Fields] OR ("covid19"[All Fields] AND "vaccine"[All Fields]) OR "covid19 vaccine"[All Fields])) OR "moderna covid 19 vaccine"[All Fields] OR "moderna covid 19 vaccine"[All Fields] OR "moderna covid 19 vaccine"[All Fields] OR "Spikevax"[All Fields] OR ("2019 ncov vaccine mrna 1273"[MeSH Terms] OR ("2019 ncov"[All Fields] AND "vaccine"[All Fields] AND "mRNA 1273"[All Fields]) OR "2019 ncov vaccine mrna 1273"[All Fields] OR "elasomeran"[All Fields]) OR "CX-024414"[All Fields] OR "tak 919"[All Fields] OR "tak 919"[All Fields] OR ("2019 ncov vaccine mrna 1273"[MeSH Terms] OR ("2019 ncov"[All Fields] AND "vaccine"[All Fields] AND "mRNA 1273"[All Fields]) OR "2019 ncov vaccine mrna 1273"[All Fields])) AND (2020/11/01:2022/06/18[Date - Publication] OR 2020/11/01:2022/06/18[Date - Create] OR 2020/11/01:2022/06/18[Date - Entry])

Appendix 11.22a SOCV: Detailed summary of Cumulative cases that met Brighton's Collaboration Level of diagnostic certainty 1 to 3, and their WHO-UMC causality assessment

Case ID	Patient Age (Years)	Patient Gender	ALL PT'S	Brighton Collaboration Classification	WHO/UMC Causality Assessment	MAH Comment	Narrative (Complete)
[redacted]	48	Female	Cutaneous vasculitis, Ecchymosis, Fibrin D dimer increased, Joint swelling, Myalgia, Pain in extremity, Petechiae, Pyrexia, Rash, Swelling	2	Possible	48 yo female with MHx of HPT who experienced hypersensitivity vasculitis 8 days following initial vaccine dose with elevated D dimer and CRP. Biopsy consistent. Also had other symptoms that are unclear if systemic or secondary to SOCV.	This regulatory authority case was reported by a physician (subsequently medically confirmed) and describes the occurrence of HYPERSENSITIVITY VASCULITIS (cutaneious leucocytoclastic vasculitis) and FIBRIN D DIMER INCREASED (Coagulation activation (elevated D-dimers)) in a 48-year-old female patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Hypertension arterial. Concomitant products included CANDESARTAN CILEXETIL (ATACAND) for an unknown indication. On 24-Feb-2021, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form. On 04-Mar-2021, the patient experienced HYPERSENSITIVITY VASCULITIS (cutaneious leucocytoclastic vasculitis) (seriousness criterion hospitalization prolonged), PAIN IN EXTREMITY (stabbing pains on the soles of both feet), RASH (exanthema in the area of both ankles extending to the arches of the feet) and SWELLING (swelling back of hand). On 05-Mar-2021, the patient experienced FIBRIN D DIMER INCREASED (Coagulation activation (elevated D-dimers)) (seriousness criterion hospitalization), JOINT SWELLING (painful swelling developed in the area of the left wrist and on the back of the hand), ECCHYMOSIS (ecchymosis in the medial ankles), PETECHIAE (petechiae in lower legs and the left forearm) and PYREXIA (febrile body temperature). On an unknown date, the patient experienced MYALGIA (muscle ache like pain in area of feet). The patient was hospitalized from 05-Mar-2021 to 09-Mar-2021 due to FIBRIN D DIMER INCREASED and HYPERSENSITIVITY VASCULITIS. In March 2021, HYPERSENSITIVITY VASCULITIS (cutaneious leucocytoclastic vasculitis) had resolved. At the time of the report, FIBRIN D DIMER INCREASED (Coagulation activation (elevated D-dimers)), PAIN IN EXTREMITY (stabbing pains on the soles of both feet), MYALGIA (muscle ache like pain in area of feet), RASH (exanthema in the area of both ankles extending to the arches of the feet), JOINT SWELLING (painful swelling developed in the area of the left wrist and on the back of the hand), SWELLING (swelling back of hand), ECCHYMOSIS (ecchymosis in the medial ankles), PETECHIAE (petechiae in lower legs and the left forearm) and PYREXIA (febrile body temperature) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 05-Mar-2021, Blood lactate dehydrogenase: 370 (abnormal) elevated. On 05-Mar-2021, C-reactive protein increased: 33.1 mg/l (abnormal) elevated. On 05-Mar-2021, Fibrin D dimer (0.19-0.5): 7.31 (abnormal) elevated and >5000 mcg/l (abnormal) elevated.

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							On 08-Mar-2021, Biopsy skin: abnormal (abnormal) The histopathology findings of the skin biopsy of 08-Mar-2021 were consistent with cutaneous leukocytoclastic small-vessel vasculitis in a somewhat later stage of evolution. No evidence of IgA or IgM in the immunofluorescence.. mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) was withdrawn on an unknown date. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered HYPERSENSITIVITY VASCULITIS (cutaneious leucocytoclastic vasculitis) and FIBRIN D DIMER INCREASED (Coagulation activation (elevated D-dimers)) to be possibly related. No further causality assessments were provided for PAIN IN EXTREMITY (stabbing pains on the soles of both feet), MYALGIA (muscle ache like pain in area of feet), RASH (exanthema in the area of both ankles extending to the arches of the feet), JOINT SWELLING (painful swelling developed in the area of the left wrist and on the back of the hand), SWELLING (swelling back of hand), ECCHYMOSIS (ecchymosis in the medial ankles), PETECHIAE (petechiae in lower legs and the left forearm) and PYREXIA (febrile body temperature). Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Reporter did not allow further contact Most recent FOLLOW-UP information incorporated above includes: On 06-Apr-2021: Translation follow-up received.
[redacted]	34	Female	Contusion, Cutaneous vasculitis, Erythema, Pain in extremity	3	Possible	34 yo female with cutaneous vasculitis 12 days after first dose of vaccine. No systemic complaints. No biopsy.	This case was received via [redacted] (Reference number: [redacted] on 06-Apr-2021 and was forwarded to Moderna on 06-Apr-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of CUTANEOUS VASCULITIS (Leukocytodastic Vasculitis) in a 34-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 025J20A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 23-Dec-2020, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 04-Jan-2021, the patient experienced CUTANEOUS VASCULITIS (Leukocytodastic Vasculitis) (seriousness criterion medically significant), ERYTHEMA (Erythema), CONTUSION (red painful bruises) and PAIN IN EXTREMITY (Pain in extremity). At the time of the report,

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							CUTANEOUS VASCULITIS (Leukocytodastic Vasculitis), ERYTHEMA (Erythema), CONTUSION (red painful bruises) and PAIN IN EXTREMITY (Pain in extremity) had not resolved. 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 concomitant medication were provided. 12 days after receiving the vaccine the patient developed red painful bruises to both feet that start mildly, but continued to worsen over the next several days. The patient went to see his dermatologist and was diagnosed with Leukocytodastic Vasculitis. Treatment medication was not provided. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Reporter did not allow further contact
[redacted]	52	Male	Cutaneous vasculitis	3	Possible	52 yo male with MHx of HPT and DM who experienced cutaneous vasculitis 17 days after second vaccine dose, D dimer elevated. No biopsy reported.	This case was initially received via European Medicines Agency (Reference number: [redacted] on 06-May-2021. The most recent information was received on 09-Jun-2022 and was forwarded to Moderna on 09-Jun-2022. This regulatory authority case was reported by a physician and describes the occurrence of CUTANEOUS VASCULITIS (Vasculitis) in a 52-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3000494) for COVID-19 vaccination. Concurrent medical conditions included Diabetes (Type II Diabetes) and Hypertension arterial (HTA). On 17-Feb-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 17-Mar-2021, received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. On 28-Mar-2021, after starting mRNA-1273 (Spikevax), the patient experienced CUTANEOUS VASCULITIS (Vasculitis) (seriousness criterion hospitalization). The patient was hospitalized on 04-Apr-2021 due to CUTANEOUS VASCULITIS. In 2021, CUTANEOUS VASCULITIS (Vasculitis) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):

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							On 07-Apr-2021, SARS-CoV-2 test: negative (Negative) Negative. On 08-Apr-2021, Fibrin D dimer: 1908 ng/ml 1908 ng/mL. On 08-Apr-2021, Ultrasound Doppler: observing the presence of a venous lumen Doppler MII: Doppler ultrasound of the miizDO is performed, observing the presence of a venous lumen occupied by multiple echogenic foci, with severe slowness in its movement, although it collapses to pressure with the transducer, which affects the venous lumen of the superficial femoral vein, with no venous flow at rest, although when resting distal pressure in calf presents venous flow with doppler filling, being compatible with severe slowing of venous flow which may be a prethrombotic stage if the state of venous vascular slowing remains. On an unknown date, Antiphospholipid antibodies: weak positive (Positive) weak positive lupus anticoagulant with a ratio of 1.34. On an unknown date, Biopsy skin: leukocytoclastic vasculitis In the findings of the anatomic pathology of the skin biopsy, a section of skin was seen that showed an epidermis without significant alterations with orthokeratin. In superficial dermis, marked signs of acute vascular damage were notable, showing a discrete peripheral lymphocytic infiltrate, with leukocytoclasis, hematic extravasation, deposit of fibrinoid material, isolated microthrombi and prominent endothelium. No accompanying eosinophils were identified. A mild edema of papillary dermis was associated, without other findings, and respecting the deep dermis. The initial suspected diagnosis of leukocytoclastic vasculitis was confirmed.. On an unknown date, Blood homocysteine: within normal range (normal) within normal range. On an unknown date, C-reactive protein: 1.34 mg/dl 1.34 mg/dL. On an unknown date, Cardiolipin antibody: within normal range (normal) within normal range. On an unknown date, Coombs direct test: negative (Negative) negative. On an unknown date, Electrophoresis protein: within normal range (normal) within normal range. On an unknown date, Full blood count: within normal range (normal) within normal range. On an unknown date, Immunoglobulins: within normal range (normal) within normal range. On an unknown date, Prothrombin time: 16.7 sec 16.7 sec. On an unknown date, Red blood cell sedimentation rate: within normal range (normal) within normal range. On an unknown date, Urine analysis: within normal range (normal) within normal range. For mRNA-1273 (Spikevax) (Unknown), the reporter considered CUTANEOUS VASCULITIS (Vasculitis) to be related. No concomitant medications were reported.

Case ID	Patient Age (Years)	Patient Gender	ALL PT'S	Brighton Collaboration Classification	WHO/UMC Causality Assessment	MAH Comment	Narrative (Complete)
							No treatment information was provided by the reporter. Company Comment: This regulatory authority case concerns a 52-year-old male patient, with no relevant medical history reported, who experienced the unexpected serious (hospitalization) AESI cutaneous vasculitis 11 days after receiving a second dose of mRNA-1273 vaccine. About 18 days after vaccination patient was admitted for an eight-day clinical picture of skin rash on both legs of non-pruritic erythematous appearance with petechiae up to the root of lower limbs, without disappearance upon diascopy. Notable laboratory tests were CRP 1.34 mg/dL; prothrombin time 16.7 seconds, weak positive lupus anticoagulant with a ratio of 1.34 and D-dimer of 1908 ng/mL; direct Coombs negative. Skin biopsy was done which confirmed the clinical impression of leukocytoclastic vasculitis in thighs and both ankles. Lesions disappeared with rest without the need for anti-inflammatory or steroid treatment. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 09-Jun-2022: Follow-up received include : Medical history (Diabetes, Hypertension arterial) added , Lab test (Doppler Scan) added. On 17-Jun-2022: Follow-up received on 17 Jun 2022-Reference number added On 17-Jun-2022: Follow-up received on 17 Jun 2022-Reference number added On 20-Jun-2022: Follow-up received on 20 Jun 2022-No new information received On 21-Jun-2022: Follow-up received on 21 Jun 2022-Reference number added, sender comment updated On 23-Jun-2022: Follow-up received on 23 Jun 2022-Reference number added
[redacted]	28	Male	Cutaneous vasculitis, Rash	2	Possible	24 yo male with cutaneous vasculitis and rash 2 days following his first dose of vaccine. No systemic symptoms, elevated CRP. Biopsy consistent with SOCV.	This case was received via [redacted] (Reference number: [redacted] on 18-May-2021 and was forwarded to Moderna on 18-May-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of CUTANEOUS VASCULITIS (Cutaneous vasculitis) in a 28-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 026L20A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 30-Dec-2020, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 01-Jan-2021, the patient experienced CUTANEOUS VASCULITIS (Cutaneous vasculitis) (seriousness criterion medically significant) and RASH (Rash). At the time of the

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							report, CUTANEOUS VASCULITIS (Cutaneous vasculitis) and RASH (Rash) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 01-Jan-2021, Red blood cell sedimentation rate (0-30): increased (High) increased. On 11-Feb-2021, Red blood cell sedimentation rate (0-30): increased (High) increased. On 01-Mar-2021, Biopsy skin: abnomal (abnormal) leukocytoclastic vasculitis. 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 concomitant medications were reported. Treatment information was not provided. Company comment:Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.
[redacted]	39	Female	Blood blister, Cutaneous vasculitis, Rash, Rash macular	1	Possible	39 yo female who experienced cutaneous vasculitis 11 days following her first vaccine dose. No systemic complaints. Biopsy consistent with SOCV. No abnormal labs reported.	This case was received via [redacted] (Reference number: [redacted] on 18-May-2021 and was forwarded to Moderna on 18-May-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of CUTANEOUS VASCULITIS (Cutaneous vasculitis) in a 39-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 011L20A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concomitant products included FLUOXETINE HYDROCHLORIDE (PROZAC) for an unknown indication. On 12-Jan-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 23-Jan-2021, the patient experienced CUTANEOUS VASCULITIS (Cutaneous vasculitis) (seriousness criterion medically significant), BLOOD BLISTER (Blood blister), RASH MACULAR (Rash macular) and RASH (Rash). The patient was treated with PREDNISONE for Leukocytoclastic vasculitis, at a dose of 1 dosage form. At the time of the report, CUTANEOUS VASCULITIS (Cutaneous vasculitis), BLOOD BLISTER (Blood blister), RASH MACULAR (Rash macular) and RASH (Rash) had not resolved.

