20.11.10. Myocarditis/Pericarditis: WHO UMC Case Causality assessment: Case Listings

Case ID	Country	PT	Event Seriousness	ALL PTs	Age	Gender	Event Outcome	Medical History	Concomitant Medications	Dose	TTO	WHO	WW Identifier
4.1(b)		Myocarditis	Serious	Myocarditis	17	Male	Recovering/Resolving			2	3	Possible	4.1(b)
		Myocarditis	Serious	Asthenia, Chest discomfort, Chest pain, Malaise, Myocarditis, Myocarditis infectious, Vomiting	15	Male	Recovering/Resolving			2	1	Possible	
		Myocarditis	Serious	Myocarditis	17	Male	Recovering/Resolving			2	6	Possible	
		Myocarditis	Serious	Myocarditis	16	Male	Recovering/Resolving			Unknown	0	Possible	
		Myocarditis	Serious	Myocarditis	15	Male	Recovering/Resolving			Unknown	2	Possible	
		Myocarditis	Serious	Myocarditis	17	Male	Recovering/Resolving			2	3	Possible	
		Myocarditis	Serious	Myocarditis	13	Male	Recovering/Resolving			1	2	Possible	
		Myocarditis	Serious	Chest discomfort, Chest pain, Myocarditis	15	Male	Recovering/Resolving	Troponin I increased(C); Protein C increased(C)		2	4	Possible	
		Myocarditis	Serious	Myocarditis	17	Male	Recovering/Resolving			2	3	Possible	
		Pericarditis	Serious	Myocarditis, Pericarditis	13	Male	Recovering/Resolving			2	4	Possible	
		Myocarditis	Serious	Myocarditis	15	Male	Not Recovered/Not Resolved			2	2	Possible	
		Myocarditis	Serious	Myocarditis	17	Male	Recovering/Resolving	Accommodation disorder(C); Papilloma(H)		2	3	Possible	
		Myocarditis	Serious	Myocarditis	16	Male	Not Recovered/Not Resolved			2	2	Possible	
		Myocarditis	Serious	Myocarditis	14	Male	Recovering/Resolving			2	2	Possible	
		Myocarditis	Serious	Arthralgia, Chest pain, Myocarditis, Pyrexia, Troponin I increased	16	Male	Recovering/Resolving			Unknown	1	Possible	
		Myocarditis	Serious	Myocarditis, Pyrexia	16	Male	Recovering/Resolving			2	3	Possible	
		Myocarditis	Serious	Myocarditis	16	Male	Not Recovered/Not Resolved	Asthma(C)		Unknown	25	Possible	
		Pericarditis	Serious	Chest pain, Pericarditis	13	Male	Recovering/Resolving			1	2	Possible	
		Myocarditis	Serious	Myocarditis	17	Male	Recovering/Resolving	Myocarditis(H)		2	1	Possible	
		Myocarditis	Serious	Myocarditis, Pyrexia	17	Male	Recovered/Resolved			2	2	Possible	
		Myocarditis	Serious	Myocarditis	16	Male	Recovering/Resolving			Unknown	2	Possible	
		Myocarditis	Serious	Myocarditis	15	Male	Recovered/Resolved			2	5	Possible	
		Myocarditis	Serious	Myocarditis, Pyrexia	17	Male	Not Recovered/Not Resolved			2	3	Possible	
		Myocarditis	Serious	Myocarditis	17	Male	Recovering/Resolving	Epilepsy(H)	KEPPRA XR	1	3	Possible	
		Myocarditis	Serious	Myocarditis	17	Male	Recovering/Resolving	COVID-19(H)		2	3	Possible	
		Myocarditis	Serious	Hypoaesthesia, Myocarditis	16	Male	Recovered/Resolved			1	3	Possible	
		Myocarditis	Serious	Myocarditis	17	Male	Recovering/Resolving			Unknown	Unknown	Possible	
		Myocarditis	Serious	Myocarditis	14	Female	Unknown			1	3	Possible	
		Pericarditis	Serious	Pain in extremity, Pericarditis, Pyrexia	15	Female	Recovering/Resolving			1	0	Possible	
		Myocarditis	Serious	Chest pain, Myocarditis, Troponin increased	14	Male	Recovered/Resolved			2	3	Possible	
		Myocarditis	Serious	Myocarditis	15	Male	Recovering/Resolving			2	2	Possible	
		Myocarditis	Serious	Myocarditis	15	Male	Not Recovered/Not Resolved	Milk allergy; Seasonal allergy	LOMUDAL; MOMETASONE; AERIUS [DESLORATADINE]	1	27	Possible	

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Myocarditis	Serious	Chest pain, Myocarditis	15	Male	Not Recovered/Not Resolved			Unknown	2	Possible		
Myocarditis	Serious	Myocarditis	17	Male	Unknown			1	4	Possible		
Myocarditis	Serious	Electrocardiogram QT prolonged, Malaise, Myocarditis, Palpitations	37	Male	Not Recovered/Not Resolved	HypertensionFH; Anxiety(H)		2	1	Possible		
Pericarditis	Serious	Pericarditis	21	Male	Recovering/Resolving			2	1	Possible		
Myocarditis	Serious	Myocarditis	20	Male	Recovering/Resolving	Patent ductus arteriosus repair		2	5	Possible		
Myocarditis	Serious	Myocarditis	18	Male	Not Recovered/Not Resolved			2	3	Possible		
Pericarditis	Serious	Chest pain, COVID-19 immunisation, Heart rate increased, Pericarditis	37	Female	Recovering/Resolving	Comirnaty		2	3	Possible		
Myocarditis	Serious	COVID-19 immunisation, Myocarditis	31	Male	Recovering/Resolving	COMIRNATY		2	23	Possible		
Myocarditis	Serious	Acute pulmonary oedema, COVID-19 immunisation, Myocarditis	37	Male	Recovered/Resolved	COMIRNATY		2	3	Possible		
Myocarditis	Serious	Myocarditis	37	Male	Recovered/Resolved			2	3	Possible		
Myocarditis	Serious	Myocarditis	23	Male	Recovering/Resolving			2	3	Possible		
Myocarditis	Serious	Myocarditis, Pericarditis	29	Female	Not Recovered/Not Resolved	Drug hypersensitivity	WELLBUTRIN	2	2	Possible		
Myocarditis	Serious	Chest pain, Heart rate increased, Myocarditis, Pain in jaw	19	Male	Recovering/Resolving	Myocarditis(C)		2	3	Possible		
Myocarditis	Serious	Myocarditis	21	Male	Unknown			2	3	Possible		
Myocarditis	Serious	Myocarditis, Pain	24	Male	Recovered/Resolved	Anxiety(H); Depression(H)	LEXAPRO	2	3	Possible		
Pericarditis	Serious	Pericarditis	37	Female	Recovering/Resolving			2	5	Possible		
Pericarditis	Serious	Chest pain, Dyspnoea, Extrasystoles, Inappropriate schedule of product administration, Palpitations, Pericarditis	28	Male	Not Recovered/Not Resolved			2	4	Possible		
Myocarditis	Serious	Myocarditis	20	Male	Recovering/Resolving			2	2	Possible		
Myocarditis	Serious	Dyspnoea, Myocarditis, Pyrexia	28	Male	Recovered/Resolved			2	1	Possible		
Myocarditis	Serious	Chest pain, Dyspnoea, Myocarditis	33	Male	Unknown			2	0	Possible		
Pericarditis	Serious	Injection site pain, Pericarditis, Pyrexia	31	Male	Unknown			2	16	Possible		
Myocarditis	Serious	Myocarditis, Pyrexia	20	Male	Unknown			2	3	Possible		
Myocarditis	Serious	Myocarditis, Pyrexia	28	Male	Recovered/Resolved			2	2	Possible		
Pericarditis	Serious	Chest pain, Dyspnoea exertional, Pericarditis	40	Female	Recovered/Resolved	Drug hypersensitivity; Eczema(H)	DUPIXENT; MIRENA	2	3	Possible		
Myocarditis	Serious	Myocarditis, Pyrexia	20	Male	Recovered/Resolved with Sequelae			2	2	Possible		
Myocarditis	Serious	Acute myocardial infarction, Chest pain, Dyspnoea, Myocardial infarction, Myocarditis, Troponin increased	25	Male	Not Recovered/Not Resolved	Allergy to vaccine		2	0	Possible		
Myocarditis	Serious	Chest discomfort, Dizziness, Hyperhidrosis, Myocarditis, Palpitations	27	Male	Recovered/Resolved	COVID-19 VACCINE MODERNA		2	4	Possible		
Myocarditis	Serious	Electrocardiogram normal, Myocardial infarction, Myocarditis	19	Male	Recovering/Resolving			2	3	Possible		

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Myocarditis	Serious	Myocarditis	21	Male	Recovered/Resolved			2	2	Possible
Pericarditis	Serious	Pericarditis	30	Female	Unknown			2	13	Possible
Pericarditis	Serious	Myocarditis, Pericarditis, Pyrexia	22	Male	Recovered/Resolved			2	2	Possible
Myocarditis	Serious	Myocarditis	27	Male	Recovering/Resolving	Cholecystectomy(H); Drug hypersensitivity		2	21	Possible
Pericarditis	Serious	COVID-19 immunisation, Pericarditis	29	Male	Recovering/Resolving	COMIRNATY		2	29	Possible
Myocarditis	Serious	Myocarditis	22	Male	Recovering/Resolving			2	3	Possible
Myocarditis	Serious	Myocarditis	21	Male	Unknown			2	2	Possible
Myocarditis	Serious	Myocarditis	20	Male	Not Recovered/Not Resolved			2	3	Possible
Myocarditis	Serious	Chest discomfort, Myocarditis, Tachycardia	19	Male	Recovered/Resolved			2	2	Possible
Myocarditis	Serious	Malaise, Myocarditis, Pericarditis, Pyrexia, Vomiting	24	Male	Recovered/Resolved			2	2	Possible
Myocarditis	Serious	Myocarditis	22	Male	Recovered/Resolved			2	1	Possible
Myocarditis	Serious	Myocarditis, Ventricular dysfunction	21	Male	Recovering/Resolving	Tobacco user(H)		2	2	Possible
Myocarditis	Serious	Dyspnoea, Myocarditis	25	Male	Recovering/Resolving			2	5	Possible
Myocarditis	Serious	Myocarditis	24	Male	Not Recovered/Not Resolved			2	7	Possible
Pericarditis	Serious	Pericarditis	18	Female	Not Recovered/Not Resolved			2	3	Possible
Myocarditis	Serious	Myocarditis	20	Male	Recovered/Resolved			2	3	Possible
Myocarditis	Serious	Myocarditis	20	Male	Not Recovered/Not Resolved			2	2	Possible
Pericarditis	Serious	Pericarditis	23	Male	Recovering/Resolving			2	19	Possible
Myocarditis	Serious	Myocarditis	38	Male	Unknown			2	4	Possible
Myocarditis	Serious	Myocarditis	23	Male	Not Recovered/Not Resolved			2	3	Possible
Pericarditis	Serious	Pericarditis	32	Male	Recovering/Resolving			2	1	Possible
Myocarditis	Serious	COVID-19 immunisation, Myocarditis, Pericarditis	24	Male	Recovering/Resolving	COMIRNATY(H)		2	28	Possible
Myocarditis	Serious	Congestive cardiomyopathy, Myocarditis	29	Male	Not Recovered/Not Resolved			2	3	Possible
Myocarditis	Serious	Myocarditis	39	Male	Recovered/Resolved			2	3	Possible
Pericarditis	Serious	Pericardial effusion, Pericarditis	26	Male	Not Recovered/Not Resolved	Food allergy	TESTOSTERONE CYPIONATE; PERCOCET [OXYCODONE HYDROCHLORIDE;PARACETAMOL]; MELOXICAM; ASPRIN	2	253	Possible
Myocarditis	Serious	Chest discomfort, Depressed mood, Dyspnoea, Interchange of vaccine products, Myocarditis, Pyrexia, Rhinorrhoea	19	Male	Not Recovered/Not Resolved	PFIZER BIONTECH COVID-19 VACCINE(H)		2	1	Possible
Myocarditis	Serious	Asthenia, Chest discomfort, Chest pain, Chills, Influenza like illness, Myocarditis, Presyncope, Vomiting	33	Male	Recovered/Resolved			2	1	Possible
Myocarditis	Serious	Chest discomfort, Chills, Cough, Dyspnoea, Fatigue, Myocarditis, Pyrexia	35	Male	Unknown		FLONASE [FLUTICASONE PROPIONATE]	2	1	Possible
Myocarditis	Serious	Anaphylactic reaction, Bronchospasm, Chest pain, Dyspnoea, Headache, Hypotension, Myocarditis, Palpitations, Vertigo	40	Female	Recovered/Resolved	Drug hypersensitivity; Childhood asthma(H)	MULTIVITAMINS [VITAMINS NOS]; CALCIUM; ZINC; VITAMIN C [ASCORBIC ACID]	2	33	Possible
Myocarditis	Serious	Chest pain, Headache, Myocarditis, Pyrexia	27	Male	Recovered/Resolved			2	3	Possible

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Myocarditis	Serious	Impaired work ability, Myocarditis	24	Male	Recovering/Resolving			2	4	Possible
Pericarditis	Serious	Chest pain, Pericarditis, Pyrexia	18	Female	Recovering/Resolving			2	1	Possible
Myocarditis	Serious	Myocarditis	18	Male	Recovered/Resolved			2	2	Possible
Myocarditis	Serious	Maternal exposure during pregnancy, Myocarditis	29	Female	Recovering/Resolving	Myocarditis(H)		2	31	Possible
Myocarditis	Serious	Myocarditis	33	Male	Unknown			2	1	Possible
Myocarditis	Serious	Myocarditis	34	Male	Recovering/Resolving			2	7	Possible
Myocarditis	Serious	Chest pain, Malaise, Myocarditis	29	Male	Not Recovered/Not Resolved			2	0	Possible
Myocarditis	Serious	Myocarditis	37	Male	Recovering/Resolving	Peptic ulcer(C); Alcohol use(C); Substance use(C); Nicotine dependence(C); Obesity(C)	ESOMEPRAZOLE	2	1	Possible
Myocarditis	Serious	Myocarditis, Pyrexia	18	Male	Recovering/Resolving			2	3	Possible
Myocarditis	Serious	Myocarditis	18	Male	Recovering/Resolving			2	1	Possible
Pericarditis	Serious	Pericarditis	25	Male	Recovering/Resolving	(H)		2	33	Possible
Pericarditis	Serious	Chest pain, Hospitalisation, Pericarditis	25	Female	Recovering/Resolving	Abstains from alcohol(C); Non-tobacco user(C)	YASMIN	2	1	Possible
Myocarditis	Serious	Myocarditis	31	Male	Recovering/Resolving			2	4	Possible
Myocarditis	Serious	Myocarditis	23	Male	Recovering/Resolving			2	2	Possible
Myocarditis	Serious	Myocarditis	37	Male	Not Recovered/Not Resolved			2	4	Possible
Myocarditis	Serious	Myocarditis	18	Male	Recovering/Resolving			2	3	Possible
Myocarditis	Serious	Myocarditis	18	Male	Recovering/Resolving			2	2	Possible
Myocarditis	Serious	Myocarditis	33	Male	Not Recovered/Not Resolved			2	2	Possible
Pericarditis	Serious	Cardiac disorder, Pericarditis	21	Male	Recovering/Resolving	Ageusia(C); COVID-19(C); Adverse drug reaction(H); Gastrointestinal inflammation(C); Anosmia(C); General physical health deterioration(C)		2	17	Possible
Myocarditis	Serious	Myocarditis, Pyrexia	18	Male	Recovering/Resolving			2	2	Possible
Pericarditis	Serious	Chest discomfort, Concomitant disease aggravated, COVID-19 immunisation, Dizziness, Pericarditis	39	Male	Not Recovered/Not Resolved	Emergency care examination(H); Chest discomfort(H); Chest discomfort(H); COMIRNATY		2	41	Possible
Pericarditis	Serious	Pericarditis	31	Female	Recovering/Resolving			2	1	Possible
Myocarditis	Serious	Chest discomfort, Myocarditis	22	Male	Recovering/Resolving			2	3	Possible
Myocarditis	Serious	Asthenia, Chest pain, Chills, Gait disturbance, Myocarditis, Nausea, Palpitations, Peripheral coldness, Pyrexia	34	Male	Recovered/Resolved	Asthma(C)		2	1	Possible
Pericarditis	Serious	Pericarditis	25	Female	Not Recovered/Not Resolved	Endometriosis(C); Asthma(C); Hypothyroidism(C)		2	1	Possible
Pericarditis	Serious	Pericarditis	33	Male	Recovering/Resolving			2	0	Possible
Myocarditis	Serious	Myocarditis, Pyrexia	30	Male	Unknown	Food allergy		2	2	Possible
Myocarditis	Serious	Myocarditis, Pyrexia	28	Male	Unknown			2	2	Possible
Myocarditis	Serious	Chest pain, Dyspnoea, Myocarditis, Palpitations, Pyrexia	23	Male	Recovering/Resolving			2	3	Possible
Myocarditis	Serious	Chest pain, Myocarditis, Pyrexia	22	Male	Unknown			2	2	Possible
Myocarditis	Serious	Myocarditis	27	Male	Recovering/Resolving	Pyrexia(H)		2	1	Possible

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Myocarditis	Serious	Myocarditis, Ventricular extrasystoles	19	Female	Recovering/Resolving			2	0	Possible	
Myocarditis	Serious	Myocarditis	31	Male	Recovering/Resolving			2	2	Possible	
Myocarditis	Serious	Myocarditis	18	Male	Recovering/Resolving	Seasonal allergy; Asthma(C)		2	13	Possible	
Myocarditis	Serious	Cardiac failure, Myocarditis	40	Female	Unknown			2	29	Possible	
Myocarditis	Serious	Myocarditis	19	Male	Recovering/Resolving			2	3	Possible	
Myocarditis	Serious	Myocarditis	20	Male	Recovering/Resolving			2	2	Possible	
Pericarditis	Serious	Myocarditis, Pericarditis	20	Male	Unknown			2	2	Possible	
Pericarditis	Serious	Inflammation, Pericarditis	20	Male	Recovered/Resolved			2	10	Possible	
Myocarditis	Serious	Myocarditis, Pericarditis	23	Female	Recovering/Resolving	Diarrhoea(H); Iron deficiency anaemia(H)		2	39	Possible	
Myocarditis	Serious	Cardiac failure, Myocarditis, Pericarditis	22	Male	Recovering/Resolving			2	2	Possible	
Pericarditis	Serious	Chest discomfort, Chest pain, Cough, Dyspnoea, Pericardial effusion, Pericarditis, Pyrexia	24	Male	Recovering/Resolving			2	1	Possible	
Myocarditis	Serious	Headache, Myocarditis	27	Female	Not Recovered/Not Resolved			2	1	Possible	
Myocarditis	Serious	Chest pain, Myocarditis	18	Male	Unknown			2	2	Possible	
Myocarditis	Serious	Chest pain, Dizziness, Dyspnoea, Feeling abnormal, Myocarditis, Presyncope	37	Female	Not Recovered/Not Resolved	Autoimmune thyroiditis(C); Hypocalcaemia(C)	NP THYROID;4.1(b) [OMEPRAZOLE]; VITAMIN D3; CALCIUM; MAGNESIUM OXIDE; CALCITRIOL	2	3	Possible	
Myocarditis	Serious	Chest discomfort, Chest pain, Dyspnoea, Ejection fraction decreased, Myocardial oedema, Myocarditis, Pain, Pain in jaw, Pericardial effusion, Pericarditis, Pyrexia, Sleep disorder, Ventricular hypokinesia	21	Male	Recovered/Resolved		ASPIRIN (E.C.); COLCHICINE; IBUPROFEN; FENTANYL; METOPROLOL SUCCINATE	2	1	Possible	
Myocarditis	Serious	Back pain, Chest pain, Dyspnoea, Myocarditis, Pain, Pain in extremity	19	Male	Recovered/Resolved			2	1	Possible	
Pericarditis	Serious	Arthralgia, Back pain, Chest pain, Hypopnoea, Musculoskeletal pain, Pain, Painful respiration, Pericarditis	35	Male	Recovered/Resolved	Blood cholesterol increased(C); Migraine(C)	ALLEGRA; EXCEDRIN [CAFFEINE;PARACETAMOL]	2	102	Possible	
Myocarditis	Serious	Chest pain, Dyspnoea, Myocarditis	23	Male	Unknown			2	2	Possible	
Pericarditis	Serious	Pericarditis	21	Male	Not Recovered/Not Resolved	Cerebral palsy(C)		2	0	Possible	
Pericarditis	Serious	Palpitations, Pericarditis	35	Male	Not Recovered/Not Resolved	Blood cholesterol increased(H); Lymphadenopathy(H)	VITAMIN D [COLECALCIFEROL]	2	3	Possible	
Pericarditis	Serious	Chest pain, Fatigue, Palpitations, Pericarditis, Tachycardia	23	Female	Recovering/Resolving			2	26	Possible	
Myocarditis	Serious	Myocarditis, Pyrexia, Ventricular hypokinesia	18	Male	Recovering/Resolving			2	3	Possible	
Pericarditis	Serious	Chest pain, Nausea, Pericarditis	19	Male	Unknown	Epilepsy(H)		2	1	Possible	
Myocarditis	Serious	Chest pain, Myocarditis	18	Male	Recovered/Resolved			2	1	Possible	
Myocarditis	Serious	Myocarditis	19	Male	Recovered/Resolved			2	0	Possible	
Myocarditis	Serious	Myocarditis	22	Male	Unknown		IBUPROFEN	2	2	Possible	
Pericarditis	Serious	Chest pain, COVID-19 immunisation, Pericarditis	30	Male	Unknown	COMIRNATY		2	23	Possible	