Case ID	Patient Age (Years)	Patient Gender	ALL PT'S	Brighton Collaboration Classification	WHO/UMC Causality Assessment	MAH Comment	Narrative (Complete)
							DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 26-Jan-2021, Biopsy: abnormal (abnormal) leukocytoclastic vasculitis. On 26-Jan-2021, Blood test: normal (normal) normal. On 05-Mar-2021, Blood test: normal (normal) normal. 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. On 23JAN2021 the patient experienced red splotches on her leg and stomach. She went to urgent care on 26JAN2021 and had blood work done, which was normal. She was referred to a dermatologist and had a biopsy done. The dermatologist diagnosed her with Leukocytoclastic vasculitis and prescribed her prednisone for 3 weeks. When the patient stopped the steroids, she reported flaring up all over her body, red splotches and blood blisters from feet to neck. She was placed back on steroids. The patient does not plan on receiving her second dose.
[redacted]	53	Female	Arthralgia, Cutaneous vasculitis, Malaise, Pyrexia, Rash, Urinary tract infection, Vasculitic rash	2	Possible	53 yo female with history of multiple medical problems who presented with a cutaneous rash, cutaneous vasculitis and UTI one day following her first vaccine dose. Biopsy showed leukoclastic vasculitis.	This case was received via [redacted] (Reference number: [redacted] on 01-Jun-2021 and was forwarded to Moderna on 01-Jun-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of ARTHRALGIA (Arthralgia), CUTANEOUS VASCULITIS (Cutaneous vasculitis), MALAISE (Malaise), PYREXIA (Pyrexia), RASH (Rash), URINARY TRACT INFECTION (Urinary tract infection) and VASCULITIC RASH (Vasculitic rash) in a 53-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The patient's past medical history included Cholelithiasis (Alcohol use disorder), Depression, Gallbladder polyp (noted on 01/2021 - less than 5 mm - reimage in 6 months.), Hyperlipidemia, Vaginal dryness (Menopausal vaginal dryness), Prediabetes, Sleep difficult, Cataract and Mandible closed fracture. Concurrent medical conditions included Allergy to antibiotic, Hepatitis C virus genotype 3a positive, Cirrhosis liver, Cirrhosis biliary and GERD. Concomitant products included NITROFURANTOIN for Urinary tract infection. On 08-Apr-2021, the patient received dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 09-Apr-2021, the patient experienced

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							ARTHRALGIA (Arthralgia) (seriousness criterion hospitalization), CUTANEOUS VASCULITIS (Cutaneous vasculitis) (seriousness criteria hospitalization and medically significant), MALAISE (Malaise) (seriousness criterion hospitalization), PYREXIA (Pyrexia) (seriousness criterion hospitalization), RASH (Rash) (seriousness criterion hospitalization), URINARY TRACT INFECTION (Urinary tract infection) (seriousness criterion hospitalization) and VASCULITIC RASH (Vasculitic rash) (seriousness criterion hospitalization). At the time of the report, ARTHRALGIA (Arthralgia), CUTANEOUS VASCULITIS (Cutaneous vasculitis), MALAISE (Malaise), PYREXIA (Pyrexia), RASH (Rash), URINARY TRACT INFECTION (Urinary tract infection) and VASCULITIC RASH (Vasculitic rash) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 09-Apr-2021, Biopsy skin: showed leukocytoclastic vasculitis (Inconclusive) Showed leukocytoclastic vasculitis. 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. Treatment information was not provided. Company Comment: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.
[redacted]	77	Female	Cutaneous vasculitis	2	Possible	77 yo female with cutaneous vasculitis 4 days following her initial dose of vaccine. Biopsy revealed superficial necrosis and acute and subacute deep inflammation of skin appendages and vessels.	This regulatory authority case was reported by a physician and describes the occurrence of CUTANEOUS VASCULITIS ([redacted] in a 77-year-old female patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination. No medical history was provided by the reporter. Concomitant products included COLECALCIFEROL (VITAMIN D3 [redacted], ACETYLSALICYLIC ACID [redacted], ROSUVASTATIN and GINKGO BILOBA EXTRACT (TEBOKAN) for an unknown indication. On 29-Jan-2021, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form. On 02-Feb-2021, the patient experienced CUTANEOUS VASCULITIS [redacted] (seriousness criterion medically significant). In February 2021, CUTANEOUS VASCULITIS [redacted] was resolving.

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							DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In February 2021, Biopsy skin: unknown (abnormal) Superficial necrosis as well as acute to subacute deep-seated inflammation, involving skin adnexal structures and blood vessels. The action taken with mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) was unknown. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered CUTANEOUS VASCULITIS [redacted] to be possibly related. No treatment medications provided by the reporter Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. Most recent FOLLOW-UP information incorporated above includes: On 10-Jun-2021: Translation received on 18-JUN-2021 and has lab results.
[redacted]	67	Female	Cutaneous vasculitis	3	Possible	67 yo female with multiple medical comorbidities including reactivation of Epstein-Barr viremia, reported cutaneous vasculitis 14 days following her initial dose of vaccine. No biopsy was performed.	This case was received via [redacted] (Reference number: [redacted]) on 22-Jun-2021 and was forwarded to Moderna on 22-Jun-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of CUTANEOUS VASCULITIS (Cutaneous vasculitis) in a 67-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 016M20A) for COVID-19 vaccination. The patient's past medical history included Influenza like illness. Concurrent medical conditions included Biliary cirrhosis primary (Reported that the condition is under control), Depression, Anxiety, Hypertension and Migraine. Concomitant products included LORAZEPAM (ATIVAN), SERTRALINE HYDROCHLORIDE (ZOLOFT), VALACICLOVIR HYDROCHLORIDE (VALTREX), HYDROCHLOROTHIAZIDE, LOSARTAN POTASSIUM (HYZAAR), URSODIOL and SUMATRIPTAN (IMITREX [SUMATRIPTAN]) for an unknown indication. On 12-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 26-Feb-2021, the patient experienced CUTANEOUS VASCULITIS (Cutaneous vasculitis) (seriousness criterion medically significant). The patient was treated with PREDNISONE at a dose of 1 dosage form and

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							AZATHIOPRINE SODIUM (IMURAN [AZATHIOPRINE SODIUM]) at a dose of 1 dosage form. At the time of the report, CUTANEOUS VASCULITIS (Cutaneous vasculitis) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, SARS-CoV-2 test: negative (Negative) Negative result was reported. 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 patient experienced severe leukocytoclastic vasculitis and no further information on vasculitis was available. The reporter stated that the patient had an Epstein-Barr viremia that was thought to represent reactivation which was not the normal process. Company comment: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. Case is confounded by patient's comorbidities.
[redacted]	54	Female	Condition aggravated, Cutaneous vasculitis, Petechiae, Purpura	2	Possible	54 yo female with medical conditions included Iodine allergy, Penicillin allergy, Sulfonamide allergy (sulfa), Fibromyalgia, Breast cancer, Eczema and Rosacea on multiple ongoing medications. 28 days after her first vaccine dose (date of second vaccine dose unknown), she experienced Cutaneous vasculitis (time not specified), Petechiae, and Purpura. Skin biopsy showed leukocytoclastic vasculitis.	This case was received via [redacted] (Reference number: [redacted] on 06-Jul-2021 and was forwarded to Moderna on 06-Jul-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of CUTANEOUS VASCULITIS (Cutaneous vasculitis) in a 54-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 009C21A and 038A21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Iodine allergy, Penicillin allergy, Sulfonamide allergy (sulfa), Fibromyalgia, Breast cancer, Eczema and Rosacea. Concomitant products included AMLODIPINE BESILATE, BENAZEPRIL HYDROCHLORIDE (AMLODIPINE AND BENAZEPRIL HYDROCHLORIDE), ANASTROZOLE, CALCIUM, COLECALCIFEROL (CALCIUM +VIT D), DESONIDE and FLUTICASONE for an unknown indication. On 28-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On an unknown date, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 25-Apr-2021, the patient experienced CUTANEOUS VASCULITIS (Cutaneous vasculitis)

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							(seriousness criterion medically significant), CONDITION AGGRAVATED (Condition aggravated), PETECHIAE (Petechiae) and PURPURA (Purpura). At the time of the report, CUTANEOUS VASCULITIS (Cutaneous vasculitis), CONDITION AGGRAVATED (Condition aggravated), PETECHIAE (Petechiae) and PURPURA (Purpura) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 25-Apr-2021, Biopsy skin abnormal: leukocytoclastic vasculitis (abnormal) leukocytoclastic vasculitis. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Treatment information was not provided by the reporter. Labs on 25-Apr-2021 with unknown results include full blood count, metabolic function test, and urine analysis. Patient developed petechial and purpuric rash on both legs 2-3 days after the 1st Moderna vaccine dose and developed similar events after the 2nd shot. Company Comment: Very limited information regarding these events has been provided at this time and a causal relationship cannot be excluded.
[redacted]	35	Female	Urticarial vasculitis	1	Possible	35 yo female who reported rash approximately 4 days following both vaccine doses on the lower extremities. Patient developed petechial and purpuric rash on both legs 2-3 days after the 1st Moderna vaccine dose and developed similar events after the 2nd shot. This is a literature case. LITERATURE REFERENCE: Larson V, Seidenberg R, Caplan A, Brinster NK, Meehan SA, Kim RH. Clinical and histopathological spectrum of delayed adverse cutaneous reactions following COVID-19 vaccination. J Cutan Pathol. 2021	This literature-study case was reported in a literature article and describes the occurrence of URTICARIAL VASCULITIS (Urticarial vasculitis) in a 35-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. LITERATURE REFERENCE: Larson V, Seidenberg R, Caplan A, Brinster NK, Meehan SA, Kim RH. Clinical and histopathological spectrum of delayed adverse cutaneous reactions following COVID-19 vaccination. J Cutan Pathol. 2021 Concurrent medical conditions included Acne vulgaris, Allergic rhinitis and Erythema edematous (Patient continued to develop erythematous and edematous plaques on her trunk and extremities for five weeks at which time a skin biopsy was performed.). 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 URTICARIAL VASCULITIS (Urticarial vasculitis) (seriousness criterion medically significant). The patient was treated with METHYLPREDNISOLONE for Adverse event, at an unspecified dose and frequency and DAPSONE for Adverse event, at an unspecified dose and frequency. At the time of the

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							report, URTICARIAL VASCULITIS (Urticarial vasculitis) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In 2021, Biopsy skin: sparse interstitial (abnormal) sparse interstitial infiltrate with neutrophils and eosinophils, mild leukocytoclasia and few extravasated erythrocytes.Neutrophils were also seen within vessel walls where there were hints of fibrin deposition and persistence of lesion (Inconclusive) Persistence of lesion 5 week later led to biopsy which demonstrated evidence of vascular injury.. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter considered URTICARIAL VASCULITIS (Urticarial vasculitis) to be possibly related. Concomitant medications were not provided by the reporter. Additional treatment drugs included antihistamines. Patient developed urticarial vasculitis, required initiation of dapsone along with antihistamine to suppress her lesion. Patient cutaneous symptoms showed improvement after taking treatment medication. It was reported the clinical and histopathologic features of delayed cutaneous adverse reactions from 12 patients after receiving an mRNA COVID-19 vaccine. It was reported that the patient 9 development of urticaria within 24 hours of vaccination provided a strong temporal association. Reactivation of known urticarial vasculitis had been reported in one patient following an unspecified mRNA vaccine, however there have been no reports to date of de novo urticarial vasculitis following COVID-19 vaccination. Patient declined her second dose due to persistent symptoms. Company Comment: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. This case was linked to [redacted] (Patient Link).
[redacted]	53	Female	Cutaneous vasculitis	3	Possible	Minimal information provided for this 53 yo female who experienced cutaneous vasculitis 19 days after vaccine dose. No biopsy available.	This case was received via European Medicines Agency (Reference number [redacted] on 09-Aug-2021 and was forwarded to Moderna on 09-Aug-2021. This regulatory authority case was reported by a consumer and describes the occurrence of CUTANEOUS VASCULITIS [redacted] in a 53-year-old

Case ID	Patient Age (Years)	Patient Gender	ALL PT'S	Brighton Collaboration Classification	WHO/UMC Causality Assessment	MAH Comment	Narrative (Complete)
							female patient who received mRNA-1273 (Spikevax) (batch no. ABV3374) for Prophylactic vaccination. No Medical History information was reported. On 05-Mar-2021, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 24-Mar-2021, the patient experienced CUTANEOUS VASCULITIS [redacted] seriousness criteria hospitalization and medically significant). On 07-Apr-2021, CUTANEOUS VASCULITIS [redacted] had resolved. The action taken with mRNA-1273 (Spikevax) (Unknown) was unknown. No concomitant medications were reported. No treatment medications were reported. Company Comment: Limited information regarding the event has been provided at this time and a causal relationship cannot be excluded. Event term, onset date and outcome captured per SD Authority reporting. Event seriousness per assessment by Authority and per IME list Most recent FOLLOW-UP information incorporated above includes: On 25-Aug-2021: Non-significant follow up appended
[redacted]	50	Male	Cutaneous vasculitis, Muscular weakness, Myalgia, Petechiae	3	Possible	50 yo male with DM and hyperuricemia with the event of cutaneous vasculitis 13 days following vaccine dose (some inconsistencies in translation re: timing). ANA and CRP elevated. No biopsy reported.	This case was initially received via European Medicines Agency (Reference number: [redacted] on 25-Aug-2021. The most recent information was received on 25-Aug-2021 and was forwarded to Moderna on 30-Aug-2021. This regulatory authority case was reported by a consumer and describes the occurrence of CUTANEOUS VASCULITIS [redacted] PETECHIAE [redacted] and MYALGIA [redacted] in a 50-year-old male patient who received mRNA-1273 (Spikevax) for Prophylactic vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Arterial hypertension, Type 2 diabetes mellitus and Hyperuricaemia.

Case ID	Patient Age (Years)	Patient Gender	ALL PT'S	Brighton Collaboration Classification	WHO/UMC Causality Assessment	MAH Comment	Narrative (Complete)
							On 12-May-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 02-Apr-2021, the patient experienced CUTANEOUS VASCULITIS [redacted] (seriousness criteria hospitalization and medically significant), PETECHIAE [redacted] (seriousness criterion hospitalization) and MYALGIA [redacted] (seriousness criterion hospitalization). On an unknown date, the patient experienced MUSCULAR WEAKNESS (muscle weakness of the upper and lower leg). The patient was treated with CORTISONE for Adverse event, at an unspecified dose and frequency. On 25-May-2021, CUTANEOUS VASCULITIS [redacted] PETECHIAE [redacted] and MYALGIA (petechiale Einblutung beider Unterschenkel, V.a. leukozytoklastische Vaskulitis, Myalgin und muskuläre Schwäche der Ober- und Unterschenkel, Livedo) had not resolved. At the time of the report, MUSCULAR WEAKNESS (muscle weakness of the upper and lower leg) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Antinuclear antibody: increase (High) borderline elevated. On an unknown date, C-reactive protein: increase (High) CRP increase. The action taken with mRNA-1273 (Spikevax) (Intramuscular) was unknown. No concomitant medications were provided. Patient had petechial hemorrhage in both lower legs, suspected leukocytoclastic vasculitis, myalgia, and muscle weakness of the upper and lower legs, livedo.Symptoms rapidly alleviated after cortisone therapy. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Events

Case ID	Patient Age (Years)	Patient Gender	ALL PT'S	Brighton Collaboration Classification	WHO/UMC Causality Assessment	MAH Comment	Narrative (Complete)
							seriousness captured as per Regulatory Authority assessment in Source Document. Most recent FOLLOW-UP information incorporated above includes: On 25-Aug-2021: Translation recieved on3 0-Aug-2021.Lab data, treatment drug and inarrative updated.
[redacted]	54	Male	Ageusia, Asthenia, Feeling abnormal, Headache, Hypokinesia, Mucosal disorder, Purpura, Pyrexia, Rash, Rash erythematous, Secretion discharge, Somnolence	3	Possible	54 yo male who reported purpura, bleeding rash and erythematous rash 8 days following his first vaccine dose. He also reported ageusia, fever, and headache. No medical interaction was reported or Covid-19 evaluations. No biopsy.	This spontaneous case was reported by a consumer and describes the occurrence of PURPURA (hundreds of dots on the legs, they are bleeding), MUCOSAL DISORDER (blood all over his mucous, with a mix of yellow, grey and red mucous), RASH ERYTHEMATOUS (rash/red little dots all over the body), SECRETION DISCHARGE (blood all over his mucous, with a mix of yellow, grey and red mucous) and SOMNOLENCE (sleeping like crazy, sleeping 80 percent of the time) in a 54-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 054C21A and 066021A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 23-Jul-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 23-Aug-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 31-Jul-2021, the patient experienced PURPURA (hundreds of dots on the legs, they are bleeding), MUCOSAL DISORDER (blood all over his mucous, with a mix of yellow, grey and red mucous), RASH ERYTHEMATOUS (rash/red little dots all over the body), SECRETION DISCHARGE (blood all over his mucous, with a mix of yellow, grey and red mucous), SOMNOLENCE (sleeping like crazy, sleeping 80 percent of the time), HYPOKINESIA (can not move), ASTHENIA (lack of energy), AGEUSIA (can not taste anything), FEELING ABNORMAL (feels like "crap"), PYREXIA (Fever), HEADACHE (Headache), RASH (Rash both legs) and RASH (Rash all over). At the time of the report, PURPURA (hundreds of dots on the legs, they are bleeding) and RASH (Rash both legs) was resolving and MUCOSAL DISORDER (blood all over his mucous, with a mix of yellow, grey and red mucous), RASH ERYTHEMATOUS (rash/red little dots all over the body), SECRETION DISCHARGE (blood all over his mucous, with a mix of yellow, grey and red mucous), SOMNOLENCE (sleeping like crazy, sleeping 80 percent of the time), HYPOKINESIA (can not move), ASTHENIA (lack of energy), AGEUSIA (can not taste anything), FEELING ABNORMAL (feels like "crap"), PYREXIA (Fever), HEADACHE (Headache) and RASH (Rash all over) had not resolved. mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown) and mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosing remained unchanged.