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Myocarditis	Serious	Myocarditis	18	Male	Recovering/Resolving			2	3	Possible
Myocarditis	Serious	Myocarditis	19	Male	Recovering/Resolving			2	3	Possible
Myocarditis	Serious	Abdominal pain upper, Influenza like illness, Myocarditis	38	Male	Not Recovered/Not Resolved	Hypersensitivity; Nephrolithiasis(H); Hidradenitis(H); Ex-tobacco user(H)		2	0	Possible
Myocarditis	Serious	Myocarditis	19	Male	Recovering/Resolving	Non-tobacco user(C); Alcohol use(C); Nephropathy(C); Liver disorder(C)		2	2	Possible
Pericarditis	Serious	Chest pain, Heart rate increased, Hyperhidrosis, Hypertension, Lymphadenopathy, Nausea, Pain, Pericarditis	26	Female	Unknown			2	0	Possible
Myocarditis	Serious	Myocarditis	25	Male	Recovered/Resolved			2	2	Possible
Myocarditis	Serious	Myocarditis	18	Male	Recovering/Resolving			2	1	Possible
Myocarditis	Serious	Myocarditis, Pyrexia	28	Male	Recovered/Resolved			2	3	Possible
Myocarditis	Serious	Influenza like illness, Myocarditis	26	Male	Recovering/Resolving			2	2	Possible
Myocarditis	Serious	Myocarditis	39	Male	Recovering/Resolving	Autoimmune thyroiditis(C)	EUTHYROX	2	2	Possible
Myocarditis	Serious	Myocarditis	29	Male	Recovering/Resolving	Adenoidectomy; Obesity(C); Drug hypersensitivity		2	1	Possible
Myocarditis	Serious	Enterocolitis, Myocarditis	26	Male	Recovering/Resolving	Hepatic function abnormal(C)		2	2	Possible
Myocarditis	Serious	Myocarditis	18	Male	Recovering/Resolving	Depression(H)	MELATONIN AGB	2	3	Possible
Myocarditis	Serious	Inappropriate schedule of product administration, Myocarditis	26	Male	Recovering/Resolving	Myocarditis(H); Hypertension(C)		2	4	Possible
Myocarditis	Serious	Myocarditis	26	Female	Recovering/Resolving			2	55	Possible
Myocarditis	Serious	Myocarditis	20	Female	Not Recovered/Not Resolved			2	3	Possible
Pericarditis	Serious	Pericarditis	39	Male	Recovered/Resolved			2	21	Possible
Myocarditis	Serious	Myocarditis	30	Female	Recovering/Resolving			2	23	Possible
Myocarditis	Serious	Myocarditis	22	Male	Unknown			2	23	Possible
Myocarditis	Serious	Myocarditis	34	Male	Not Recovered/Not Resolved			2	5	Possible
Myocarditis	Serious	Blood pressure decreased, Chest pain, Myocarditis, Nausea, Pyrexia	18	Male	Not Recovered/Not Resolved			2	3	Possible
Pericarditis	Serious	Chest pain, Dyspnoea exertional, Fatigue, Influenza like illness, Pericarditis	32	Female	Not Recovered/Not Resolved	Gluten sensitivity(H); Alcohol use(C)		2	11	Possible
Myocarditis	Serious	Myocarditis, Pyrexia	22	Male	Recovering/Resolving			2	3	Possible
Myocarditis	Serious	Chest pain, Hyperhidrosis, Myocarditis	20	Male	Not Recovered/Not Resolved			2	3	Possible
Pericarditis	Serious	Medication error, Pericarditis	40	Male	Recovered/Resolved with Sequelae			2	8	Possible
Myocarditis	Serious	C-reactive protein increased, Ejection fraction decreased, Myocarditis, Pyrexia, Troponin increased, White blood cell count increased	37	Male	Unknown	Gout(C); Asthma(C); Attention deficit hyperactivity disorder(H); Obesity(H)	MEDIKINET; REPEVAX; FOSTER [BECLOMETASONE DIPROPIONATE;FORMOTEROL FUMARATE]; PNEUMOVAX 23; ALLOPURINOL	2	29	Possible
Myocarditis	Serious	Myocarditis, Pyrexia, Taste disorder	27	Male	Recovering/Resolving	Lipids abnormal(C)		2	1	Possible
Myocarditis	Serious	Chest pain, Myocarditis, Pericarditis	32	Male	Recovered/Resolved			2	4	Possible
Myocarditis	Serious	Chest pain, Myocarditis	25	Male	Unknown			2	3	Possible
Myocarditis	Serious	Myocarditis	36	Male	Unknown		FUROSEMIDE; METOPROLOL TARTRATE; CALCITRIOL	2	4	Possible

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Myocarditis	Serious	Chest pain, Myocarditis, Sensory disturbance	23	Male	Recovered/Resolved			2	2	Possible		
Myocarditis	Serious	Chest pain, Myocarditis	34	Female	Recovered/Resolved			2	0	Possible		
Pericarditis	Serious	Dyspnoea, Induced labour, Maternal exposure during pregnancy, Pericarditis, Premature delivery	28	Female	Not Recovered/Not Resolved	Drug hypersensitivity		2	1	Possible		
Myocarditis	Serious	Myocarditis	20	Male	Unknown			2	10	Possible		
Myocarditis	Serious	Myocarditis	22	Male	Recovered/Resolved			2	2	Possible		
Myocarditis	Serious	Myocarditis	18	Male	Recovered/Resolved	Food allergy; Milk allergy		2	2	Possible		
Myocarditis	Serious	Chills, Feeling abnormal, Myocarditis, Pyrexia	31	Male	Recovered/Resolved			2	3	Possible		
Myocarditis	Serious	Chest pain, Headache, Heart rate increased, Myalgia, Myocarditis, Pyrexia, Swelling, Vaccination site pain	30	Female	Not Recovered/Not Resolved			2	0	Possible		
Myocarditis	Serious	Myocarditis	27	Male	Recovering/Resolving			2	3	Possible		
Myocarditis	Serious	Myocarditis	22	Male	Recovered/Resolved	Drug hypersensitivity(H); Faropenem sodium(H)		2	1	Possible		
Myocarditis	Serious	Myocarditis	28	Male	Recovering/Resolving			2	3	Possible		
Myocarditis	Serious	Myocarditis	18	Male	Recovering/Resolving	Bicuspid aortic valve(H)	LOSARTAN	2	3	Possible		
Pericarditis	Serious	Pericarditis	24	Male	Not Recovered/Not Resolved			2	40	Possible		
Myocarditis	Serious	Myocarditis, Pyrexia	27	Male	Recovering/Resolving			2	18	Possible		
Myocarditis	Serious	Myocarditis	27	Male	Recovered/Resolved			2	3	Possible		
Myocarditis	Serious	Myocarditis, Pyrexia	20	Male	Unknown			2	1	Possible		
Myocarditis	Serious	Myocarditis	27	Male	Not Recovered/Not Resolved			2	4	Possible		
Myocarditis	Serious	Myocarditis, Pyrexia	27	Male	Unknown			2	1	Possible		
Myocarditis	Serious	Chest pain, Dyspnoea, Myocarditis	18	Male	Not Recovered/Not Resolved			2	23	Possible		
Myocarditis	Serious	Myocarditis	24	Male	Recovering/Resolving			2	0	Possible		
Pericarditis	Serious	Pericarditis	31	Male	Recovering/Resolving			2	2	Possible		
Pericarditis	Serious	Chest pain, Pericarditis	24	Male	Recovering/Resolving			2	2	Possible		
Myocarditis	Serious	Chest pain, Myocarditis, Pyrexia	25	Male	Recovered/Resolved			2	3	Possible		
Myocarditis	Serious	Myocarditis	37	Male	Recovering/Resolving	Familial risk factorFH		2	3	Possible		
Myocarditis	Serious	Chest discomfort, Cough, Dyspnoea, Fatigue, Headache, Hyperhidrosis, Impaired work ability, Myocarditis, Pyrexia	19	Male	Recovering/Resolving	(H)		2	0	Possible		
Pericarditis	Serious	Pericarditis	35	Male	Recovering/Resolving	Drug hypersensitivity; Drug hypersensitivity; Alcoholism(C)		2	1	Possible		
Myocarditis	Serious	Abdominal pain upper, Chest discomfort, Discomfort, Malaise, Musculoskeletal pain, Myocarditis, Pyrexia	21	Male	Recovering/Resolving	Asthma(C)		2	3	Possible		
Myocarditis	Serious	Chest pain, Myocarditis	22	Male	Recovering/Resolving			2	4	Possible		
Myocarditis	Serious	Myocarditis, Pericarditis	23	Male	Not Recovered/Not Resolved			2	2	Possible		
Myocarditis	Serious	Myocarditis	30	Male	Recovering/Resolving			2	2	Probable		
Myocarditis	Serious	Myocarditis, Pyrexia	37	Female	Not Recovered/Not Resolved	Palpitations(C)		2	7	Possible		

4.1(b)

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

4.1(b)

4.1(b)	Pericarditis	Serious	Abdominal distension, C-reactive protein increased, Chest discomfort, Chest pain, Cough, Deep vein thrombosis, Discomfort, Dizziness, Dyspnoea, Ejection fraction decreased, Hyperhidrosis, Myalgia, Myocarditis, Pain, Pain in extremity, Pericardial effusion, Pericardial fibrosis, Pericarditis, Peripheral swelling, Pyrexia, Red blood cell sedimentation rate increased, Troponin increased	30	Male	Not Recovered/Not Resolved	Dyslipidaemia(H)		2	1	Possible	
	Myocarditis	Serious	Abdominal distension, C-reactive protein increased, Chest discomfort, Chest pain, Cough, Deep vein thrombosis, Discomfort, Dizziness, Dyspnoea, Ejection fraction decreased, Hyperhidrosis, Myalgia, Myocarditis, Pain, Pain in extremity, Pericardial effusion, Pericardial fibrosis, Pericarditis, Peripheral swelling, Pyrexia, Red blood cell sedimentation rate increased, Troponin increased	30	Male	Not Recovered/Not Resolved	Dyslipidaemia(H)		2	1	Possible	
	Myocarditis	Serious	Chest pain, Malaise, Myocarditis, Pyrexia	25	Male	Recovering/Resolving	Migraine(H); COMIRNATY; COVID-19 immunisation	ISOPTIN [VERAPAMIL]	2	3	Probable	4.1(b)
	Myocarditis	Serious	Myocarditis	24	Male	Recovering/Resolving	Tobacco user(C)		2	2	Possible	
	Myocarditis	Serious	Dyspnoea, Myocarditis, Palpitations	27	Male	Not Recovered/Not Resolved			2	2	Possible	
	Myocarditis	Serious	Chest pain, Myocarditis, Pain, Pyrexia	25	Male	Not Recovered/Not Resolved			2	2	Possible	
	Myocarditis	Serious	Chest crushing, Chest discomfort, Chest pain, Hyperdynamic left ventricle, Myalgia, Myocarditis, Painful respiration, Pleuritic pain, Pyrexia	21	Male	Unknown	Asthma(C); Depression(C)		2	2	Possible	
	Myocarditis	Serious	Myocarditis	19	Male	Unknown			2	3	Possible	
	Myocarditis	Serious	Arthralgia, Chest discomfort, Headache, Malaise, Myocarditis	20	Male	Recovering/Resolving	Seasonal allergy		2	4	Possible	
	Myocarditis	Serious	Chest pain, Chills, Headache, Myocarditis	26	Male	Recovered/Resolved			2	2	Possible	
	Myocarditis	Serious	Chest pain, Inappropriate schedule of product administration, Myocarditis	28	Male	Recovering/Resolving	Tobacco user(C)		2	3	Possible	
	Myocarditis	Serious	Myocarditis	20	Male	Unknown			2	1	Probable	
	Myocarditis	Serious	Myocarditis	21	Male	Unknown	Non-tobacco user(H)		2	1	Possible	
	Myocarditis	Serious	Chest pain, Myocarditis	18	Male	Not Recovered/Not Resolved			2	3	Possible	
	Myocarditis	Serious	Myalgia, Myocarditis, Pyrexia	21	Male	Not Recovered/Not Resolved	Tobacco user(C)		2	4	Possible	
	Myocarditis	Serious	Myocarditis	20	Male	Recovered/Resolved			2	4	Possible	
	Myocarditis	Serious	Chest discomfort, Chest pain, Left ventricular dysfunction, Myocarditis, Nasopharyngitis, Pericarditis, Sleep disorder, Stress	23	Male	Recovered/Resolved	Dyspnoea(C); Asthma(C); Depression(H)	4.1(b) [SALBUTAMOL]	2	2	Probable	
	Myocarditis	Serious	Chest pain, Chills, Fatigue, Myalgia, Myocarditis, Nausea	27	Male	Recovered/Resolved	Food allergy	BUPROPION	2	4	Probable	
	Myocarditis	Serious	Cardio-respiratory arrest, Headache, Myocardial necrosis marker increased, Myocarditis, Pyrexia, Ventricular fibrillation	20	Male	Not Recovered/Not Resolved	Lung assist device therapy		2	2	Possible	
	Myocarditis	Serious	Myocarditis	29	Male	Not Recovered/Not Resolved			2	4	Possible	
	Myocarditis	Serious	Chest pain, Myocarditis	28	Male	Recovering/Resolving	Myocarditis(H); Familial risk factor(H); Seasonal allergy; Non-tobacco user(C)		2	3	Possible	
	Myocarditis	Serious	Chest pain, Hypersensitivity, Myocarditis, Pyrexia, Vaccination site lymphadenopathy	29	Male	Unknown			2	0	Possible	
	Myocarditis	Serious	Chest pain, Dyspnoea exertional, Fatigue, Myocarditis, Pyrexia	21	Male	Recovering/Resolving	Seasonal allergy; Food allergy; Tobacco user(C)	AERIUS [DESLORATADINE]	2	1	Possible	

4.1(b)													
	Myocarditis	Serious	Fatigue, Hypertension, Myocardial infarction, Myocarditis, Pain, Tremor, Vomiting	21	Male	Recovering/Resolving	Mood altered(H); Hypertension(C); Pregnancy(H)		2	3	Possible	
	Myocarditis	Serious	Chest pain, Myocarditis, Product administered to patient of inappropriate age	17	Male	Recovered/Resolved	Type 1 diabetes mellitus(C)	INSULIN	1	1	Possible	
	Myocarditis	Serious	Chest pain, Chills, Fatigue, Myocarditis, SARS-CoV-2 test positive, Tachycardia	15	Male	Not Recovered/Not Resolved	Wolff-Parkinson-White syndrome(H)	GARDASIL 9	2	1	Possible	
	Myocarditis	Serious	Chest pain, Myocarditis, Palpitations, Product administered to patient of inappropriate age, Vaccination complication	15	Female	Recovered/Resolved	Tic(C)	GUANFACINE	Unknown	1	Probable	4.1(b)
	Myocarditis	Serious	Chest pain, Myocarditis	17	Male	Not Recovered/Not Resolved			2	3	Possible	
	Myocarditis	Serious	Myocarditis, Pyrexia	16	Male	Recovering/Resolving			2	2	Possible	
	Pericarditis	Serious	Chest pain, Pericarditis, Pyrexia	14	Male	Recovering/Resolving			2	1	Probable	
	Myocarditis	Serious	Chest pain, Malaise, Myocarditis, Pyrexia	13	Male	Recovering/Resolving			2	3	Possible	
	Myocarditis	Serious	Chest pain, COVID-19 immunisation, Myocarditis	17	Female	Recovering/Resolving	Comirnaty(H)		2	0	Possible	
	Myocarditis	Serious	Chest pain, Chills, Myalgia, Myocarditis, Pyrexia	28	Male	Recovered/Resolved	Not reported	VITAMIN D [VITAMIN D NOS]; FISH OIL; SIMVASTATIN	2	32	Probable	
	Myocarditis	Serious	Cardiac arrest, Inappropriate schedule of product administration, Myocarditis, Pyrexia, Vaccination complication	55	Male	Recovering/Resolving	Hypertension(C)		2	5	Possible	
	Myocarditis	Serious	Chest pain, Myocarditis, Pyrexia	19	Male	Unknown	Type 1 diabetes mellitus(C); Dyslipidaemia(C)	INSULIN GLARGINE; INSULIN REGULAR [INSULIN BOVINE]; ZOCOR	2	1	Possible	
	Myocarditis	Serious	Chest pain, Myocarditis	23	Male	Recovered/Resolved	Gout(C)	COLCHICINE; FAMOTIDINE	2	2 days	possible	
	Myocarditis	Serious	Myocarditis	36	Male	Not Recovered/Not Resolved	Not reported		2	2 days	Possible	
	Pericarditis	Serious	Chest pain, Pericardial effusion, Pericarditis, Pleuritic pain	75	Male	Recovered/Resolved	Rhinitis allergic(C); Hypertension(C); Hyperlipidaemia(C)	ATENOLOL; MONTELUKAST; ROSUVASTATIN; OLMESARTAN; TAMSULOSIN; ACETYLSALICYLIC ACID	2	0 day	Possible	
	Myocarditis	Serious	Dyspnoea, Malaise, Myocarditis, Pyrexia	37	Male	Recovered/Resolved	Factor V Leiden carrier(C); Drug hypersensitivity	TYLENOL	2	1 day	possible	
	Myocarditis	Serious	Chest pain, Dyspnoea, Myocarditis, Pyrexia	28	Male	Recovered/Resolved	Hypertension(C)	RAMIPRIL	2	1 month 6 days	possible	
	Myocarditis	Serious	Myocarditis	21	Male	Not Recovered/Not Resolved	Asthma(C)		2	2 days	Possible	
	Pericarditis	Serious	Arrhythmia, Atrial fibrillation, Cardiac flutter, Chest pain, Dizziness, Pericarditis	51	Male	Not Recovered/Not Resolved	Cardiac pacemaker insertion	LIPITOR	2	5 days	Possible	
	Myocarditis	Serious	Myocarditis	73	Male	Recovering/Resolving	Malignant melanoma(H)		2	1 month 8 days	possible	
	Myocarditis	Serious	Chest pain, Dyspnoea, Myocarditis	29	Male	Recovering/Resolving			Dose 2	4	Possible	
	Myocarditis	Serious	Myocarditis	33	Female	Not Recovered/Not Resolved			Dose 2	1	Possible	
	Pericarditis	Serious	Chest pain, Pericarditis, Pleuritic pain	20	Female	Not Recovered/Not Resolved	Drug hypersensitivity; Hypertension(C); Lupus nephritis(C); Aspergillus infection(H)	CELLCEPT [MYCOPHENOLATE MOFETIL]; LISINOPRIL; PLAQUENIL [HYDROXYCHLOROQUINE PHOSPHATE]; AMLODIPINE; CARVEDILOL; HYDRALAZINE; CRESEMBA	Dose 2	1	Possible	
	Myocarditis	Serious	Myocarditis	18	Male	Not Recovered/Not Resolved			Dose 2	3	Possible	
	Myocarditis	Serious	Chest pain, Feeling of body temperature change, Myalgia, Myocarditis	29	Male	Not Recovered/Not Resolved	Alcohol abuse(C); Tobacco user(C); Drug abuse(H)		Dose 2	2	Possible	
	Myocarditis	Serious	Chest pain, Dyspnoea, Fatigue, Myocarditis, Pain, Palpitations, Tachycardia	30	Female	Not Recovered/Not Resolved	Migraine(C)	AMITRIPTYLINE; COVID-19 MRNA VACCINE BNT162B2	Dose 3	4	Possible	
	Myocarditis	Serious	Myocarditis	35	Male	Recovering/Resolving	Viral myocarditis(H); Tobacco user(C); Allergy to chemicals		Dose 2	3	Possible	
	Myocarditis	Serious	Myocarditis	15	Male	Recovered/Resolved			Dose 2	2	Possible	
	Pericarditis	Serious	Pericarditis	26	Male	Not Recovered/Not Resolved	COVID-19 VACCINE MODERNA		Dose 2	14	Possible	
	Myocarditis	Serious	Myocarditis	19	Male	Recovered/Resolved			Dose 2	3	Possible	