Case ID	Patient Age (Years)	Patient Gender	ALL PT'S	Brighton Collaboration Classification	WHO/UMC Causality Assessment	MAH Comment	Narrative (Complete)
							Relevant concomitant medications included, Immune Vitamins were reported. Treatment information was not provided. Patient said that all the symptoms started 8 days after the first dose and he is still experiencing these symptoms. Most recent FOLLOW-UP information incorporated above includes: On 01-Sep-2021: Follow-up information included updated reporter address and contact details. On 09-Sep-2021: FU received: Patient reported with an image
[redacted]	51	Female	Cutaneous vasculitis	3	Possible	Case with very limited information. 51 yo female who had leukoplastic vasculitis diagnosis by dermatologist following vaccination. No dating provided. No medical evaluation or biopsy available.	This regulatory authority case was reported by an other health care professional and describes the occurrence of CUTANEOUS VASCULITIS (Cutaneous vasculitis / Severe Flare Up Of Leucocytoclastic Vasculitis Post Vaccination-Assessed By Derm To Be Possible Adr) in a 51-year-old female patient who received mRNA-1273 (COVID 19 Vaccine Moderna) for COVID-19 vaccination. No Medical History information was reported. 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 CUTANEOUS VASCULITIS (Cutaneous vasculitis / Severe Flare Up Of Leucocytoclastic Vasculitis Post Vaccination- Assessed By Derm To Be Possible Adr) (seriousness criterion medically significant). At the time of the report, CUTANEOUS VASCULITIS (Cutaneous vasculitis / Severe Flare Up Of Leucocytoclastic Vasculitis Post Vaccination- Assessed By Derm To Be Possible Adr) outcome was unknown. 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. Concomitant product use was not provided by the reporter. No treatment information was provided. Company comment: Based on the current available information and temporal association between the use of the product and the start of event, a causal relationship cannot be excluded. Very limited information regarding this event has been provided at this time. Further detailed information regarding temporal association (vaccination and event dates) is necessary.

Case ID	Patient Age (Years)	Patient Gender	ALL PT'S	Brighton Collaboration Classification	WHO/UMC Causality Assessment	MAH Comment	Narrative (Complete)
[redacted]	37	Female	Burning sensation, Feeling hot, Purpura, Rash erythematous, Swelling	3	Possible	37 yo female with history of drug allergy to fluconazole who reported burning sensation, feeling hot, purpura, erythrocytic rash and swelling 7 days following her initial dose. No biopsy reported.	This case was received via another Manufacturer (Reference number: [redacted] on 07-Sep-2021 and was forwarded to Moderna on 07-Sep-2021. The license partner had received the report from [redacted] Reference number: [redacted] This regulatory authority case was reported by an other health care professional and describes the occurrence of BURNING SENSATION (Burning sensation), FEELING HOT (Feeling hot), PURPURA (Purpura), RASH ERYTHEMATOUS (Rash erythematous) and SWELLING (Swelling) in a 37-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 003B21A) for COVID-19 vaccination. Concurrent medical conditions included Drug allergy (Fluconazole). Concomitant products included MELATONIN for an unknown indication. On 24-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On an unknown date, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 31-Mar-2021, the patient experienced BURNING SENSATION (Burning sensation), FEELING HOT (Feeling hot), PURPURA (Purpura), RASH ERYTHEMATOUS (Rash erythematous) and SWELLING (Swelling). At the time of the report, BURNING SENSATION (Burning sensation), FEELING HOT (Feeling hot), PURPURA (Purpura), RASH ERYTHEMATOUS (Rash erythematous) and SWELLING (Swelling) had not resolved. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. No treatment medications were reported.
[redacted]	59	Female	Fatigue, Purpura	3	Possible	59 yo female with multiple medical conditions including Sjogren's syndrome, and on multiple medications, reported fatigue and purpura, efflorescent purpura. Patient reported event started day following second vaccine dose and persisted 3 months. No medical evaluation or biopsy available.	This case was received via European Medicines Agency (Reference number: [redacted] on 08-Sep-2021 and was forwarded to Moderna on 08-Sep-2021. This regulatory authority case was reported by a physician and describes the occurrence of FATIGUE [redacted] and PURPURA [redacted] in a 59-year-old female patient who received mRNA-1273 (Spikevax) for Vaccination. The patient's past medical history included Backache, unspecified, Sjoegren's syndrome and Angioplasty (Recently had angioplasty in the groin). Concurrent medical conditions included Abdominal herniation, Gastric bypass NOS, Constipation chronic and Hypothyreosis.

Case ID	Patient Age (Years)	Patient Gender	ALL PT'S	Brighton Collaboration Classification	WHO/UMC Causality Assessment	MAH Comment	Narrative (Complete)
							Concomitant products included MACROGOL 4000, POTASSIUM CHLORIDE, SODIUM BICARBONATE, SODIUM CHLORIDE (MOVICOL [MACROGOL 4000;POTASSIUM CHLORIDE;SODIUM BICARBONATE;SODIUM CHLORIDE]), ACETYLSALICYLIC ACID, MAGNESIUM OXIDE [redacted], METHENAMINE HIPPURATE (HIPREX [METHENAMINE HIPPURATE]), LEVOMEPROMAZINE MALEATE (LEVOMEPROMAZINE ORION), BISACODYL (TOILAX) and FOLIC ACID (FOLSYRE ORIFARM) for an unknown indication. On 12-May-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) I dosage form. On 13-May-2021, the patient experienced FATIGUE ([redacted] (seriousness criterion disability) and PURPURA ([redacted] (seriousness criterion disability). At the time of the report, FATIGUE [redacted] and PURPURA [redacted] had not resolved. For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered FATIGUE [redacted] and PURPURA [redacted] to be possibly related. No treatment information was provided. Fatigue and efflorescent purpura after the second dose of COVID-19 vaccine. Both symptoms are persisting three months later. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Events seriousness was captured as per Regulatory Authority assessment in Source Document. Most recent FOLLOW-UP information incorporated above includes: On 08-Sep-2021: Translation document received on 13-Sep-2021, contain No new information.

Case ID	Patient Age (Years)	Patient Gender	ALL PT'S	Brighton Collaboration Classification	WHO/UMC Causality Assessment	MAH Comment	Narrative (Complete)
[redacted]	70	Female	Purpura	3	Possible	Minimal information for a 70 yo female who reported purpura starting 12 days following vaccination (dose number not provided). No biopsy reported.	This case was received via European Medicines Agency (Reference number: [redacted] on 10-Sep-2021 and was forwarded to Moderna on 10-Sep-2021. This regulatory authority case was reported by a physician and describes the occurrence of PURPURA (Purpura) in a 70-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 214009) for COVID-19 vaccination. No Medical History information was reported. On 16-Jul-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 28-Jul-2021, after starting mRNA-1273 (Spikevax), the patient experienced PURPURA (Purpura). At the time of the report, PURPURA (Purpura) was resolving. mRNA-1273 (Spikevax) (Intramuscular) was withdrawn on 16-Jul-2021. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No relevant concomitant medications were reported. No treatment information was provided. Most recent FOLLOW-UP information incorporated above includes: On 10-Sep-2021: Translation document received on 16-Sep-2021 contains no new information.
[redacted]	54	Male	Contusion, Pruritus, Purpura, Submaxillary gland enlargement	3	Possible	54 yo male who had a MHx of Vit D deficiency who reported contusions, pruritic, purpura, sub-maxillary node enlargement, bruising and swelling in both axillae. No biopsy available.	This case was received via [redacted] (Reference number: [redacted] on 14-Sep-2021 and was forwarded to Moderna on 14-Sep-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of CONTUSION (Contusion), PRURITUS (Pruritus), PURPURA (Purpura) and SUBMAXILLARY GLAND ENLARGEMENT (Submaxillary gland enlargement) in a 54-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The patient's past medical history included Vitamin D deficiency. Concomitant products included CHOLECALCIFEROL for an unknown indication. On 02-Apr-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 04-Apr-2021, the patient experienced CONTUSION (Contusion), PRURITUS (Pruritus), PURPURA (Purpura) and SUBMAXILLARY GLAND ENLARGEMENT (Submaxillary gland enlargement). At the time of the report, CONTUSION (Contusion), PRURITUS (Pruritus), PURPURA (Purpura) and

Case ID	Patient Age (Years)	Patient Gender	ALL PT'S	Brighton Collaboration Classification	WHO/UMC Causality Assessment	MAH Comment	Narrative (Complete)
							SUBMAXILLARY GLAND ENLARGEMENT (Submaxillary gland enlargement) had not resolved. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No treatment medication was reported. No Concomitant medication was reported. Patient developed large bruising and swelling in both axilla, this lasted several months. Now has some small patches of purpura in axilla witch itch. Patient ordered CBC (laboratory investigation).
[redacted]	46	Male	Purpura, Vaccination site pain	3	Possible	46 yo male who reported bruising of about 3 cm diameter in 5 spots occurring 7 days following his first vaccine dose. No other information or biopsy available.	This case was received via [redacted] Reference number [redacted] on 05-Aug-2021 and was forwarded to Moderna on 18-Sep-2021. This case was reported by a vaccine recipient via the Drug Information Center. On 15-Jul-2021, the patient received the 1st dose of this vaccine. After the vaccination, vaccination site pain developed. On 22-Jul-2021, bruising of about 3 cm in diameter developed in 5 spots. On an unknown date, bruising disappeared. The outcome of vaccination site pain and bruising was reported as resolved. No follow-up investigation will be made.
[redacted]	45	Female	Dizziness, Dyspnoea, Eczema, Fatigue, Hypersensitivity, Pruritus, Rash, Urticarial vasculitis, Vasculitis, Vomiting	3	Possible	45 yo female who reported hypersensitive and vasculitis 6 days following her initial vaccine dose. She also reported hospitalization 2 months later with dizziness, fatigue, hypersensitivity, pruritis, rash, vasculitis, urticarial vasculitis, and vomiting. It is unclear if this was persistent from initial events. No medical evaluation or biopsy available.	This regulatory authority case was reported by a consumer and describes the occurrence of HYPERSENSITIVITY (Hypersensitivity reaction), VASCULITIS (Vasculitis), URTICARIAL VASCULITIS (urticaria vasculitis) and ECZEMA (acute eczema) in a 45-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. On 15-Jul-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 21-Jul-2021, the patient experienced HYPERSENSITIVITY (Hypersensitivity reaction) (seriousness criterion hospitalization prolonged) and VASCULITIS (Vasculitis) (seriousness criteria hospitalization prolonged and medically significant). On an unknown date, the patient experienced URTICARIAL VASCULITIS (urticaria vasculitis) (seriousness criteria hospitalization and medically significant) and ECZEMA (acute eczema) (seriousness criterion hospitalization). The patient was hospitalized from 04-Sep-2021 to 10-Sep-2021 due to DIZZINESS, DYSPNOEA,

Case ID	Patient Age (Years)	Patient Gender	ALL PT'S	Brighton Collaboration Classification	WHO/UMC Causality Assessment	MAH Comment	Narrative (Complete)
							FATIGUE, HYPERSENSITIVITY, PRURITUS, RASH, VASCULITIS and VOMITING. On 11-Sep-2021, HYPERSENSITIVITY (Hypersensitivity reaction) had resolved. At the time of the report, VASCULITIS (Vasculitis), URTICARIAL VASCULITIS (urticaria vasculitis) and ECZEMA (acute eczema) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. Oral steroid and anti-itch cream were used as treatment and icing is recommended to relieve discomfort. The patient was hospitalized and diagnosed with Urticaria vasculitis and acute eczema after vaccination. Company Comment: This case concerns a 45-year-old, female patient with no relevant medical history, who experienced the unexpected events of dyspnea, hypersensitivity, vasculitis, vomiting, dizziness, fatigue, pruritus, rash, urticaria vasculitis and acute eczema. The events dyspnea, hypersensitivity, vasculitis, vomiting, dizziness, fatigue, pruritus, rash occurred 6 days after mRNA-1273 vaccine administration while the events urticaria vasculitis and acute eczema occurrence unknown with respect to mRNA-1273 vaccine administration. The rechallenge was not applicable, as the event happened after the first dose. The events were considered related to the product per the reporter's assessment. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.
[redacted]	64	Female	Cholestasis, Vascular purpura	3	Possible	64 yo female reported to have experienced vascular purpura and cholestasis starting 3 days following her first vaccine dose. No additional information or biopsy reported.	This case was received via European Medicines Agency (Reference number[redacted] on 17-Sep-2021 and was forwarded to Moderna on 17-Sep-2021. This regulatory authority case was reported by a physician and describes the occurrence of VASCULAR PURPURA (Purpura vascular) and CHOLESTASIS (Cholestasis) in a 64-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 3002616) for COVID-19 vaccination. Concurrent medical conditions included Thrombophlebitis, Uterine fibroid, Congenital hydrocephalus, Hypercholesterolaemia since 1997, Ovarian cyst NOS, Hypothyroidism, Major depressive disorder NOS and Type II diabetes mellitus since 1997. On 03-Jun-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 06-Jun-2021, the patient experienced VASCULAR PURPURA (Purpura vascular) (seriousness criterion hospitalization) and CHOLESTASIS (Cholestasis) (seriousness criterion medically significant). At the time of the report, VASCULAR PURPURA

Case ID	Patient Age (Years)	Patient Gender	ALL PT'S	Brighton Collaboration Classification	WHO/UMC Causality Assessment	MAH Comment	Narrative (Complete)
							(Purpura vascular) was resolving and CHOLESTASIS (Cholestasis) had not resolved. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Concomitant medication was not provided. Treatment medication was not provided. Company Comment: This case concerns a 64-year-old, female patient with relevant medical history of thrombophlebitis, who experienced the unexpected events of vascular purpura and cholestasis. The events occurred approximately 4 days after the first dose of Spikevax. The rechallenge was not applicable, as the events happened after the first dose. The events was considered related to the product per the reporter's assessment. The benefit-risk relationship of Spikevax is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 17-Sep-2021: Translation document received on 23-Sep-2021 included no new information.
[redacted]	41	Female	Cognitive disorder, Contusion, Cutaneous vasculitis, Dyspnoea exertional, General physical health deterioration, Memory impairment, Microcytic anaemia, Myalgia, Petechiae, Pyrexia, Rash, Retinal haemorrhage, Sleep disorder	3	Possible	41-year-old, female patient with no previous relevant medical history, who experienced the unexpected events of microcytic anemia, cutaneous vasculitis, sleep disorder, retinal hemorrhage, myalgia, memory impairment, cognitive disorder, petechiae, and contusion. The events occurred 13 days after her second vaccine dose except cutaneous vasculitis which happened on the same day after the second dose of vaccine. The reporter assessed the events as possible.	This case was received via European Medicines Agency (Reference number: [redacted] on 17-Sep-2021 and was forwarded to Moderna on 17-Sep-2021. This regulatory authority case was reported by a physician and describes the occurrence of MICROCYTIC ANAEMIA [redacted], CUTANEOUS VASCULITIS [redacted], SLEEP DISORDER [redacted] RETINAL HAEMORRHAGE [redacted], MYALGIA [redacted] MEMORY IMPAIRMENT [redacted] COGNITIVE DISORDER [redacted], PETECHIAE [redacted] and CONTUSION [redacted] in a 41-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 3001946) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Asthma [redacted] and Allergy [redacted]. On 28-May-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 28-May-2021, the patient experienced CUTANEOUS VASCULITIS [redacted](seriousness criteria disability and medically significant), RASH [redacted], DYSPNOEA EXERTIONAL [redacted] GENERAL PHYSICAL HEALTH DETERIORATION [redacted] and PYREXIA [redacted]. On 11-Jun-2021, the patient experienced MICROCYTIC ANAEMIA

Case ID	Patient Age (Years)	Patient Gender	ALL PT'S	Brighton Collaboration Classification	WHO/UMC Causality Assessment	MAH Comment	Narrative (Complete)
							[redacted] (seriousness criteria disability and medically significant), SLEEP DISORDER [redacted] (seriousness criterion medically significant), RETINAL HAEMORRHAGE [redacted] (seriousness criterion medically significant), MYALGIA [redacted] (seriousness criterion medically significant), MEMORY IMPAIRMENT [redacted] (seriousness criterion medically significant), COGNITIVE DISORDER [redacted] (seriousness criterion medically significant), PETECHIAE [redacted] (seriousness criterion medically significant) and CONTUSION [redacted] (seriousness criterion medically significant). On 04-Jun-2021, PYREXIA [redacted] had resolved. At the time of the report, MICROCYTIC ANAEMIA [redacted] CUTANEOUS VASCULITIS [redacted], SLEEP DISORDER [redacted], RETINAL HAEMORRHAGE [redacted], MYALGIA [redacted], MEMORY IMPAIRMENT [redacted] COGNITIVE DISORDER [redacted], PETECHIAE [redacted] CONTUSION [redacted] DYSPNOEA EXERTIONAL [redacted] and GENERAL PHYSICAL HEALTH DETERIORATION [redacted] was resolving and RASH [redacted] had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 28-May-2021, Body temperature: high (High) >40 degrees Celsius.. In 2021, Biopsy skin: abnormal (abnormal) No findings of eosinophils, conclusion of chronic vasculitis, uncertain association with vaccination. Biopsies are taken more than 48 hours after onset (patient / doctor delay).. In 2021, Blood test: abnormal (abnormal) Findings of microcytic anemia and some isolated abnormal blood tests (ASAT).. For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered MICROCYTIC ANAEMIA [redacted], CUTANEOUS VASCULITIS [redacted] SLEEP DISORDER [redacted] RETINAL HAEMORRHAGE [redacted] MYALGIA [redacted] MEMORY IMPAIRMENT [redacted], COGNITIVE DISORDER [redacted] PETECHIAE [redacted] CONTUSION [redacted] RASH [redacted], DYSPNOEA EXERTIONAL [redacted], GENERAL PHYSICAL HEALTH

Case ID	Patient Age (Years)	Patient Gender	ALL PT'S	Brighton Collaboration Classification	WHO/UMC Causality Assessment	MAH Comment	Narrative (Complete)
							DETERIORATION [redacted] and PYREXIA [redacted] to be possibly related. No concomitant medication reported. No Treatment Medication reported. Company comment: This case concerns a 41-year-old, female patient with no previous relevant medical history, who experienced the unexpected events of microcytic anemia, cutaneous vasculitis, sleep disorder, retinal hemorrhage, myalgia, memory impairment, cognitive disorder, petechiae, and contusion. The events occurred 13 days after except cutaneous vasculitis which happened on the same day after the first dose of mRNA-1273 (Moderna COVID-19 Vaccine). The rechallenge was not applicable since only information about the first dose was disclosed. The reporter assessed the events as possible. The benefit-risk relationship of mRNA-1273 (Moderna COVID-19 Vaccine) is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 17-Sep-2021: Translation received on 23-Sep-2021 included no new information.
[redacted]	35	Female	Purpura	3	Possible	35 yo female who experienced purpura 7 days after her initial vaccine dose. Her MHx included asthma, Supraventricular tachycardia, and epilepsy. No biopsy was reported.	This case was received via European Medicines Agency (Reference number: [redacted] on 22-Sep-2021 and was forwarded to Moderna on 22-Sep-2021. This regulatory authority case was reported by a physician and describes the occurrence of PURPURA (Purpura) in a 35-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 3002537) for COVID-19 vaccination. Concurrent medical conditions included Epilepsy (Primary generalized epilepsy), Asthmatic, Agenesis depressor anguli oris muscle (Right lower limb agenesis) and Tachycardia supraventricular (SVT). On 03-Jun-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form once a day. On 10-Jun-2021, after starting mRNA-1273 (Spikevax), the patient experienced PURPURA (Purpura). At the time of the report, PURPURA (Purpura) was resolving. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medication reported. No treatment information was provided. Most recent FOLLOW-UP information incorporated above includes: On 22-Sep-2021: Translation Document Received on 27-Sep-2021and medical history was added.

Case ID	Patient Age (Years)	Patient Gender	ALL PT'S	Brighton Collaboration Classification	WHO/UMC Causality Assessment	MAH Comment	Narrative (Complete)
[redacted]	67	Female	Cutaneous vasculitis	3	Possible	67 yo female who reported purpura 11 days following a vaccine dose (unknown number). She reported purpura had resolved 2 weeks later. No biopsy was performed.	This case was received via European Medicines Agency (Reference number: [redacted] on 24-Sep-2021 and was forwarded to Moderna on 24-Sep-2021. This regulatory authority case was reported by a consumer and describes the occurrence of CUTANEOUS VASCULITIS ([redacted] in a 67-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 3002330) for COVID-19 vaccination. Concurrent medical conditions included Hypothyroidism. Concomitant products included LEVOTHYROXINE SODIUM (EUTIROX) for Hypothyroidism. On 17-May-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 28-May-2021, the patient experienced CUTANEOUS VASCULITIS ([redacted] (seriousness criterion medically significant). On 13-Jun-2021, CUTANEOUS VASCULITIS ([redacted] had resolved. mRNA-1273 (Spikevax) (Intramuscular) was withdrawn on 17-May-2021. No treatment medication provided. Company Comment: This case concerns a 67-year-old female patient with no relevant history, who experienced the unexpected serious event of Cutaneous vasculitis. The event occurred 12 days after unpecified dose of (Spikevax). The rechallenge was not applicable as there is no information regarding the doses. The benefit-risk relationship of Spikevax is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 24-Sep-2021: Translation received on 29-SEP-2021: Concomitant drug information updated.
[redacted]	65	Female	Cutaneous vasculitis	3	Possible	65F enrolled in clinical trial who experienced cutaneous vasculitis 9 days after receiving Spikevax. Patient has multiple medical conditions and concomitant medications that may be contributory, however assessment by clinical investigator led to high suspicion for leukocytoclastic vasculitis but no biopsy performed. Case assess as BC level 3 and WHO-UMC casuality assessed as possibel based on temporal association.	This report was received from business partner GlaxoSmithKline, with assigned Manufacturer Control Number of [redacted] This 65-year-old female subject was enrolled in an open label study titled A Phase III, randomized, open-label, controlled, multi-center study to evaluate the immune response and safety of both Herpes Zoster subunit vaccine in healthy adults aged 50 years and older AND the influenza virus vaccine in healthy adults aged 18 years and older when administered sequentially or co-administered with mRNA-1273 booster vaccination. The subject received the 1st dose of COVID-19 Vaccine Moderna (intramuscular) .5 ml

Case ID	Patient Age (Years)	Patient Gender	ALL PT'S	Brighton Collaboration Classification	WHO/UMC Causality Assessment	MAH Comment	Narrative (Complete)
							on 4th November 2021 11:48, for prophylaxis. The subject's past medical history included uterine fibroid, appendicitis, gallstones and mental disorder. Concurrent medical conditions included bipolar disorder, depression, asthma, hyperlipidemia, hypertension and arthritis. Concomitant products included INFLUENZA VACCINE, COVID-19 VACCINE, lamotrigine (Lamictal), fluticasone furoate + umeclidinium bromide + vilanterol trifenatate (Trelegy Ellipta), cariprazine hydrochloride (Vraylar), atorvastatin, amlodipine, lisinopril, valproic acid (Depakote) and duloxetine hydrochloride (Cymbalta). On 13th November 2021, 9 days after receiving COVID-19 Vaccine Moderna, the subject developed mild - grade 1 leukocytoclastic vasculitis (Non-serious). The outcome of leukocytoclastic vasculitis was recovered/resolved on 18th November 2021. The investigator considered that there was a reasonable possibility that the leukocytoclastic vasculitis may have been caused by COVID-19 Vaccine Moderna. Investigator comments: Subject presented in office with a rash that began on neck and continued to both arms and legs. Subject was not in distress, and sub-investigator examined the rash. Sub-I determined the rash to be leukocytoclastic vasculitis. subject was instructed to call office with any worsening, but subject was eligible to receive shingles vaccination per sub-I. Information received on 22Nov2021: Event: Subject is a 65 year-old female who was randomized and dosed with mRNA booster in HZ Sequential group on 04 November 2021. On 13 November 2021 the subject developed a rash on herneck described as "red dots" starting on her neck and spreading eventually on to the arms and then legs. The rash was initially pruritic but this resolved fairly quickly. She was seen by the sub-PI who is a pulmonologist and diagnosed with "leukocytoclastic vasculitis". There was no dermatology consult done and no treatment administered. Subject received HZ vaccine on schedule. MHx: mental disorder NOS/HTN/Uterine fibroid/hyperlipidemia/appendicitis Medications: Cymbalta/Lamictil/Trillogy/Vrelar/atorvastatin/amlodipine/Lisinopril The SC is making a follow-up call to the subject today. I will be contacting the Sub-PI or PI once I get some f/u information from the SC (will f/u this evening or in the morning). Clearly, we need more information as the diagnosis of small vessel WBC mediated vasculitis usually requires blood testing +/- biopsy. Would be interested to know if the subject had palpable purpura. Not sure why the HZ vaccine was given in this scenario.

Case ID	Patient Age (Years)	Patient Gender	ALL PT'S	Brighton Collaboration Classification	WHO/UMC Causality Assessment	MAH Comment	Narrative (Complete)
							Information received on 19Jan2022: Rationale for Related Assessment: per sub investigator: subject's symptoms developed post mrna-1273 vaccination. there is a reasonable possibility that the event may have been caused by mrna-1273 vaccination but not study procedure. Narrative remark: Sub investigator did not request any tests to be performed as the case could be identified upon visual examination. This case contains an event assessed by the investigator as a non-serious adverse event of special interest (AESI). This case contains an event assessed by the investigator as a non serious possible immune mediated disorder (pIMD). Follow-up information received on 01-JUN -2022. This follow-up was considered non-significant Summary of changes: No new information Investigator text: subject presented in office with a rash that began on neck and continued to both arms and legs. subject was not in distress, and sub-investigator examined the rash. sub-i determined the rash to be leukocytoclastic vasculitis. subject was instructed to call office with any worsening, but subject was eligible to receive shingles vaccination per sub-i. sub investigator did not request any tests to be performed as the case could be identified upon visual examination. Follow-up information received on 06-JUN-2022, 10-JUN-2022 This follow-up was considered significant. Summary of changes: Narrative updated Company comment: This case concerns a 65-year-old female subject with a medical history of bipolar disorder, depression, asthma, hyperlipidemia, hypertension and arthritis, among others who experienced the unlisted non-serious adverse event of special interest of grade I leukocytoclastic vasculitis. The event occurred 9 days after the 1st dose of COVID-19 Vaccine Moderna. The event was considered resolved. The event was considered related to IP in agreement with the Investigator based on close temporal association and nature of the event.
[redacted]	14	Female	Cutaneous vasculitis, Fatigue, Pyrexia	1	Unassessable	Literature report of a 14-year-old female patient who received mRNA-1273 and on an unknown date, experienced cutaneous vasculitis with biopsy findings of infiltration of lymphocytes into the subcutaneous vessel wall with fibrinoid necrosis. No medical history or concomitant medications were provided. Laboratory evaluation including WBC, Rh factor, ESR, C3/C4, ANCA, ANA was normal except for slightly elevated CRP. In light of the missing information that would	This literature-non-study case was reported in a literature article and describes the occurrence of CUTANEOUS VASCULITIS (cutaneous arteritis/ cutaneous polyarteritis nodosa) in a 14-year-old female patient who received mRNA-1273 (COVID 19 Vaccine Moderna) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. LITERATURE REFERENCE:

Case ID	Patient Age (Years)	Patient Gender	ALL PT'S	Brighton Collaboration Classification	WHO/UMC Causality Assessment	MAH Comment	Narrative (Complete)
						be beneficial in further characterizing causality, WHO-UMC causality is classified as unassessable.	Ogawa T, Aitake U, Nomura T. Cutaneous arteritis following mRNA-1273 Moderna COVID-19 vaccination. J Eur Acad Dermatol Venereol. 2022 No Medical History information was reported. On an unknown date, the patient received second dose of mRNA-1273 (COVID 19 Vaccine Moderna) (unknown route) 1 dosage form. On an unknown date, the patient experienced CUTANEOUS VASCULITIS (cutaneous arteritis/ cutaneous polyarteritis nodosa) (seriousness criterion medically significant). an unknown date, the patient experienced PYREXIA (fever) and FATIGUE (fatigue). The patient was treated with LOXOPROFEN ongoing since an unknown date for Arteritis, at an unspecified dose and frequency. At the time of the report, CUTANEOUS VASCULITIS (cutaneous arteritis/ cutaneous polyarteritis nodosa) was resolving and PYREXIA (fever) and FATIGUE (fatigue) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Antineutrophil cytoplasmic antibody: normal (normal) Normal. On an unknown date, Antinuclear antibody: normal (normal) Normal. On an unknown date, Biopsy skin: abnormal (abnormal) revealed an infiltration of lymphocytes into the subcutaneous vessel wall with fibrinoid necrosis. On an unknown date, Body temperature: 38 degree celcius (High) 38 degree celcius. On an unknown date, C-reactive protein (lessthan or equal to 0.30-Unknown): 0.48 mg/dl (High) 0.48 mg/dL. On an unknown date, Complement factor C3: normal (normal) Normal. On an unknown date, Complement factor C4: normal (normal) Normal. On an unknown date, Physical examination: abnormal (abnormal) confirmed several hyperpigmented, slightly tender, 5–10 mm subcutaneous nodules present bilaterally on her lower limbs. On an unknown date, Red blood cell sedimentation rate: normal (normal) Normal. On an unknown date, Rheumatoid factor: normal (normal) Normal. On an unknown date, White blood cell count: normal (normal) Normal. For mRNA-1273 (COVID 19 Vaccine Moderna) (Unknown), the reporter considered CUTANEOUS VASCULITIS (cutaneous arteritis/ cutaneous polyarteritis nodosa), PYREXIA (fever) and FATIGUE (fatigue) to be related. Concomitant medications were not reported.