4.1(b)

Myocarditis	Serious	Myocarditis	18	Male	Not Recovered/Not Resolved			Dose 2	2	Possible	
Pericarditis	Serious	Pericarditis	18	Male	Recovering/Resolving			Dose 2	16	Possible	
Myocarditis	Serious	Myocarditis	22	Male	Recovered/Resolved			Dose 2	3	Possible	
Myocarditis	Serious	Chest pain, Dyspnoea, Heart rate increased, Musculoskeletal pain, Myocarditis, Pericarditis	20	Male	Not Recovered/Not Resolved			Dose 2	1	Possible	
Pericarditis	Serious	COVID-19 immunisation, Pericarditis	40	Male	Unknown	COMIRNATY		Dose 2	34	Possible	
Myocarditis	Serious	Asthenia, Chest discomfort, Chest pain, Cold sweat, Decreased appetite, Discomfort, Dizziness, Dyspnoea, General physical health deterioration, Head discomfort, Malaise, Musculoskeletal stiffness, Myocarditis, Palpitations	27	Male	Recovering/Resolving	Overweight(H)		Dose 2	33	Possible	
Pericarditis	Serious	Pericarditis	25	Female	Not Recovered/Not Resolved	Spikevax(H)		Dose 2	1	Possible	
Myocarditis	Serious	Myocarditis, Pyrexia	29	Male	Recovered/Resolved	Seasonal allergy		Dose 2	3	Possible	
Myocarditis	Serious	Myocarditis	22	Female	Recovering/Resolving	Juvenile myoclonic epilepsy(C); Asthma(C)		Dose 2	16	Possible	
Myocarditis	Serious	Myocarditis	34	Male	Unknown			Dose 2	2	Possible	
Myocarditis	Serious	Cardiomyopathy, Chest pain, Myocarditis, Oedema	22	Male	Unknown	Drug hypersensitivity; Depression(C); Anxiety(C); Vitamin D deficiency(C); Hepatic steatosis(H); COVID-19(H)	ESCITALOPRAM OXALATE; VITAMIN D [VITAMIN D NOS]; MULTIVITAMIN [VITAMINS NOS]; FLAX OIL	Dose 3	6	Possible	
Myocarditis	Serious	Myocarditis	37	Male	Recovering/Resolving			Dose 2	3	Possible	
Myocarditis	Serious	Myocarditis, Pyrexia	15	Male	Unknown			Dose 2	2	Possible	
Myocarditis	Serious	Myocarditis	16	Male	Recovered/Resolved			Dose 2	3	Possible	
Myocarditis	Serious	Hypoxic-ischaemic encephalopathy, Myocarditis, Pyrexia, Ventricular fibrillation	27	Male	Unknown			Dose 2	2	Possible	
Myocarditis	Serious	Fatigue, Myocarditis, Pyrexia	34	Male	Recovering/Resolving			Dose 2	1	Possible	
Myocarditis	Serious	Myocarditis	27	Male	Recovering/Resolving	Asthma(C); Hypertonic bladder(C); Micturition urgency(C)	ALFUZOSIN ORION; GIONA; TOVIAZ; BUVENTOL	Dose 2	23	Possible	
Pericarditis	Serious	Pericarditis	31	Male	Not Recovered/Not Resolved			Dose 2	4	Possible	
Myocarditis	Serious	Chest pain, Myocardial necrosis marker increased, Myocarditis	28	Male	Recovering/Resolving			Dose 2	3	Possible	
Myocarditis	Serious	Chest discomfort, Myocarditis	20	Male	Unknown	Catheterisation cardiac		Dose 2	4	Possible	
Pericarditis	Serious	Pericarditis	17	Male	Recovering/Resolving	Attention deficit hyperactivity disorder(C)	RITALIN; MELATONIN AGB; ATARAX [HYDROXYZINE HYDROCHLORIDE]	Dose 2	7	Possible	
Myocarditis	Serious	Blood creatine phosphokinase increased, Myocarditis, Troponin increased	18	Male	Not Recovered/Not Resolved	COVID-19 VACCINE MODERNA(H)		Dose 2	0	Possible	
Myocarditis	Serious	Chest pain, Myocarditis	23	Male	Unknown			Dose 2	1	Possible	
Myocarditis	Serious	Myocarditis	19	Male	Recovering/Resolving			Dose 2	2	Possible	
Myocarditis	Serious	Chest pain, Cold sweat, Dyspnoea, Fatigue, Illness, Malaise, Myocarditis, Palpitations, Pericarditis, Tachycardia	24	Male	Recovering/Resolving			Dose 2	1	Possible	
Myocarditis	Serious	Myocarditis	39	Male	Unknown	Neuroborreliosis(H)		Dose 2	3	Possible	

4.1(b)	Myocarditis	Serious	Blood test abnormal, Cardiac monitoring, Chest discomfort, Chest pain, Chest X-ray normal, Dyspnoea, Electrocardiogram, Hypopnoea, Monocyte count increased, Myocarditis, Neutrophil count increased, Painful respiration, Respiratory viral panel, Troponin increased, White blood cell count increased	25	Male	Not Recovered/Not Resolved			Dose 2	1	Possible	
	Myocarditis	Serious	Arthralgia, Chest pain, Dyspnoea, Ejection fraction decreased, Erectile dysfunction, Fatigue, Heart rate, Hyperhidrosis, Incoherent, Myocarditis, Night sweats, Pain, Palpitations, Paraesthesia, Pyrexia, Tachycardia, Urinary retention	29	Male	Not Recovered/Not Resolved			Dose 2	2	Possible	
	Myocarditis	Serious	Myocarditis	16	Male	Not Recovered/Not Resolved	Drug hypersensitivity; Food allergy		Dose 2	2	Possible	
	Myocarditis	Serious	Myalgia, Myocarditis, Pyrexia	18	Male	Recovered/Resolved			Dose 2	1	Possible	
	Myocarditis	Serious	Arthralgia, Chills, Eye pain, Headache, Myalgia, Myocarditis, Pyrexia, Troponin increased	20	Male	Unknown			Dose 2	24	Possible	
	Myocarditis	Serious	Chest pain, Chills, Dizziness, Dyspnoea, Myocarditis, Nausea, Pyrexia, Vomiting	30	Male	Recovering/Resolving	COVID-19 VACCINE MODERNA(H)		Dose 2	5	Possible	
	Myocarditis	Serious	Myocarditis	20	Male	Recovering/Resolving			Dose 2	1	Possible	
	Myocarditis	Serious	Myocarditis	28	Male	Recovered/Resolved			Dose 2	3	Possible	
	Pericarditis	Serious	Malaise, Pericarditis, Pyrexia	17	Male	Recovering/Resolving			Dose 2	1	Possible	
	Pericarditis	Serious	Pericarditis	39	Female	Not Recovered/Not Resolved		SYSTEN CONTI	Dose 2	29	Possible	
	Myocarditis	Serious	Myocarditis	14	Male	Recovering/Resolving			Dose 2	1	Possible	
	Myocarditis	Serious	Myocarditis	33	Female	Recovering/Resolving			Dose 2	1	Possible	
	Myocarditis	Serious	Myocarditis	34	Male	Not Recovered/Not Resolved	COVID-19 VACCINE MODERNA(H)		Dose 2	1	Possible	
	Myocarditis	Serious	Myocarditis	17	Male	Unknown			Dose 2	4	Possible	
	Myocarditis	Serious	Cerebral infarction, Embolic stroke, Myocarditis	38	Female	Recovering/Resolving			Dose 2	29	Possible	
	Myocarditis	Serious	Chest discomfort, Chest pain, Headache, Myocarditis, Pericarditis, Pyrexia	14	Male	Recovered/Resolved			Dose 2	1	Possible	
	Myocarditis	Serious	Myocarditis, Pyrexia	17	Male	Recovered/Resolved			Dose 2	3	Possible	
	Myocarditis	Serious	Myocarditis	22	Male	Recovering/Resolving			Dose 2	2	Possible	
	Myocarditis	Serious	Abdominal pain upper, Activated partial thromboplastin time, Blood test, C-reactive protein, Cardiac monitoring, Chest pain, Chest X-ray abnormal, Diarrhoea, Echocardiogram, Electrocardiogram, Electrocardiogram abnormal, Full blood count, Headache, Human chorionic gonadotropin, Inflammation, Lipase, Metabolic function test, Muscle injury, Myocarditis, Nausea, Pericarditis, Prothrombin time, Red blood cell sedimentation rate, Respiratory viral panel, Sleep disorder, Troponin I, Troponin increased, Urine analysis, Vomiting	26	Female	Unknown	Drug hypersensitivity; Food allergy; Food allergy; Mycotic allergy; Gastritis(H)		Dose 3	3	Possible	
	Pericarditis	Serious	Myocarditis, Pericarditis	22	Male	Recovering/Resolving	Food allergy; Milk allergy	EFFEXOR SR; EFFEXOR SR; 4.1(b)	Dose 2	2	Possible	

4.1(b)	Myocarditis	Serious	Anxiety, C-reactive protein increased, Cardiac imaging procedure abnormal, Chest discomfort, Chest pain, Chills, Cough, Ear pain, Echocardiogram normal, Ejection fraction normal, Electrocardiogram abnormal, Electrocardiogram T wave inversion, Fatigue, Headache, Hyperhidrosis, Left ventricular dilatation, Magnetic resonance imaging heart, Malaise, Myocardial oedema, Myocarditis, N-terminal prohormone brain natriuretic peptide increased, Nausea, Pain, Pericardial fibrosis, Pleuritic pain, Pyrexia, Red blood cell sedimentation rate increased, Retching, Sleep disorder, Troponin increased, Ventricular hypokinesia, Vomiting	39	Female	Recovered/Resolved	Drug hypersensitivity; Drug hypersensitivity		Dose 3	0	Possible	
	Myocarditis	Serious	Chest pain, Dyspnoea, Fatigue, Myocarditis, Tachycardia	19	Female	Recovering/Resolving			Dose 2	3	Possible	
	Myocarditis	Serious	Chest pain, Myocarditis	25	Male	Recovering/Resolving			Dose 2	4	Possible	
	Pericarditis	Serious	Myocarditis, Pericarditis	21	Male	Recovering/Resolving	Bundle branch block right(H)		Dose 2	3	Possible	
	Myocarditis	Serious	Cardiac arrest, Hypoxic-ischaemic encephalopathy, Myocarditis, Pulseless electrical activity, Seizure, Ventricular fibrillation	30	Male	Not Recovered/Not Resolved			Dose 2	3	Possible	
	Pericarditis	Serious	Atrioventricular block second degree, Chest discomfort, Headache, Hypoaesthesia, Malaise, Myocarditis, Pericarditis, Platelet count increased, Pyrexia	34	Male	Recovering/Resolving	Sinusitis(H); Gastric cancer(C); Lung neoplasm malignant(C); Aneurysm ruptured(H)		Dose 2	5	Possible	
	Myocarditis	Serious	Arthralgia, Fatigue, Myocarditis, Pyrexia	21	Male	Unknown			Dose 2	3	Possible	
	Myocarditis	Serious	Chest discomfort, Dyspnoea, Myocarditis, Pain in extremity, Pyrexia	23	Male	Recovering/Resolving	Sleep apnoea syndrome(C); Tobacco abuse(C); Alcohol use(C)		Dose 2	27	Possible	
	Pericarditis	Serious	C-reactive protein, Chest pain, Chest X-ray, Differential white blood cell count, Dizziness, Electrocardiogram, Fatigue, Fibrin D dimer, Full blood count, Magnetic resonance imaging abnormal, Magnetic resonance imaging heart, Metabolic function test, Pericarditis, Troponin	27	Female	Not Recovered/Not Resolved	Drug hypersensitivity; Drug hypersensitivity; Seasonal allergy		Dose 2	0	Possible	
	Pericarditis	Serious	Blood test, Breast pain, Chest pain, Computerised tomogram, Electrocardiogram, Musculoskeletal pain, Pain, Pericarditis	32	Female	Not Recovered/Not Resolved			Dose 3	6	Possible	
	Myocarditis	Serious	Angina pectoris, Catheterisation cardiac, Echocardiogram, Myocarditis, Sleep disorder, Troponin I	22	Male	Recovered/Resolved			Dose 2	3	Possible	
	Myocarditis	Serious	C-reactive protein increased, Carditis, Chest discomfort, Chest pain, Chest X-ray normal, Dyspnoea, Echocardiogram, Electrocardiogram abnormal, Hypoaesthesia, Laboratory test, Lymphadenopathy, Myocarditis, Pain in extremity, Paraesthesia, Troponin increased	34	Female	Not Recovered/Not Resolved			Dose 3	1	Possible	
	Myocarditis	Serious	Blood creatine phosphokinase increased, C-reactive protein increased, Chest pain, Dyspnoea, Echocardiogram, Ejection fraction, Myalgia, Myocarditis, Pyrexia, Troponin increased	19	Male	Unknown			Dose 2	2	Possible	

4.1(b)													
	Myocarditis	Serious	Blood creatine phosphokinase increased, Chest pain, Chills, Diarrhoea, Echocardiogram normal, Electrocardiogram abnormal, Electrocardiogram ST segment elevation, Fatigue, Hyperhidrosis, Myocarditis, Pericarditis, Pyrexia, SARS-CoV-2 test negative, Troponin I increased, Viral test negative, Vomiting	26	Female	Recovered/Resolved			Dose 3	3	Possible	
	Myocarditis	Serious	Chest pain, Dyspnoea, Eye pain, Fatigue, Heart rate irregular, Hypertension, Lymphadenopathy, Myocarditis, Palpitations, Pyrexia, Respiration abnormal, Seizure, Tachycardia, Tremor	36	Female	Not Recovered/Not Resolved	Hypersensitivity(H); Suspected COVID-19(H); Clinical trial participant(H); Back pain(H)	COVID-19 VACCINE ASTRAZENECA; CO-CODAMOL	Dose 3	0	Possible	4.1(b)
	Myocarditis	Serious	Myocarditis	34	Female	Recovering/Resolving			Dose 2	2	Possible	
	Myocarditis	Serious	Myocarditis	30	Male	Recovering/Resolving			Dose 2	3	Possible	
	Myocarditis	Serious	Myocarditis	26	Male	Recovering/Resolving			Dose 2	3	Possible	
	Myocarditis	Serious	Myocarditis	24	Male	Recovering/Resolving			Dose 2	3	Possible	
	Myocarditis	Serious	Myocarditis	35	Female	Recovering/Resolving	Mitral valve prolapse(C)		Dose 2	8	Possible	
	Myocarditis	Serious	Myocarditis	15	Male	Recovered/Resolved with Sequelae	Overweight(C)		Dose 2		Possible	
	Myocarditis	Serious	Chest discomfort, Chest pain, Hypoxia, Myocarditis, Palpitations	25	Male	Unknown	Asthma(C); COMIRNATY		Dose 2		Possible	
	Myocarditis	Serious	Myocarditis	25	Male	Recovered/Resolved			Dose 2	1	Possible	
	Pericarditis	Serious	Arthralgia, Chest pain, Dyspnoea, Echocardiogram abnormal, Pain, Pericardial effusion, Pericarditis	40	Male	Recovered/Resolved	End stage renal disease(C); Blood cholesterol increased(C); Hypertension(C); Gout(C); Mesangioproliferative glomerulonephritis(C)		Dose 2	31	Possible	
	Myocarditis	Non Serious	C-reactive protein decreased, Chest pain, Dyspnoea, Echocardiogram abnormal, Electrocardiogram abnormal, Fatigue, Headache, Myocarditis, Nausea, Pericarditis, Pyrexia, Sinus tachycardia, Troponin normal, Vomiting	21	Female	Recovered/Resolved	Obesity(H)		Dose 2	1	Possible	
	Myocarditis	Serious	Chest pain, Dyspnoea exertional, Electrocardiogram abnormal, Electrocardiogram ST segment elevation, Myocarditis, Pyrexia, Troponin increased	30	Male	Unknown			Dose 2	1	Possible	
	Myocarditis	Serious	Chest pain, Electrocardiogram change, Electrocardiogram ST segment elevation, Myocarditis	17	Male	Not Recovered/Not Resolved			Dose 2		Possible	
	Myocarditis	Serious	Chest pain, Dyspnoea, Fatigue, Hospitalisation, Myocarditis, Tachycardia	18	Male	Recovering/Resolving	Asthma(C); SARS-COV-2 VACCINE; COVID-19 VACCINE	SALBUTAMOL	Dose 3	4	Possible	
	Myocarditis	Serious	Myocarditis	28	Male	Recovering/Resolving			Dose 2	3	Possible	
	Pericarditis	Serious	Chest pain, Dyspnoea, Fatigue, Flank pain, Gastric ulcer, Palpitations, Pericarditis, Peripheral swelling	38	Male	Not Recovered/Not Resolved	COVID-19 VACCINE MODERNA(H); Herpes zoster oticus(H)	COVID-19 VACCINE MODERNA	Dose 2	71	Possible	
	Myocarditis	Serious	Chest discomfort, Dyspnoea, Malaise, Myalgia, Myocarditis, Pyrexia	28	Male	Recovering/Resolving	Substance use(H); Tobacco user(C); SPIKEVAX(H)		Dose 2	1	Possible	
	Myocarditis	Serious	Myocarditis	35	Female	Recovering/Resolving			Dose 2	3	Possible	
	Myocarditis	Serious	Chest pain, Myocarditis	16	Male	Recovered/Resolved			Dose 2	2	Possible	