Case ID	Patient Age (Years)	Patient Gender	ALL PT'S	Brighton Collaboration Classification	WHO/UMC Causality Assessment	MAH Comment	Narrative (Complete)
							Patient symptoms include fever, fatigue,she developed multiple tender erythematous lesions on her lower limbs. Treatment also include Treatment with topical corticosteroids and oral antihistamines was ineffective Company comment: This case concerns a 14-year-old female patient with no medical history provided who experienced serious unexpected event of Cutaneous vasculitis and non-serious expected events of Pyrexia and Fatigue. The day after receiving the second dose of mRNA-1273 the patient presented with a fever of up to 38°C and fatigue, which resolved spontaneously on the same day. One week later, she developed multiple tender erythematous lesions on her lower limbs. Treatment with topical corticosteroids and oral antihistamines was ineffective. A physical examination confirmed several hyperpigmented, slightly tender, 5–10 mm subcutaneous nodules present bilaterally on her lower limbs. A skin biopsy revealed an infiltration of lymphocytes into the subcutaneous vessel wall with fibrinoid necrosis compatible with the pathological diagnosis of medium-sized vessel vasculitis. She had no obvious manifestations suggestive of extracutaneous involvement. Laboratory tests revealed a slight elevation of C-reactive protein (0.48 mg/dL; normal, ≤0.30 mg/dL) with a normal white blood cell count and erythrocyte sedimentation rate. Complementary examinations revealed that the rheumatoid factor, antinuclear antibody titre, antineutrophil cytoplasmic antibody and complement components (C3, C4) were within the normal ranges. The patient was diagnosed with cutaneous arteritis. After 1 month of loxoprofen treatment, the skin lesions improved. The Reporter assessed the events as related to the Company product. The benefit-risk relationship of mRNA-1273 is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 03-Feb-2022: Follow up received by safety 03-Feb-2022 included an Email with FTA received from SARA team and contains Significant information in Lab data
[redacted]	30	Male	Cutaneous vasculitis	2	Unlikely	Consumer report received via regulatory authority of a 30-year-old male patient with a history of Crohn's disease, neurodermatitis and hepatic steatosis, who, on an unknown date after dose 2 of mRNA-1273, experienced cutaneous vasculitis with a biopsy performed 3-4 months later reportedly indicating evidence of leukocytoclastic vasculitis. Considering the patient's confounding conditions and unclear timeline of events and diagnostic workup, WHO-UMC causality is classified as unlikekly.	This case was received via European Medicines Agency (Reference number: [redacted] on 04-Feb-2022 and was forwarded to Moderna on 04-Feb-2022. This regulatory authority case was reported by a consumer and describes the occurrence of CUTANEOUS VASCULITIS (Leukocytoclastic vasculitis) in a 30-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. Allergy included allergic to various foods. Concurrent conditions included Crohn's disease, neurodermatitis and hepatic steatosis. In June 2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. In June 2021, the

Case ID	Patient Age (Years)	Patient Gender	ALL PT'S	Brighton Collaboration Classification	WHO/UMC Causality Assessment	MAH Comment	Narrative (Complete)
							patient experienced CUTANEOUS VASCULITIS (Leukocytoclastic vasculitis) (seriousness criterion medically significant). At the time of the report, CUTANEOUS VASCULITIS (Leukocytoclastic vasculitis) had not resolved. Concomitant drugs were not reported. Treatment was not reported. Treatment of Crohn's disease with adalimumab (Humira).Fluctuating reddening of the skin about two weeks after the second vaccination different places. It was reported that biopsy was done on Oct 2021 with evidence of a leukocytoclastic vasculitis. Company Comment This is a regulatory case concerning a 30-year-old male patient with medical history of Crohn's disease, neurodermatitis and hepatic steatosis,who experienced the serious unexpected AESI event of Cutaneous vasculitis.The event occurred on an unknown day in Jun 2021 after administration of the second dose of mRNA-1273 (Spikevax).The date of administration of the vaccine was reported as an unknown date in Jun 2021.The medical history of Crohn's disease, neurodermatitis and hepatic steatosis remains as confounders.The benefit-risk relationship of mRNA-1273 (Spikevax) Vaccine is not affected by this report. Limited information regarding this event has been provided at this time
[redacted]	49	Male	Erythema, Purpura	2	Unassessable	Case report presented at a scientific meeting of a 49-year-old male patient who experienced erythema and purpura 9 days after receiving dose 1 of an unspecified mRNA vaccine with (presumably from biopsy) "perivascular lymphocytes, neutrophils, nuclear dust, and bleeding images were noted in the tissue at the purpura". No further information such as medical history, concomitant medications and clinical course was provided. In light of the missing information that would be beneficial in further characterizing causality, WHO-UMC causality is classified as unassessable.	This case was received via [redacted] (Reference number: [redacted] on 31-Jan-2022 and was forwarded to Moderna on 08-Feb-2022. This case was presented at [redacted]. Since the proprietary name of the suspect drug was not specified, the drug is handled as a [redacted] product in this case report. Case 1: A 49-year-old male patient. He received the 1st COVID-19 mRNA vaccination (proprietary name unknown), and experienced oval to ring-shaped purpura, erythema of legs 9 days later. Perivascular lymphocytes, neutrophils, nuclear dust, and bleeding images were noted in the tissue at the purpura. Follow-up investigation will be made. Companion cases: 2022TJP014443, 2022TJP016189, 2022TJP016190, 2022TJP016191, 2022TJP016192
[redacted]	32	Female	Cutaneous vasculitis	3	Possible based on TTO	HA report from consumer of 32F with no medical history or concomitant medications reported who experienced cutaneous vasculitis 4 days after dose 3 Spikevax and approximately 12 and 11 months after receiving Comirnaty. No biopsy was performed and while it is reported that other causes including Crohn's under immunosuppression were ruled out, these are still considered to potentially have a causal association. Case classified as BC level 3 and	This case was received via European Medicines Agency (Reference number: [redacted] on 18-May-2022 and was forwarded to Moderna on 18-May-2022. This regulatory authority case was reported by a consumer and describes the occurrence of CUTANEOUS VASCULITIS (Leukocytoclastic vasculitis) in a 32-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 000102A) for COVID-19 vaccination.

Case ID	Patient Age (Years)	Patient Gender	ALL PT'S	Brighton Collaboration Classification	WHO/UMC Causality Assessment	MAH Comment	Narrative (Complete)
						WHO-UMC causality is classified as possible.	Previously administered products included for Prophylactic vaccination: COMIRNATY on 19-Feb-2021 and COMIRNATY on 12-Mar-2021. Past adverse reactions to the above products included No adverse event with COMIRNATY and COMIRNATY. On 04-Feb-2022, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 3 dosage form. On 08-Feb-2022, the patient experienced CUTANEOUS VASCULITIS (Leukocytoclastic vasculitis) (seriousness criterion medically significant). At the time of the report, CUTANEOUS VASCULITIS (Leukocytoclastic vasculitis) had not resolved. The action taken with mRNA-1273 (Spikevax) (Intramuscular) was unknown. No concomitant medication was reported. It was reported that the diagnosis and suspected diagnosis was supported by the following clarifying examinations: Through a skin PE at the dermatologist. The differential diagnoses were excluded: Complications in known Crohn's disease under immunosuppression were ruled out. No treatment medication was reported. Company comment- This regulatory authority case concerns a 32-year-old female patient with no reported medical history, who experienced unexpected, serious (medically significant) adverse event of special interest Leukocytoclastic vasculitis 4 days after vaccination with a dose of mRNA-1273. The first two doses of COVID-19 vaccination were comirnaty, thus an interchange of vaccine products was also noted in the case. The patient was diagnosed thru a skin physical examination done by a dermatologist. The outcome of the events was reported as not resolved. 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]	32	Female	Cutaneous vasculitis	3	Possible based on TTO	HA report from consumer of 32F with no medical history or concomitant medications reported who experienced cutaneous vasculitis 4 days after dose 3 Spikevax and approximately 12 and 11 months after receiving Comirnaty. No biopsy was performed and while it is reported that other causes including Crohn's under immunosuppression were ruled out, these are still considered to potentially have a causal association. Case classified as BC level 3 and WHO-UMC causality is classified as possible.	This case was received via European Medicines Agency (Reference number: [redacted] on 02-Jun-2022 and was forwarded to Moderna on 02-Jun-2022. This regulatory authority case was reported by a consumer and describes the occurrence of CUTANEOUS VASCULITIS (secured) in a 32-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 000102A) for COVID-19 vaccination. Previously administered products included for COVID-19 immunisation: Comirnaty BNT162b2 on 19-Feb-2021 and Comirnaty BNT162b2 on 12-Mar-2021. Past adverse reactions to the above products included No adverse event with Comirnaty BNT162b2 and Comirnaty BNT162b2.

Case ID	Patient Age (Years)	Patient Gender	ALL PT'S	Brighton Collaboration Classification	WHO/UMC Causality Assessment	MAH Comment	Narrative (Complete)
							Concurrent medical conditions included Crohn's. On 04-Feb-2022, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 3 dosage form. On 08-Feb-2022, the patient experienced CUTANEOUS VASCULITIS (secured). At the time of the report, CUTANEOUS VASCULITIS (secured) outcome was unknown. The action taken with mRNA-1273 (Spikevax) (Intramuscular) was unknown. No Concomitant medications were provided. It was reported that Clarification secured by PE skin, dermatology exclusion, complication in known M.Crohn under immunosuppression. No treatment medications were provided. COMPANY COMMENT: This is a regulatory case concerning a 32-year-old female patient with medical history of Crohn's disease, Comirnaty BNT162b2 on 19-Feb-2021 and on 12-Mar-2021 who experienced the unexpected event of CUTANEOUS VASCULITIS (AESI) 4 days after a dose of mRNA-1273 vaccine. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Event´s seriousness assessed as reporting.

Appendix 11.22b SOCV: Literature Search Methodology

((((((((((Administration site vasculitis) OR (Cutaneous vasculitis)) OR (Haemorrhagic urticaria)) OR (Haemorrhagic vasculitis)) OR (Injection site vasculitis)) OR (Palpable purpura)) OR (Purpura)) OR (Purpura non-thrombocytopenic)) OR (Urticarial vasculitis)) OR (Vaccination site vasculitis)) OR (Vascular purpura)) OR (Vasculitic rash)) AND ("mrna vaccines"[MeSH Terms] OR "2019 ncov vaccine mrna 1273"[MeSH Terms] OR ("2019 ncov vaccine mrna 1273"[MeSH Terms] OR ("2019 ncov"[All Fields] AND "vaccine"[All Fields] AND "mRNA 1273"[All Fields]) OR "2019 ncov vaccine mrna 1273"[All Fields] OR "mRNA 1273"[All Fields] OR "mRNA 1273"[All Fields] OR ("2019 ncov vaccine mrna 1273"[MeSH Terms] OR ("2019 ncov"[All Fields] AND "vaccine"[All Fields] AND "mRNA 1273"[All Fields]) OR "2019 ncov vaccine mrna 1273"[All Fields] OR "mrna1273"[All Fields]) OR ("modernatx"[All Fields] AND "1273"[All Fields]) OR "1273"[All Fields] OR ("2019 ncov vaccine mrna 1273"[MeSH Terms] OR ("2019 ncov"[All Fields] AND "vaccine"[All Fields] AND "mRNA 1273"[All Fields]) OR "2019 ncov vaccine mrna 1273"[All Fields] OR "m 1273"[All Fields]) OR "m 1273"[All Fields] OR ("moderna"[All Fields] AND ("covid 19 vaccines"[MeSH Terms] OR ("covid 19"[All Fields] AND "vaccines"[All Fields]) OR "covid 19 vaccines"[All Fields] OR ("covid19"[All Fields] AND "vaccine"[All Fields]) OR "covid19 vaccine"[All Fields])) OR "moderna covid 19 vaccine"[All Fields] OR "moderna covid 19 vaccine"[All Fields] OR "moderna covid 19 vaccine"[All Fields] OR "Spikevax"[All Fields] OR ("2019 ncov vaccine mrna 1273"[MeSH Terms] OR ("2019 ncov"[All Fields] AND "vaccine"[All Fields] AND "mRNA 1273"[All Fields]) OR "2019 ncov vaccine mrna 1273"[All Fields] OR "elasomeran"[All Fields]) OR "CX-024414"[All Fields] OR "tak 919"[All Fields] OR "tak 919"[All Fields] OR ("2019 ncov vaccine mrna 1273"[MeSH Terms] OR ("2019 ncov"[All Fields] AND "vaccine"[All Fields] AND "mRNA 1273"[All Fields]) OR "2019 ncov vaccine mrna 1273"[All Fields]))) AND (2022/01/01:2022/06/18[Date - Publication] OR 2022/01/01:2022/06/18[Date - Create] OR 2022/01/01:2022/06/18[Date - Entry]))

Appendix 11.23a Polymyalgia Rheumatica and exacerbation or flar:-up-Overview of Flare/Aggravated and New-Onset PMR cases with case summaries and company comments- Reporting Period 01 Jan 2022 to 18 Jun 2022

Overview of Flare/Aggravated and New Onset PMR cases with case summaries and company comments- Reporting Period 01 Jan to 18 Jun 2022