4.1(b)													4.1(b)
	Myocarditis	Serious	Myocarditis	18	Male	Recovering/Resolving			Dose 2	2	Possible		
	Myocarditis	Serious	Chest pain, Dyspnoea, Fatigue, Myocarditis, Pain, Pericardial effusion, Pericarditis, Tachycardia	39	Female	Not Recovered/Not Resolved		COVID-19 VACCINE ASTRAZENECA	Dose 3	1	Possible		
	Myocarditis	Serious	Chills, Myocarditis, Nausea, Vomiting	20	Male	Unknown	Substance use(C)		Dose 2		Possible		
	Myocarditis	Serious	Influenza like illness, Myocarditis	21	Male	Unknown			Dose 2		Possible		
	Myocarditis	Serious	C-reactive protein increased, Chest pain, Myocarditis, Troponin	25	Male	Not Recovered/Not Resolved			Dose 3	1	Possible		
	Myocarditis	Serious	C-reactive protein increased, Chest pain, Chest X-ray normal, Computerised tomogram thorax normal, Echocardiogram abnormal, Effusion, Electrocardiogram abnormal, Fatigue, Fibrin D dimer increased, Magnetic resonance imaging abnormal, Myocarditis, Nausea, Tachycardia, Troponin increased	23	Male	Not Recovered/Not Resolved	Schizophrenia(C)		Dose 3	4	Possible		
	Myocarditis	Non Serious	C-reactive protein increased, Echocardiogram normal, Electrocardiogram ST segment elevation, Myocarditis, Troponin increased	24	Male	Not Recovered/Not Resolved	Arnold-Chiari malformation(C); Scoliosis(C); Anxiety(C); Depression(C)		Dose 3	3	Possible		
	Myocarditis	Serious	Myocarditis	20	Male	Unknown	Myocarditis(H)		Dose 2	2	Probable		
	Myocarditis	Serious	Chest pain, Feeling cold, Malaise, Myocarditis	33	Male	Recovering/Resolving	SPIKEVAX		Dose 2	1	Possible		
	Myocarditis	Serious	Adenovirus test, Cardiac telemetry normal, Chest pain, Echocardiogram, Electrocardiogram normal, HIV test negative, Human metapneumovirus test, Human rhinovirus test, Influenza A virus test negative, Influenza B virus test, Influenza virus test negative, Myocarditis, Respiratory syncytial virus test negative, SARS-CoV-2 test negative, Troponin increased	25	Male	Not Recovered/Not Resolved			Dose 3	1	Possible		
	Myocarditis	Serious	Myocarditis, Pyrexia	21	Male	Recovering/Resolving			Dose 2	3	Possible		
	Myocarditis	Serious	Myocarditis	22	Male	Recovering/Resolving			Dose 2	3	Possible		
	Myocarditis	Serious	Myocarditis	14	Male	Recovering/Resolving			Dose 2	3	Possible		
	Myocarditis	Serious	Myocarditis	20	Male	Recovered/Resolved	SPIKEVAX		Dose 2		Possible		
	Myocarditis	Serious	Chest pain, Myocarditis	33	Female	Unknown	COVID-19(H); Myocardial ischaemiaFH		Dose 2		Possible		
	Myocarditis	Serious	Back pain, Chest discomfort, Cough, Dyspnoea, Maternal exposure during pregnancy, Myocarditis, Night sweats, Palpitations	30	Female	Unknown	Hypothyroidism(C)	LEVOTHYROXINE	Dose 2		Possible		
	Pericarditis	Serious	Pericarditis	17	Male	Recovered/Resolved			Dose 2	4	Possible		
	Pericarditis	Serious	Angina pectoris, Cardiovascular disorder, Chest pain, Dyspnoea, Exercise tolerance decreased, Pericarditis, Sinus arrhythmia	24	Female	Recovering/Resolving	SPIKEVAX(H)		Dose 2		Possible		
	Myocarditis	Serious	Myocarditis	34	Male	Recovering/Resolving	Tobacco user(C)		Dose 2	45	Possible		
	Myocarditis	Serious	Chest pain, Myocarditis, Pyrexia	19	Female	Not Recovered/Not Resolved		COLCHICINE; DOXYCYCLINE; MEBEVERINE; SUMATRIPTAN	Dose 2	3	Possible		

4.1(b)													4.1(b)
	Pericarditis	Serious	Chest pain, Fatigue, Pericarditis	22	Male	Recovering/Resolving		COVID-19 VACCINE MODERNA; COVID-19 VACCINE MODERNA	Dose 3	1	Possible		
	Myocarditis	Serious	Chest pain, Dyspnoea, Fatigue, Myocarditis, Palpitations	34	Male	Recovering/Resolving	Electrocardiogram(H)		Dose 3	2	Possible		
	Myocarditis	Serious	Chest pain, Myocarditis	35	Male	Not Recovered/Not Resolved	Congenital cystic kidney disease(C)	COVID-19 VACCINE ASTRAZENECA	Dose 3	4	Possible		
	Myocarditis	Serious	Chest pain, Chills, Dyspnoea, Fatigue, Myalgia, Myocarditis, Palpitations, Pyrexia, Syncope	29	Male	Not Recovered/Not Resolved			Dose 3	0	Possible		
	Myocarditis	Serious	Myocarditis	16	Male	Recovering/Resolving			Dose 2	2	Possible		
	Myocarditis	Serious	Chest pain, Echocardiogram, Electrocardiogram, Electrocardiogram T wave inversion, Flank pain, Hyperhidrosis, Myocarditis, Pain, Pericardial effusion, Troponin, Vomiting	35	Male	Unknown	Renal cell carcinoma(H); Drug hypersensitivity; Drug hypersensitivity		Dose 3	2	Possible		
	Myocarditis	Serious	Myocarditis	39	Male	Recovering/Resolving			Dose 3		Possible		
	Pericarditis	Serious	Chest pain, Dyspnoea, Hypoaesthesia, Influenza like illness, Pericarditis, Pyrexia, Syncope	29	Male	Recovering/Resolving	Temporomandibular joint syndrome(H); Tuberculosis(H)	PFIZER BIONTECH COVID-19 VACCINE; PFIZER BIONTECH COVID-19 VACCINE	Dose 3	0	Possible		
	Myocarditis	Serious	Chest pain, Left ventricular dysfunction, Myocarditis, Palpitations, Tachycardia	21	Male	Recovering/Resolving		PFIZER BIONTECH COVID-19 VACCINE; PFIZER BIONTECH COVID-19 VACCINE	Dose 3	2	Possible		
	Myocarditis	Serious	Blood potassium decreased, Cardiac telemetry, Chest discomfort, Chest pain, Differential white blood cell count, Echocardiogram, Electrocardiogram normal, Fibrin D dimer normal, Full blood count, Hypokalaemia, Laboratory test abnormal, Myocarditis, Nausea, Sleep disorder, Troponin increased	21	Male	Unknown	Urticaria(H)		Dose 3	2	Possible		
	Myocarditis	Serious	Cardiomyopathy, Catheterisation cardiac abnormal, Chest pain, Echocardiogram, Ejection fraction, Electrocardiogram ST segment elevation, Myocarditis, Troponin increased, Vaccination complication	23	Male	Not Recovered/Not Resolved			Dose 3	0	Possible		
	Myocarditis	Serious	Anticoagulant therapy, Blood creatine phosphokinase abnormal, Blood creatine phosphokinase MB, C-reactive protein abnormal, Chest pain, Chest X-ray, Differential white blood cell count abnormal, Echocardiogram, Electrocardiogram, Fibrin D dimer increased, Full blood count abnormal, Influenza A virus test, Influenza B virus test, Laboratory test abnormal, Metabolic function test abnormal, Myocarditis, N-terminal prohormone brain natriuretic peptide abnormal, SARS-CoV-2 test, Troponin I abnormal	31	Male	Unknown			Dose 3	5	Possible		
	Myocarditis	Serious	Abdominal pain upper, Back pain, Chest pain, Dyspnoea, Myocarditis, Palpitations, Pyrexia, Troponin I abnormal	30	Male	Unknown			Dose 2	3	Possible		

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

20.11.11. Myocarditis/Pericarditis: WHO UMC Case Causality assessment: Case Narratives

Case ID	WW Identifier	Narrative	MAH Comment
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 04-Oct-2021 and was forwarded to Moderna on 04-Oct-2021. This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myopericarditis) in a 17-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. No Medical History information was reported. On 20-Aug-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 18-Sep-2021, received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. On 21-Sep-2021, the patient experienced MYOCARDITIS (Myopericarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Myopericarditis) was resolving. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. No concomitant medication reported. No treatment was provided. Company comment: This case concerns a 17-year-old, male patient with no relevant medical history, who experienced the expected event of myocarditis. The event myocarditis occurred 3 days after the second dose of mRNA-1273 vaccine administration. The rechallenge was unknown as there's no information available about the first dose. The patient age and gender remains confounders. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. The RA SD contained the same dose number for 2 different dates of vaccine	17 years old male with unknown medical history who 3 days after the 2nd dose was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as results for all the laboratory and imaging test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, a causal relationship cannot be excluded due to the lack of other information.

Case ID	WW Identifier	Narrative	MAH Comment
		administration. The onset latency was captured as 33 days instead of 3 days and the onset from the last dose was captured as 4 days instead of 3 days. RA SD coding was captured and maintained.	
4.1(b)	4.1(b)	This case was initially received via European Medicines Agency (Reference number: 4.1(b)) on 05-Oct-2021. The most recent information was received on 15-Oct-2021 and was forwarded to Moderna on 15-Oct-2021. This regulatory authority case was reported by a physician and describes the occurrence of CHEST DISCOMFORT (Chest pressure), CHEST PAIN (Chest pain), MALAISE (General malaise), VOMITING (Vomiting), ASTHENIA (Weakness), MYOCARDITIS (Perimyocarditis) and MYOCARDITIS INFECTIOUS (Myocarditis infectious) in a 15-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 3004954 and 3004954) for COVID-19 immunisation. No Medical History information was reported. On 13-Aug-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 13-Sep-2021, received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to 1 dosage form. On 14-Sep-2021, the patient experienced CHEST DISCOMFORT (Chest pressure) (seriousness criteria hospitalization and life threatening), CHEST PAIN (Chest pain) (seriousness criteria hospitalization and life threatening), MALAISE (General malaise) (seriousness criteria hospitalization and life threatening), VOMITING (Vomiting) (seriousness criteria hospitalization and life threatening), ASTHENIA (Weakness) (seriousness criteria hospitalization and life threatening), MYOCARDITIS (Perimyocarditis) (seriousness criteria hospitalization and medically significant) and MYOCARDITIS	15 years old male with unknown medical history who next days after the 2nd dose experienced chest pain, chest discomfort, malaise, vomiting, and asthenia, was hospitalized was diagnosed with myocarditis. Laboratory values showed elevated troponin, elevated CRP, abnormal ECG, and Echo. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for any other infectious process. There is a diagnosis of myocarditis infectious but no information provided for this diagnoisis. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and ECG and Echo results; a causal relationship cannot be excluded due to the lack of other information.