Cases classified by the MAH as PMR Flare / Conditions Aggravated

Case ID	WWID	EULAR Case Definition Classification	WHO Causality	Case Summary / Company Comment	ALL PTs
[redacted]	[redacted]	Yes	Possible	This regulatory authority case reported by a consumer (subsequently medically confirmed) concerned a 75-year-old female who experienced disease recurrence and polymyalgia rheumatica about 7 days after she received an unspecified dose of mRNA-1273 vaccination on 21-Dec-2021. Her past history included Hypothyroidism and Polymyalgia rheumatica. No concomitant medication and treatment information were provided. The case is considered yes as it would be a flare of PMR and was medically confirmed, though no other details were provided for EULAR PMR disease criteria analysis except the age. The WHO causality is considered possible due to a reasonable TTO of 7 days.	Disease recurrence, Polymyalgia rheumatica
		Yes	Unassessable	This regulatory authority case reported by a physician concerned a 62-year-old male who experienced polymyalgia rheumatica aggravated on an unspecified date in 2021 after he received a dose of mRNA-1273 vaccination on 30-Apr-2021. His past medical history included Glomerulonephritis, COVID-19 infection in February 2022, Panic attack and Cranial arteritis. Concurrent medical conditions included Hypertension arterial and Polymyalgia rheumatica. No information on concomitant medication and treatment meds was provided. The case is considered yes for PMR, as it was reported as aggravated PMR by a physician, though it was not specifically included in the patient's medical history. The WHO is unassessable due to lack of information on TTO.	Polymyalgia rheumatica
		Yes	Unassessable	This regulatory authority case reported by a physician concerned a 67-year-old male who experienced flare of polymyalgia rheumatica on an unknown day after he received booster dose of mRNA-1273 vaccination on 21-Dec-2021. His past medical history included polymyalgia rheumatica. He received prior vaccination without reported AEs with VAXZEVRIA on 03-May-2021 and 21-Jun-2021, respectively. No concomitant medication and treatment meds were reported. The case is considered yes for PMR although no detailed information is provided, as the reported is provided by a physician and the patient had a medical history of PMR. The WHO causality is unassessable due to lack of information including an unknown TTO.	Polymyalgia rheumatica

Cases classified by the MAH as PMR New Onset

Case ID	WWID	EULAR Case Definition Classification	WHO Causality	Case Summary / Company Comment	ALL PTs
[redacted]		Yes	Possible	The information is from the original article. A 70-year-old man presented with a sudden onset of severe pain and stiffness of the neck, shoulder girdle, pelvic girdle, and thigh with restricted motion 7 days after receiving the second dose of the mRNA-1273 vaccine. Before that, the patient had developed a low-grade fever and slight malaise after the second injection. Those symptoms had been progressing, with the additional development of a headache, jaw claudication, and scalp tenderness simultaneously. The patient had previously been healthy without any medication and no family history of connective tissue disorders. A physical examination revealed tenderness of shoulder and hip joints, and upper arm with no temporal artery tenderness. The laboratory findings indicated an increased C-reactive protein (CRP) level of 15.14 mg/dL, increased erythrocyte sedimentation rate (ESR) of 75 mm/h, and normal matrix metalloproteinase-3 of 73.4 ng/mL. Rheumatoid factor, anti-cyclic citrullinated peptide antibody, anti-nucleolar antibody, myeloperoxidase-antineutrophil cytoplasmic antibody (ANCA), and proteinase 3- ANCA were negative. His serological tests demonstrated negative findings for immunoglobulin (Ig) M antibody for parvovirus B19 and positive findings for IgG antibody for cytomegalovirus, indicating no association of these viruses with the symptoms. Ultrasound revealed mild bilateral biceps tenosynovitis. Gadolinium-enhanced head magnetic resonance imaging failed to detect any wall thickening or stenoses of the temporal arteries. The fluorine-18 fluorodeoxyglucose uptake on positron emission tomography/computed tomography (PET/ CT) was increased around the bilateral shoulder joints, hip joints, greater trochanter interspinous bursa, and ischial tuberosity with no signs of temporal arteritis or large-vessel vasculitis. Contrast-enhanced CT and upper gastrointestinal endoscopy showed no sign of malignancy. The article authors thought that the patient met the classification criteria for PMR, and the imaging findings were typical for PMR. The patient's symptoms and levels of CRP and ESR abated with only acetaminophen up to 1,500 mg/day. One month after the onset, the patient's condition was resolved without any immunomodulatory interventions. Based on the information, it is considered yes for PMR. It is considered possible for WHO causality.	Polymyalgia rheumatica
		Yes	Possible	This spontaneous case reported by a consumer concerned a 70-year-old male patient who experienced polymyalgia rheumatica and arthritis reactive about 56 days after he received third dose of mRNA-1273 vaccination. His past medical history included Inguinal hernia. Concurrent medical conditions included low back pain and sciatica. No concomitant medications reported by the reporter. The patient first experienced a fever of 101.7°F last one day, severe muscular and joint pain in shoulder, elbow and hip on same day following third vaccination, which	Arthralgia, Loss of personal independence in daily activities, Myalgia, Polymyalgia

Cases classified by the MAH as PMR New Onset

Case ID	WWID	EULAR Case Definition Classification	WHO Causality	Case Summary / Company Comment	ALL PTs
				increased over next 2 months. About 56 days after vaccination, he experienced polymyalgia rheumatica, diagnosed by his family physician. He suffered loss of personal independence in daily activities due to general pain, and worsening sciatica and arthritis reactive. He was treated with oral prednisone of 10 milligram three times a day for Polymyalgia rheumatica and the symptoms were greatly improved. Red blood cell sedimentation rate increased at 22 mm/hr. The case reported by a consumer, but it was diagnosed by his family physician. His clinical presentations, labs, and the quick response to prednisone (though a slightly higher dose of 30 mg/day) seemed to meet PMR criteria. It is considered yes for PMR. It is considered possible for WHO causality as the symptoms started on the same day after vaccination and increased over about 2 months when PMR was diagnosed by his family physician.	rheumatica, Pyrexia, Sciatica
[redacted]		Yes	Possible	This information is captured from the original article. The literature-non-study case reported a case series of ten patients diagnosed with PMR after mRNA vaccines. One of them concerned in a 65-year-old male experienced new onset polymyalgia rheumatica 10 days after he received second dose of mRNA-1273 vaccination. No Medical History and concomitant medication information was reported. The clinical presentations included painful joint in shoulder, pelvic girdle, neck, knees, and wrists. Labs included increased 18F-FDG uptake in shoulders, hips, interspinous, ischiatic tuberosities and wrists, and increased CRP level at 34 mg/l. The events were improved following low dose of glucocorticoids at 0.3mg/kg/day. The PMR was reported by a group of rheumatologists and met EULAR PMR criteria. It is considered yes for PMR. The WHO causality is possible based on the TTO of 10 days and the assessment of the reporting rheumatologists.	Polymyalgia rheumatica
		Yes	Possible	This regulatory authority case reported by a physician concerned a 62-year-old female who experienced polymyalgia rheumatica on same day after she received mRNA-1273 vaccine on 19-Nov-2021. Concurrent medical conditions included Hypertension, Stag horn calculus and Psoriasis. Concomitant medications included AstraZeneca covid-19 vaccine on 14-Mar-2021, simvastatin for hypercholesterolaemia, bendroflumethiazide for hypertension, solifenacin succinate for stress incontinence, felodipine and ramipril. She suffered PMR symptoms, which improved with prednisolone 20 mg daily. ESR was increased to 58 mm/hr. The case is considered yes, based on a report from a physician though the specialty unspecified, patient's age > 50 years old, reported "PMR symptoms" though not specified, increased ESR, and the event improvement with low dose prednisolone though with an unknown speed. The WHO causality is possible	Polymyalgia rheumatica

Cases classified by the MAH as PMR New Onset

Case ID	WWID	EULAR Case Definition Classification	WHO Causality	Case Summary / Company Comment	ALL PTs
				because of the same day TTO. Of note, her history of psoriasis may confound ESR increase.	
[redacted]		Yes	Possible	This regulatory authority case reported by a physician concerned a 67-year-old male who experienced polymyalgia rheumatica, giant cell arteritis, anemia, pericardial effusion, pleural effusion, thrombocytopenia, rhinitis, serositis and episcleritis about same day after he received a dose of mRNA-1273 vaccination on 23-Dec-2021. His medical history includes hypertension, Borreliosis, condition after Lyme disease, and shingles. No concomitant medication use was provided. The patient had muscle/body aches approximately 14 days (not on same day?) after vaccination in entire left side of the body, loss of strength, pain of both legs with muscular weakness, feeling poor circulation with cold, subfebrile, macrocytic hyperchromic anemia and thrombocytopenia without hemolysis signs, thrombocytopenia, and about 4 kg weight loss in two weeks. CRP was increased, with negative autoimmune tests (ANA, p/c-anca, CCP, RF, dsdNS). Diagnosis of polymyalgia rheumatica with temporal arteritis was made. Prednisolone therapy started with 500 mg IV for 3 days, then reduction to 60 mg orally. The case is considered yes for PMR as it was reported with a diagnosis of giant cell arteritis at the same time by a physician, based on the category set. It is considered possible due to a TTO of same day.	Anaemia, Episcleritis, Giant cell arteritis, Myalgia, Pericardial effusion, Pleural effusion, Polymyalgia rheumatica, Rhinitis, Serositis, Thrombocytopenia
		Yes	Possible	This literature-non-study case reported a patient of age in 70s and unspecified gender who had no prior rheumatic diseases and no history of covid 19 infection. The patient was diagnosed with polymyalgia rheumatica 7 days after receiving second dose of mRNA-1273 vaccination. Treatments included glucocorticoids, methotrexate, and tocilizumab. No additional information was provided. The reporter considered PMR was temporally associated with vaccine administration. The case is considered yes for PMR as it is reported by the rheumatologists. The WHO causality is assessed as possible due to a TTO of 7 days, authors' view and no alternative etiology available.	Polymyalgia rheumatica

Cases classified by the MAH as PMR New Onset

Case ID	WWID	EULAR Case Definition Classification	WHO Causality	Case Summary / Company Comment	ALL PTs
[redacted]		Yes	Possible	This regulatory authority case reported by a physician concerned a 76-year-old male who experienced polymyalgia rheumatica and arthralgia about 2 days after he received second dose of mRNA-1273 vaccination on 03-Jul-2021. His medical history included Impaired renal function. Concomitant medications included aspirin cardio, rivaroxaban, amlodipine besilate, metoprolol, hydrochlorothiazide and lisinopril. The patient suffered from constant tarnishing pain in the shoulder and pelvic girdle. The laboratory showed increased erythrocyte sedimentation reaction of 36 and increased CRP of 54. Rheumatoid factors were negative. Cortisone therapy of an unknown dose was started to treat the events. However, his condition was reported as "not yet restored" after about one months. The case is yes for PMR as it was reported by a physician though unknown specialty in addition to patient's age, clinical features, and ESR/CRP which seemed to meet the EULAR PMR criteria. Of note, the steroid treatment seemed not to be very helpful for the event rapid recovery. The WHO causality is possible based on the TTO of 2 days with no alternative etiology.	Arthralgia, Polymyalgia rheumatica
		Yes	Possible	This regulatory authority case reported by a consumer concerned a 59-year-old male who experienced polymyalgia rheumatica, myalgia and limb discomfort about 10 days after he received third dose of mRNA-1273 vaccination on 21-Dec-2021. His medical conditions included Type 2 diabetes and hypertension. Concomitant medications were not provided. It was said that he developed a complete muscle hardening in his left leg, and gradually shifted over the backs to the entire shoulder-arm segment and became increasingly painful. CRP increased at 121. He was hospitalized and diagnosed with polymyalgia rheumatica. The case is considered yes for PMR as it was diagnosed in a hospital. The WHO causality is possible due to a TTO of 10 days.	Limb discomfort, Myalgia, Polymyalgia rheumatica
		Yes	Possible	This literature case concerned a 51-year-old previously healthy woman who experienced polymyalgia rheumatica 10 days after she received second dose of mRNA-1273 vaccine. She presented severe pain of the pelvic girdle and bilateral shoulder pain, but no morning stiffness or cranial symptoms for 2 weeks then search for medical attention. Ultrasound examination of the shoulders and hips at diagnosis showed bilateral biceps tenosynovitis, subdeltoid bursitis on the left side, and synovitis in both hip joints. Laboratory tests revealed elevated acute-phase reactants, Erythrocyte sedimentation rate 55 (mm/h) and C-reactive protein 29 (mg/L). An FDG-PET/CT scan showed an increased tracer uptake around the shoulder and hips, somewhat resembling the uptake pattern in PMR. The response to prednisolone treatment was rapid, with normalization of C-reactive protein (CRP) and remission of symptoms after 1 week. Based on the clinical findings, the patient was diagnosed with PMR. Although the authors think that an	Polymyalgia rheumatica

Cases classified by the MAH as PMR New Onset

Case ID	WWID	EULAR Case Definition Classification	WHO Causality	Case Summary / Company Comment	ALL PTs
				alternative diagnosis may be a reactive disease, which was "supported by the baseline PET/CT findings, with muscle uptake in the erector spinae and around the scapulae, which has not previously been reported in PMR patients. In addition, the lack of intervertebral FDG uptake decreased the likelihood of PMR, because intervertebral uptake has a high specificity for PMR", the case is considered yes for PMR, as all the EULAR PMR criteria were met. The WHO causality is possible due to a TTO of 10 days.	
[redacted]		Incomplete	Unlikely	This regulatory authority case reported by a consumer concerned a 51-year-old female who experienced polymyalgia rheumatica about 62 days after she received second dose of mRNA-1273 vaccination on 20-Jun-2021. Medical history included allergies to multiple allergens. No information concomitant medications and treatments was reported. Her clinical presentations included pain in buttocks, shoulders and back, extreme stiffness in all limbs, slight paralysis, insomnia due to pain, which were getting worse. A diagnosis of polymyalgia rheumatica was "confirmed". She was on ongoing therapy with prednisolone of unspecified dose and with unknown outcome. The PMR in the case is considered incomplete, as it was reported by a consumer without a confirmation from a rheumatologist. In addition, not all EULAR PMR criteria were met. The WHO causality is considered unlikely based on a temporal relationship of over two months.	Polymyalgia rheumatica
		Incomplete	Unlikely	This regulatory authority case reported by a physician concerned and describes an 81-year-old female who experienced polymyalgia rheumatica about 9 months after she received third dose of mRNA-1273 vaccination on 26-Mar-2021. Concurrent medical conditions included Insulin-dependent diabetes mellitus. Information on concomitant medications and treatment was not provided. Her BSR and CRP were said to increase to 23 or 22 (reference range unknown). CRP then increased to 52. The case is considered incomplete for PMR as it was reported by a physician of unknown specialty, in addition to patient's age and increased CRP. However, the WHO causality is unlikely because the TTO was about 9 months.	Polymyalgia rheumatica

Cases classified by the MAH as PMR New Onset

Case ID	WWID	EULAR Case Definition Classification	WHO Causality	Case Summary / Company Comment	ALL PTs
[redacted]		Incomplete	Unlikely	This regulatory authority case reported by a consumer concerned an 83-year-old female who experienced polymyalgia rheumatica about 11 days after she received booster TOZINAMERAN vaccination on 28-Oct-2021. She received her first and second dose of mRNA-1273 on 14-Mar-2021 and 15-Apr-2021, respectively. She described muscle and joint pain, extremely increasing pains over the course of a few weeks, pain disappeared hours after high dose of prednisolone at 100 mg. The case is considered incomplete, as labs for ESR and CRP were not available. The WHO causality is unlikely, as the event occurred after Pfizer vaccine. It has been about 7 months between Moderna vaccine and Pfizer vaccine she received.	Arthralgia, Limb discomfort, Myalgia, Pain, Polymyalgia rheumatica
		Incomplete	Unassessable	This regulatory authority case reported by a physician concerned a 77-year-old male patient who experienced polymyalgia rheumatica about 3 days after he received a dose of mRNA-1273 vaccination. No information on medical history, concomitant medications and treatment medications was provided. C-reactive protein was high at 12.2. mg/dl. No other information was available. It is considered incomplete for PMR, as one of the four EULAR criteria was met, CRP elevated. Although the case was reported by a physician, a rheumatologist was not confirmed. It is considered unassessable due to lack of sufficient information despite the TTO of about 3 days.	Polymyalgia rheumatica
		Incomplete	Unassessable	This regulatory authority case reported by a consumer (subsequently medically confirmed) concerned a 68-year-old female who experienced polymyalgia rheumatica (unknown) and condition aggravated (unknown) about 2 days after she received a dose of mRNA-1273 vaccination. Past medical history included Psoriasis, Systemic lupus erythematosus, Allergic reaction and Edema Quincke's. Concomitant medications and the treatment information was not provided. The case reported PMR confirmed by a physician of unspecified specialty. As no information except age was available, it is considered incomplete for PMR. Of note, as the patient had a history of autoimmune disease including psoriasis and SLE, they may overlap PMR in clinical presentations and labs. The WHO causality is considered unassessable due to insufficient information including status of underlying autoimmune conditions despite a TTO of 2 days.	Condition aggravated, Polymyalgia rheumatica
		Incomplete	Unassessable	This regulatory authority case reported by a physician concerned a 69-year-old male patient who experienced polymyalgia rheumatica about 11 days after he received second dose of mRNA-1273 vaccination on 20-May-2021. Past medical history included Hypertension, Polyposis coli and Testicular cancer. No concomitant medication and treatment meds were provided. The case is considered incomplete for PMR based on the event was reported by a physician of	Polymyalgia rheumatica

Cases classified by the MAH as PMR New Onset

Case ID	WWID	EULAR Case Definition Classification	WHO Causality	Case Summary / Company Comment	ALL PTs
				unspecified specialty and the patient's age. WHO causality is considered unassessable due to lack of sufficient information despite a TTO of 11 days.	
[redacted]		Incomplete	Unassessable	This regulatory authority case reported by a physician concerned a 51-year-old male who experienced polymyalgia rheumatica about 25 days after he received an unspecified dose of mRNA-1273 vaccination on 13-Jul-2021. Concurrent medical conditions included Hypothyroidism. concomitant medication and treatment meds were not provided. The case is considered incomplete for PMR based on the event was reported by a physician of unspecified specialty and the patient's age over 50 years. WHO causality is considered unassessable due to lack of sufficient information despite a TTO of 25 days.	Polymyalgia rheumatica
		Incomplete	Unassessable	This regulatory authority case reported by a physician concerned a 59-year-old male who experienced oedema peripheral and polymyalgia rheumatica same day after he received an unspecified dose of mRNA-1273 vaccination on 30-Dec-2021. His past medical history included Orbital myositis and prostate adenocarcinoma. Concurrent conditions included Sclerosis multiple. Concomitant medication included Pfizer COMIRNATY from 30-Apr to 26-Jul-2021 and prednisone. No treatment information was provided though the event was still ongoing at the time of report. The case is considered incomplete because the PMR was reported from a physician of unknown specialty, and no detailed information was available other than patient's age for PMR assessment. The WHO causality is considered unassessable due to lack of sufficient information despite a TTO of the same day. Of note, the patient's underlying multiple sclerosis and co med prednisone may be the confounding factors.	Oedema peripheral, Polymyalgia rheumatica
		Incomplete	Unassessable	This regulatory authority was reported by a consumer concerned a 61-year-old male who experienced polymyalgia rheumatica about 2 days after he received second dose of mRNA-1273 vaccination on 11-Aug-2021. No history and co med information was reported. Per his physician, the patient suffered painful hips after first dose of vaccine, with worsening painful hips and painful shoulders after second dose. The clinical presentations included painful hips and shoulder. "PMR was diagnosed, and the pain has increased after dose three". No treatment details were reported. The case is considered incomplete, as the info was from a physician of unspecified specialty, and not all EULAR PMR criteria were met. The WHO causality is considered unassessable due to insufficient information provided, for examples, when the diagnosis was made, after second or third dose, and the TTO; prior history and co meds and so on.	Arthralgia, Polymyalgia rheumatica

Cases classified by the MAH as PMR New Onset

Case ID	WWID	EULAR Case Definition Classification	WHO Causality	Case Summary / Company Comment	ALL PTs
[redacted]		Incomplete	Unassessable	This regulatory authority case reported by a physician concerned a 59-year-old female who experienced polymyalgia rheumatica on an unknown date after she received a dose of mRNA-1273 (second vaccination) on 15-Jun-2021. No history and concomitant medication information was reported. Patient had mild symptoms after taking 1st dose of Covid 19 vaccine Vaxzevria. No treatment information was available. Insufficient information was provided for PMR assessment. The case is considered incomplete as it was reported by a physician of unknown specialty. The WHO causality assessment is unassessable due to lack of information.	Polymyalgia rheumatica
		Incomplete	Unassessable	This regulatory authority case reported by a consumer concerned 66-year-old female who experienced arthritis, pain in extremity, polyarthritis, arthralgia, and polymyalgia rheumatica about 41 days after she received second dose of mRNA-1273 vaccination on 12-Dec-2021. Her medical conditions included dermatitis allergic, rhinitis allergic and familial hypercholesterolemia. She received first mRNA-1273 with no AEs on 12-Nov-2021. No concomitant medications were provided. She started to experienced soreness, pain first on shoulder and right arm then also on the left gradually increased that made her to wake up at night. Pain and swelling on right hand knuckles. At the time of the report, the above events had not resolved. She could not directly relate the current events to the vaccine, but she had never suffered this type of pain which started after the second dose and gradually increased. She was taking painkillers for treatment. She was active before and not overweight. The flu vaccination was not carried out. No lab tests were provided. The case is considered incomplete as PMR was reported by a consumer without medical confirmation. No lab tests for acute phase reactants were available, and no glucocorticoids were used and so the steroid effect was not applicable. The WHO causality is considered unassessable due to the TTO of 42 days and the patient underlying allergic constitution.	Arthralgia, Arthritis, Pain in extremity, Polyarthritis, Polymyalgia rheumatica
		Incomplete	Unassessable	This regulatory authority case reported by a consumer concerned a 66-year-old male who experienced polymyalgia rheumatica about 2 days after he received third dose of mRNA-1273 vaccination on 28-Dec-2021. No information on medical history and concomitant medication was reported. Treatment details was unavailable. Polymyalgia rheumatica was diagnosed by her doctor of unspecified specialty, who recommended reporting the event. No detailed information on clinical features, labs and steroid treatment was provided. It is considered incomplete for PMR, as it was diagnosed by a physician of unspecified specialty. The WHO causality is unassessable despite a TTO of 2 days, as no info on history, co meds and other potential confounders was available for assessment.	Polymyalgia rheumatica

Cases classified by the MAH as PMR New Onset

Case ID	WWID	EULAR Case Definition Classification	WHO Causality	Case Summary / Company Comment	ALL PTs
[redacted]		Incomplete	Unassessable	This regulatory authority case reported by a consumer concerned a 56-year-old female who experienced polymyalgia rheumatica on same day after she received third dose of mRNA-1273 vaccination on 04-Jan-2022. The occurrence of additional non-serious events is detailed below. No information on medical history and concomitant medication was available. Treatment information was not provided. The patient experienced "aggravation PMR vaccination farm severe pain" which was coded as PMR, pain in extremity and vaccination site pain. No info on detailed clinical features, lab tests and steroid treatment was available for assessment. It is considered incomplete for PMR. The WHO is considered unassessable due to lack of information, though a TTO of same day.	Pain in extremity, Polymyalgia rheumatica, Vaccination site pain
		Incomplete	Unassessable	This regulatory authority case reported by a consumer concerned a female patient of an unknown age who experienced polymyalgia rheumatica, arthralgia and pain in extremity after she received second dose of mRNA-1273 vaccination in March 2021. No information on medical history and concomitant medication was reported. Based on the patient, she developed polymyalgia rheumatica following vaccination in March 2022, with a violent reaction including strong pains in the legs and amplified for several months, violent pains also appeared in both shoulders and was unable to walk or move arms. PPR(?) was diagnosed at an emergency room in August. She was on cortisone for several months, and the events were still ongoing to disrupt her everyday life. The case reported an ER diagnosed PMR. However, her age was unknown, no labs was available, and glucocorticoids seemed unable to rapidly resolute the event. Therefore, it is considered incomplete. The WHO causality is unassessable due to lack of sufficient information.	Arthralgia, Pain in extremity, Polymyalgia rheumatica
		Incomplete	Unassessable	This regulatory authority case reported by a physician concerned an 87-year-old female who experienced polymyalgia rheumatica and hypertension on an unspecified date after she received first dose of mRNA-1273 vaccination on 04-Mar-2021. Her medical history included hypertension and HLA-B*27 positive. No concomitant medication and no treatment info were provided. The case reported PMR by a physician of unspecified specialty. No detailed clinical features, labs and steroid treatment info was available. It is considered incomplete for PMR. The WHO causality is unassessable due to lack of information. Of note, her underlying positive HLA-B*27 may be a confounder for autoimmune or immune reactive responses.	Hypertension, Polymyalgia rheumatica

Cases classified by the MAH as PMR New Onset

Case ID	WWID	EULAR Case Definition Classification	WHO Causality	Case Summary / Company Comment	ALL PTs
[redacted]		Incomplete	Unassessable	This regulatory authority case reported by a consumer (subsequently medically confirmed) and concerned a 69-year-old male who experienced polymyalgia rheumatica about 4 days after he received a dose of mRNA-1273 vaccination on 06-Jan-2022. His medical history included Drug-induced hepatitis and Chorioretinitis and apnea syndromes. His received prior COVID-19 vaccine Vaxzevria on unknown date. No detailed information on clinical features, labs and treatment was reported. The case is considered incomplete as PMR may be confirmed by a physician of unspecified specialty, in addition to patient's age. The WHO is considered unassessable due to lack of information though a TTO was two days.	Polymyalgia rheumatica
		Incomplete	Unassessable	This regulatory authority case reported by a physician concerned a 67-year-old male who experienced polymyalgia rheumatica about on an unknown date after he received second dose of mRNA-1273 vaccination on 21-May-2021. No information on medical history and co meds was reported. After the second vaccination, he had a very few pains in his right arm which developed progressively (3-4 days) throughout the body, especially shoulder girdle. He was diagnosed with rheumatic polymyalgia and treated with Prednisone 20mg/daily. The case is considered incomplete as no detailed information was available, though it was reported by a physician of unspecified specialty. Of note, as the event seemed still ongoing following prednisone treatment at the time of the Nov-2021 (6 months after vaccination). The WHO causality is considered unassessable due to lack of information including the unknown TTO and patient was improving.	Polymyalgia rheumatica
		Yes	Unassessable	This regulatory authority case reported by a consumer concerned a 74-year-old female who experienced polymyalgia rheumatica 1 day after she received third dose of mRNA-1273 vaccination on 11-Dec-2021. Concurrent condition included Diabetic Mellitus. No concomitant medication was reported. It was said that she experienced physical deterioration with muscle weakness lasting for weeks, with "clinically typical picture polymyalgia rheumatica". CRP and ESR were increased. She was "under prednisolone 20 mg response and freedom from symptoms". The case is considered incomplete for PMR as it was reported by a consumer and no details about the clinical features were provided to meet EULAR PMR criteria. The WHO is unassessable due to lack of sufficient information to exclude other potential etiologies despite a TTO of 1 day.	Polymyalgia rheumatica

Cases classified by the MAH as PMR New Onset

Case ID	WWID	EULAR Case Definition Classification	WHO Causality	Case Summary / Company Comment	ALL PTs
[redacted]		Incomplete	Unassessable	This regulatory authority case reported by a physician concerned 70-year-old male who experienced myalgia and polymyalgia rheumatica about 1 day after he received a dose of mRNA-1273 vaccination on 25-Dec-2021. He had COVID-19 infection on 29-Jan-2021. Previous covid 19 vaccination with Pfizer vaccine was on 28-Apr-2021 with no AE reported. Concomitant medication included rosuvastatin, indapamide, perindopril erbumine, ezetimibe and carbasalate. The patient was said to experience muscle pain and stiffness thighs and buttocks, and shoulders. SARS-CoV-2 test was positive. C-reactive protein increased at 81 g/L (?). Red blood cell sedimentation rate increased at 93 millimole/hour. White blood cell count increased at 13.6 nanogram/L (?). No treatment medications were reported. The case is considered incomplete for PMR as it was reported by a physician of unspecified specialty. No detailed information was provided on join pain and stiffness duration, steroid treatment and the response to treatment which needed to meet EULAR criteria. The WHO causality is unassessable due to missing information to confirm the diagnosis and exclude other factors despite a TTO of 1 day.	Myalgia, Polymyalgia rheumatica
		Incomplete	Unassessable	This regulatory authority case reported by a physician concerned an 83-year-old male who experienced polymyalgia rheumatica about 9 days after he received booster dose of mRNA-1273 vaccination on 22-Nov-2021. His medical history included atrial fibrillation, hypertensive heart disease, hypercholesterolemia, and prostatic hyperplasia. Concomitant medication included marcumar, lisinopril, simvastatin and tamsulosin. He described increasing shoulder girdle pain and pelvic pain, not response to NSAIDs. C-reactive protein was 28 mg/L. Red blood cell sedimentation rate was 140 mm/h. He was on steroid therapy and the event was ongoing at the time of report. The case is considered incomplete as the steroid dose was unknown and response to steroid was questionable, although age, clinical features and labs met the EULAR criteria. The WHO causality is unassessable due to lack of information to confirm the diagnosis and exclude other etiology despite the TTO of 1 day.	Polymyalgia rheumatica
		Incomplete	Unassessable	This regulatory authority case reported by a physician concerned a 72-year-old female who experienced polymyalgia rheumatica about 28 days after she received third dose of mRNA-1273 vaccination on 11-Nov-2021. No Medical History information was reported. Concomitant medication and treatment were not reported. C-reactive protein was 16.7. The case is considered incomplete for PMR as no detailed clinical presentations and steroid information were available other than patient's age and increased CRP, to meet the EULAR criteria. The WHO causality is considered unassessable due to lack of information including medical	Polymyalgia rheumatica

Cases classified by the MAH as PMR New Onset

Case ID	WWID	EULAR Case Definition Classification	WHO Causality	Case Summary / Company Comment	ALL PTs
				history and co meds which may be potential confounders in an elderly patient with a TTO of 1 month.	
[redacted]		Incomplete	Unassessable	This regulatory authority case reported by a physician concerned a 90-year-old male who experienced polymyalgia rheumatica about 6 days after he received first dose of mRNA-1273 vaccination on 20-Apr-2021. His past medical history included hypertension, hematoma subdural, dyslipidemia, atrioventricular block, and infarct myocardial. No concomitant medication and treatment information were reported. The case is considered incomplete as it was reported by a physician of unspecified specialty but only patient's age was available. The WHO causality is unassessable due to lack of detailed information.	Polymyalgia rheumatica
		Incomplete	Unassessable	This regulatory authority case reported by a consumer concerned a 73-year-old male who experienced polymyalgia rheumatics, fatigue, injection site, myalgia, and musculoskeletal stiffness on same day after he received a dose of mRNA-1273 vaccination on 16-Dec-2021. He received Comirnaty vaccine with no reported AEs on 11-May-2021. No medical history was provided. Co meds included omeprazole, rosuvastatin and acetylsalicylic acid. It was said that he suffered muscle pain, pain and stiffness in shoulders and pelvis with an unknown period. Lab test results included light anemia, slightly elevated C-reactive protein, and slightly elevated red blood cell sedimentation rate. No treatment and response to treatment were available. The case is considered incomplete for PMR, as not all EULAR criteria were met. The WHO causality is unassessable as no medical history and concurrent conditions including autoimmune conditions were provided, despite a TTO of same day.	Fatigue, Injection site pain, Musculoskeletal stiffness, Myalgia, Polymyalgia rheumatica
		Incomplete	Unassessable	This regulatory authority case reported by a physician concerned a 57-year-old female who experienced polymyalgia rheumatica about 54 days after she received booster dose of mRNA-1273 vaccination on 16-Dec-2021. She was infected with COVID-19. Concomitant and treatment product use was not provided by the reporter. Prior vaccination included AstraZeneca vaccine with no reported AE on 17-Apr-2021 and 01-Jul-2021. The case is considered incomplete for PMR, as it was reported by a physician of unspecified specialty. Only patient's age is provided. The WHO causality is unassessable due to lack of information.	Polymyalgia rheumatica

Cases classified by the MAH as PMR New Onset

Case ID	WWID	EULAR Case Definition Classification	WHO Causality	Case Summary / Company Comment	ALL PTs
[redacted]		Yes	Unassessable	This regulatory authority case reported by a consumer concerned a 58-year-old female who experienced polymyalgia rheumatica about 9 days after she received third dose of mRNA-1273 vaccine on 06-Dec-2021. No medical History and concomitant medication information was reported. It was said that she suffered sinusitis and chest infection, then significant urticaria, followed by extreme stiffness and pain in shoulders and hips, which was diagnosed as Polymyalgia rheumatica by rheumatologist. The information seemed a little confusion, including "now on a steroid course for 2 years". The case is considered yes, as it was confirmed by rheumatologist, though no detailed clinical presentation and progress, lab test and steroid dose and response to treatment were available. The WHO causality is unassessable, due to lack of information including history, detailed concurrent conditions such as chest infection, and co meds despite a TTO of 9 days.	Polymyalgia rheumatica
		Incomplete	Unassessable	This regulatory authority case reported by a physician concerned a 67-year-old female who experienced polymyalgia rheumatica on an unspecified date in February 2022 after she received a dose of mRNA-1273 vaccination on 07-Dec-2021. She previously received first AstraZeneca COVID-19 vaccine on unspecified date in 2021. No medical History, concomitant medication and treatment were reported. The case is considered incomplete as it was reported by a physician of unknown specialty, and only patient's age was available. The WHO causality is unassessable due to lack of sufficient information.	Polymyalgia rheumatica
		Incomplete	Unassessable	This regulatory authority case reported by a physician concerned a 53-year-old male who experienced polymyalgia rheumatica about 35 days after he received a dose of mRNA-1273 vaccination on 20-Jan-2022. His past medical history included Erysipelas, Factor II mutation, Deep vein thrombosis recurrent and Factor V Leiden mutation. Concomitant medication and treatment for the event were not provided. The case is considered incomplete, as it was reported by a physician of unknown specialty. Only patient's age was provided. No additional information was presented for EULAR PMR criteria assessment. The WHO causality is unassessable due to lack of sufficient information.	Polymyalgia rheumatica

Cases classified by the MAH as PMR New Onset

Case ID	WWID	EULAR Case Definition Classification	WHO Causality	Case Summary / Company Comment	ALL PTs
[redacted]		Incomplete	Unassessable	This spontaneous case reported by a patient concerned a 57-year-old male who experienced polymyalgia rheumatica about 2 months after he received second dose of mRNA-1273 vaccination on 12-Apr-2021. Concurrent medical conditions included spinal stenosis of lower and upper back and neck, recently worsening. Concomitant medication included [redacted] for Spinal stenosis. He received first and second dose of mRNA-1273 on 15-Mar-2021 and 12-Apr-2021, respectively. Patient stated that after 2nd dose around the middle of Jun-2021, he started experiencing a lot of shoulder, groin, and knee pain, and becoming hard to get out of bed and move around. He saw his healthcare provider on 21-Jul-2021 and was diagnosed with primary polymyalgia rheumatica. He was put on steroids of unspecified dose for about 6 months. The joint pain started to subside when he was on "high dose" steroids. The case is considered incomplete, as the PMR was diagnosed by a healthcare provider of unspecified specialty. His age is known, clinical features fit some criteria of EULAR PMR, but no lab tests are available, and "high dose" steroid for 6 months seemed not for PMR treatment, and was there any other immune conditions as differentials? The WHO causality is unassessable due to a TTO of 2 months and that insufficient information is provided for a differential.	Polymyalgia rheumatica

Appendix 11.23b Polymyalgia Rheumatica and exacerbation or flare-up: Re-evaluation of the causality assessment of the 22 possible cases presented in PBRER#2

Re-evaluation of the causality assessment of the 22 possible cases presented in PBRER#2

Case ID	WWID	Re-assessed WHO Causality	Case Summary	WHO/UMC Causality Re-assessment
[redacted]		Possible	This spontaneous report concerns a 71-year-old female who developed PMR musculoskeletal symptoms 1 day after Dose 2 of SPIKEVAX. PMR confirmed by GP.	Causality is possible given the temporal association (although new onset of PMR is noted as one day after vaccination); although no other alternate etiology is reported the clinical information provided is limited. The biologic mechanism of vaccination inducing PMR is not established, and there is no evidence of a positive rechallenge.
		Possible	This 80-year-old female with no relevant medical history developed PMR 3-4 days after Dose 2 of SPIKEVAX. Given TTO causality is possible although confounding by medical history of spinal stenosis is present.	Causality is possible given the temporal association; although no other alternate etiology is reported the clinical information provided is limited. The biologic mechanism of vaccination inducing PMR is not established, and there is no evidence of a positive rechallenge.
		Possible	This 82-year-old male developed PMR aggravated one day after Dose 1 of SPIKEVAX. Causality is possible because of TTO and history of PMR.	Causality is possible given the temporal association; although no other alternate etiology is reported the clinical information provided is limited. The biologic mechanism of vaccination inducing PMR is not established, and there is no evidence of a positive rechallenge.
		Possible	This 68-year-old male with a history of PMR developed aggravation of symptoms one day after receiving SPIKEVAX.	Causality is possible given the temporal association; although no other alternate etiology is reported the clinical information provided is limited. The biologic mechanism of vaccination inducing PMR is not established, and there is no evidence of a positive rechallenge.
		Unassessable	This 73-year-old female with a history of PMR and hypothyroidism developed PMR flare and fever a few hours after receiving Dose 1 of SPIKEVAX. Given the TTO and history of PMR causality is possible.	The case is unassessable as it is difficult to delineate possible signs and symptoms of reactogenicity from a true PMR flare as no labs were reported, and there is limited clinical information.
		Unassessable	This case concerns an 80-year-old female with medical history of PMR who experienced a PMR flare within 1 day after Dose 1 of SPIKEVAX. Approximately 1 month later, the patient received Dose 2 of SPIKEVAX. Rechallenge is unknown as event outcome is unknown. The flare-up of PMR within one day of receiving SPIKEVAX and the medical history of PMR suggest a possible causal relationship.	Although there is atemporal association of the PMR flare and vaccination, causality is unassessable as the case is strongly confounded by the discontinuation of prednisone 7 days prior to vaccination.
		Possible	This case describes a 70-year-old female who developed PMR 2 days after Dose 1 of SPIKEVAX.	Causality is possible given the temporal association; although no other alternate etiology is reported the

Re-evaluation of the causality assessment of the 22 possible cases presented in PBRER#2

Case ID	WWID	Re-assessed WHO Causality	Case Summary	WHO/UMC Causality Re-assessment
			Temporal artery biopsy was done but no findings of arteritis were reported. Patient responded to low dose steroids.	clinical information provided is limited. The biologic mechanism of vaccination inducing PMR is not established, and there is no evidence of a positive rechallenge.
[redacted]	[redacted]	Unassessable	This 65-year-old male developed a flare of PMR on the same day as SPIKEVAX was first administered.	The case is unassessable as it is difficult to delineate possible reactogenicity from a true PMR flare as no labs were reported, and there is limited clinical information. Treatment included herbal supplements.
		Possible	Two days after receiving Dose 2 of SPIKEVAX, this 75-year-old female with a known history of PMR experienced a PMR flare which spread to the knees. PMR is poorly described.	Causality is possible given the temporal association; although no other alternate etiology is reported the clinical information provided is limited (and it is unclear why the patient was treated with Doxycycline). The biologic mechanism of vaccination inducing PMR is not established, and there is no evidence of a positive rechallenge.
		Possible	This 59-year-old male developed PMR at an unknown time after the first dose of SPIKEVAX, before their second dose. PMR is poorly described but CRP and ESR were high and treated with steroids.	Causality is possible given the temporal association; although no other alternate etiology is reported the clinical information provided is limited. The biologic mechanism of vaccination inducing PMR is not established, and there is no evidence of a positive rechallenge.
		Possible	This 76-year-old female developed symptoms suggestive of PMR 5 days after receiving the first dose of vaccine. Elevated ESR and CRP confirm the diagnosis. Good response to steroids. No information on second dose is available.	Causality is possible given the temporal association; although no other alternate etiology is reported the clinical information provided is limited. The biologic mechanism of vaccination inducing PMR is not established, and there is no evidence of a positive rechallenge.
		Possible	This 71-year-old male developed PMR flare one week after receiving Dose 2 of SPIKEVAX. Elevated CRP and ESR was present. Treated with prednisone.	Causality is possible given the temporal association; although no other alternate etiology is reported the clinical information provided is limited. The biologic mechanism of vaccination inducing PMR is not established, and there is no evidence of a positive rechallenge.
		Probable	This regulatory authority case concerns a 66-year-old male who experienced PMR, pelvic pain, musculoskeletal pain, asthenia, and injected limb mobility decreased. The events occurred 21 days after a dose of SPIKEVAX. At the time of the report the outcome of the events was not recovered. Blood tests	Causality is probable given the temporal association and given the symptoms and diagnosis began after the first dose and worsened after the second (possible positive rechallenge).

Re-evaluation of the causality assessment of the 22 possible cases presented in PBRER#2

Case ID	WWID	Re-assessed WHO Causality	Case Summary	WHO/UMC Causality Re-assessment
			and echography were performed, with inconclusive results. The events appeared after the administration of the first dose of vaccine, then worsened with the administration of the second dose.	
[redacted]		Possible	This 91-year-old female with a history of PMR, experienced PMR flare 2 days after receiving Dose 2 of SPIKEVAX.	Causality is possible given the temporal association; although no other alternate etiology is reported the clinical information provided is limited. The biologic mechanism of vaccination inducing PMR is not established, and there is no evidence of a positive rechallenge.
		Possible	This case concerns a 67-year-old female with no medical history reported, who experienced serious PMR, myalgia, pyrexia, chills, and arthralgia leading to hospitalization. The events occurred on unknown number of days after receiving Dose 2 of SPIKEVAX.	Causality is possible given the temporal association; although no other alternate etiology is reported the clinical information provided is limited. The biologic mechanism of vaccination inducing PMR is not established, and there is no evidence of a positive rechallenge.
		Possible	This is a regulatory authority case concerning an 83-year-old female with no relevant medical history, who experienced serious Myalgia and PMR. The events occurred 14 days after the second dose of mRNA-1273. Diagnostic criteria for PMR were met.	Causality is possible given the temporal association; although no other alternate etiology is reported the clinical information provided is limited. The biologic mechanism of vaccination inducing PMR is not established, and there is no evidence of a positive rechallenge
		Possible	This case concerns a 70-year-old female with no relevant medical history reported, who experienced PMR. The events occurred an unknown number of days after the first dose of SPIKEVAX. The rechallenge was unknown since the events have not resolved.	Causality is possible given the temporal association; although no other alternate etiology is reported the clinical information provided is limited. The biologic mechanism of vaccination inducing PMR is not established, and there is no evidence of a positive rechallenge
		Possible	This spontaneous case concerns a 59-year-old female with no relevant medical history, who experienced PMR after receiving SPIKEVAX. The onset of the event occurred approximately 5 days after Dose 2 of SPIKEVAX. Clinical manifestations included aching and stiffness about the shoulders, hip girdle and neck, difficulty walking, dressing, and driving. Final diagnosis was performed approximately 1 month and 20 days later. Treatment with prednisone 20 mg/ day was prescribed.	Causality is possible given the temporal association; although no other alternate etiology is reported the clinical information provided is limited. The biologic mechanism of vaccination inducing PMR is not established, and there is no evidence of a positive rechallenge

Re-evaluation of the causality assessment of the 22 possible cases presented in PBRER#2

Case ID	WWID	Re-assessed WHO Causality	Case Summary	WHO/UMC Causality Re-assessment
[redacted]	[redacted]	Possible	This case concerns a 52-year-old male with no relevant medical history reported, who developed PMR. The event occurred on an unknown date after Dose 2 of SPIKEVAX.	Causality is possible given the temporal association; although no other alternate etiology is reported the clinical information provided is limited. The biologic mechanism of vaccination inducing PMR is not established, and there is no evidence of a positive rechallenge
		Possible	This regulatory case concerns a 71-year-old female patient with no relevant medical history who developed PMR. The event occurred 5 days after receiving Dose 2 of SPIKEVAX.	Causality is possible given the temporal association; although no other alternate etiology is reported the clinical information provided is limited. The biologic mechanism of vaccination inducing PMR is not established, and there is no evidence of a positive rechallenge
		Unassessable	This case concerns an adult female of unknown age with a medical history of PMR who experienced PMR flare. The events occurred 1 day after Dose 2 of SPIKEVAX. At the time of the report, the flare was resolved.	The case is unassessable as it is difficult to delineate possible signs and symptoms of reactogenicity from a true PMR flare as no labs were reported, and there is limited clinical information.
		Possible	This case concerns a 66-year-old male with no medical history reported, who was hospitalized for new onset PMR. The event occurred approximately 14 days after the first dose of mRNA-1273. Diagnostic tests included inflammatory markers increased. Treatment included prednisone and improved. Symptoms lasted for 9 months.	Causality is possible given the temporal association; although no other alternate etiology is reported the clinical information provided is limited. The biologic mechanism of vaccination inducing PMR is not established, and there is no evidence of a positive rechallenge

Appendix 11.23c Polymyalgia Rheumatica and exacerbation or flare-up: Literature Search Methodology

("Polymyalgia Rheumatica"[21] OR "Polymyalgia Rheumatica"[tw] OR polymyalgia rheumatica) 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] or vaccin*[tw]) AND ("2020/12/18"[Date - Publication] : "2022/06/18"[Date - Publication])