Case ID	WW Identifier	Narrative	MAH Comment
		INFECTIOUS (Myocarditis infectious) (seriousness criteria hospitalization, medically significant and life threatening). At the time of the report, CHEST DISCOMFORT (Chest pressure), CHEST PAIN (Chest pain), MALAISE (General malaise), VOMITING (Vomiting), ASTHENIA (Weakness), MYOCARDITIS (Perimyocarditis) and MYOCARDITIS INFECTIOUS (Myocarditis infectious) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In September 2021, C-reactive protein: high (High) 68 (increased) mg/mL. In September 2021, Echocardiogram: abnormal (abnormal) OBS slightly decreased left ventricle function. In September 2021, Ejection fraction: 45 (abnormal) 45 (%percent) and 45 (Low) low. In September 2021, Electrocardiogram: abnormal (abnormal) Monstrous ST-elevations. In September 2021, Troponin T: 2289.3 (High) 2289.3 (increased) ng/L. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Concomitant medications was not reported. Treatment history was not reported. Company Comment: This case concerns a 15 year old male with no reported medical history , who experienced expected event of myocarditis and other unexpected events of chest pain, chest pressure, weakness , asthenia and malaise . These events occurred 2 days after vaccination with the 2nd dose of mRNA-1273 (Spikevax) and 1 month and 2 days post vaccination with the 1st dose. The rechallenge for this case is not applicable. The benefit risk relationship of mRNA-1273 (	

Case ID	WW Identifier	Narrative	MAH Comment
		Spikevax) is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 15-Oct-2021: Follow-up received on 15-oct-2021. Significant follow up-seriousness criteria updated and new event added	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 04-Oct-2021 and was forwarded to Moderna on 04-Oct-2021. This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myocarditis) in a 17-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3004669) for Vaccination. No Medical History information was reported. On 08-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 14-Sep-2021, after starting mRNA-1273 (Spikevax), the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Myocarditis) was resolving. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Concomitant product use was not provided by the reporter. Lab data included Magnetic resonance imaging heart on 22-SEP-2021,Troponin I on 15-SEP-2021. It stated that myocarditis was confirmed by cardiac MRI and symptoms occurred about 6 days after administration of second dose of the Covid vaccine. Treatment information was not provided.	17 years old male with unknown medical history who 6 days after the 2nd dose was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is is possible based on temporal association between the use of the product and the start of the events. Laboratory results were not provided. A causal relationship cannot be excluded due to the lack of other information.

Case ID	WW Identifier	Narrative	MAH Comment
		Company Comment: This case concerns a 17-year-old, male patient with no relevant medical history, who experienced the expected event of myocarditis. The event myocarditis occurred 6 days after the second dose of mRNA-1273 administration. The rechallenge was unknown as there's no information available about the first dose. The patient's age and gender remains confounders. The benefit-risk relationship of mRNA-1273 is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 04-Oct-2021: Followup received on 04-oct-2021,contain no new information On 04-Oct-2021: Translation received on 07 Oct 2021 included: Event as reported by primary source has changed, added reporter's comments in inarrative supplement and updated narrative. On 05-Oct-2021: Follow up received contain no new information.	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 05-Oct-2021 and was forwarded to Moderna on 05-Oct-2021. This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myocarditis) in a 16-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3005294) for COVID-19 vaccination. No Medical History information was reported. On 13-Sep-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 13-Sep-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Myocarditis) was resolving.	

Case ID	WW Identifier	Narrative	MAH Comment
		DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Troponin: abnormal (abnormal) MILLIGRAM(S) 655,3. The action taken with mRNA-1273 (Spikevax) (Intramuscular) was unknown. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Concomitant medications was not provided by the reporter Treatment information was not provided. The dose of the vaccine was 0.5 milliliter. Company Comment: This case concerns a 16-year-old, male patient with no relevant medical history, who experienced the unexpected event of Myocarditis. The event occurred approximately 1 days after the first dose of Spikevax. The lab indicated that the level of troponin was elevated. The rechallenge was unknown since no information about the second dose was provided. The benefit-risk relationship of Spikevax is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 27-Oct-2021: Follow-up received on 27-Oct-2021, containing no new information	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b) on 06-Oct-2021 and was forwarded to Moderna on 06-Oct-2021. This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myocarditis) in a 15-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination.	15 years old male with unknown medical history who 2 days after an unknown dose was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on the temporal association between the use of the product and

Case ID	WW Identifier	Narrative	MAH Comment
		No Medical History information was reported. On 08-Sep-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) .5 milliliter. On 10-Sep-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Myocarditis) was resolving. mRNA-1273 (Spikevax) (Intramuscular) was withdrawn on 08-Sep-2021. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medications were reported. Treatment information was not provided. It was reported no rechallenge was done hence recurrence was not applicable Company Comment: This case involves a 15-year-old male subject with unknown medical history who experienced the listed serious adverse event of myocarditis f3 days after his first vaccination with mRNA-1273. In response, the vaccine was withdrawn. A re-challenge is not applicable after one dose. The benefit-risk relationship of mRNA-1273 is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 06-Oct-2021: Translation document received on 08 Oct 2021 and contains no new information.	the start of the events. A causal relationship cannot be excluded due to the lack of other information.

Case ID	WW Identifier	Narrative	MAH Comment
4.1(b)	4.1(b)	This case was received via 4.1(b) Pharmaceuticals (Reference number: 4.1(b) on 04-Oct-2021 and was forwarded to Moderna on 07-Oct-2021. This case, initially reported to the 4.1(b) by a (physician), was received via the 4.1(b) (Ref, 4.1(b) On 25-Aug-2021, the patient received the 1st dose of this vaccine. After the vaccination, there was no problem. On 22-Sep-2021, in the morning, the patient received the 2nd dose of this vaccine. On 25-Sep-2021, at 03:15, chest pain developed on admission, and troponin, CKMB, and CRP were increased. The patient was diagnosed with myocarditis based on the clinical course. On 26-Sep-2021, electrocardiogram showed negative T wave. Cardiac function was normal by echocardiography. On 01-Oct-2021, after oral administration of loxoprofen sodium hydrate and colchicine, inflammation and cardiac enzymes decreased to within the normal range. The patient was discharged from the hospital. On 02-Oct-2021, the symptoms were resolving. The outcome of myocarditis was reported as resolving. Follow-up investigation will be made . Company Comment: The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	17 years old male with unknown medical history who 3 days after the 2nd dose experienced chest pain and was found to have elevated troponin, CK and CRO, and abnormal ECG, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and ECG results; a causal relationship cannot be excluded due to the lack of other information.
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference	

Case ID	WW Identifier	Narrative	MAH Comment
		number: 4.1(b)) on 07-Oct-2021 and was forwarded to Moderna on 07-Oct-2021. This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myocarditis) in a 13-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3005241) for COVID-19 vaccination. No Medical History information was reported. On 23-Sep-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 25-Sep-2021, after starting mRNA-1273 (Spikevax), the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Myocarditis) was resolving. The action taken with mRNA-1273 (Spikevax) (Intramuscular) was unknown. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Concomitant medication was not reported. Treatment information was not reported. Company Comment: This case concerns a 13-year-old, male patient with no relevant medical history, who experienced the expected event of Myocarditis. The event occurred approximately 2 days after the dose of Moderna vaccine. The rechallenge was not applicable as limited information was provided about the Moderna Covid-19 vaccine. The event was considered related to the product per the reporter's assessment. The event of Myocarditis is consistent with the current understanding of the	

Case ID	WW Identifier	Narrative	MAH Comment
		mechanism of action of the vaccine. The benefit-risk relationship of Moderna Covid-19 vaccine is not affected by this report.	
4.1(b)	4.1(b)	This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Sep 21, 2nd dose of the Moderna Covid-19 vaccine; Sep 25, chest tightness and pain, troponin I elevation up to 4561 ng/L and CRP, waiting to perform cardiac MRI, suspected myocarditis) and CHEST PAIN (4.1(b)) in a 15-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 immunisation. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Troponin I increased on 25-Sep-2021 and Protein C increased on 25-Sep-2021. On 21-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 25-Sep-2021, the patient experienced MYOCARDITIS (Sep 21, 2nd dose of the Moderna Covid-19 vaccine; Sep 25, chest tightness and pain, troponin I elevation up to 4561 ng/L and CRP, waiting to perform cardiac MRI, suspected myocarditis) (seriousness criteria hospitalization and medically significant), CHEST PAIN (4.1(b)) (seriousness criterion hospitalization) and CHEST DISCOMFORT (chest tightness). At the time of the report, MYOCARDITIS (Sep 21, 2nd dose of the Moderna Covid-19 vaccine; Sep 25, chest tightness and pain, troponin	15 years old male with unknown medical history who 4 days after the 2nd dose experienced chest pain, chest discomfort and was found to have elevated troponin, and was diagnosed with myocarditis. ECG and cMRI results pending. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin; a causal relationship cannot be excluded due to the lack of other information.

Case ID	WW Identifier	Narrative	MAH Comment
		I elevation up to 4561 ng/L and CRP, waiting to perform cardiac MRI, suspected myocarditis), CHEST PAIN (4.1(b) [redacted]) and CHEST DISCOMFORT (chest tightness) was resolving. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. On 25-SEP-2021 the patient had an Echocardiogram and Troponin I done, Troponin was elevated to 4561 ng/L and CRP was done. Patient was waiting to perform Cardiac MRI which resulted in myocarditis. Patient was suspected to myocarditis with a peak TNL 4500 ng/ml and chest pain in remission and TNL declining and after few days of second vaccination patient had preserved cardiac function and was awaiting for Cardiac MRI. Concomitant medications and treatment information was not provided. Patient had took the second dose on 21-SEP-2021 and on 25-SEP-2021 experienced chest tightness and pain. Lab data: On unknown date Echocardiogram was done with unknown results. On 25 Sep 2021: MRI, Troponin I, Blood test was done with unknown results. Most recent FOLLOW-UP information incorporated above includes: On 08-Oct-2021: Translation received on 12-OCT-2021 contains: Event Verbatim Updated and Reporter's comment updated in narrative. On 12-Oct-2021: Significant follow up received lab data and events were added.	

Case ID	WW Identifier	Narrative	MAH Comment
4.1(b)	4.1(b)	This case was initially received via European Medicines Agency (Reference number: 4.1(b) 4.1(b) on 08-Oct-2021. The most recent information was received on 14-Oct-2021 and was forwarded to Moderna on 14-Oct-2021. This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myopericarditis in a patient who recently had the MODERNA Covid vaccine. Blood tests carried out : -CRP 61 - troponin 4700 - serodiagnosis in progress) in a 17-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 214027 and 214019) for SARS-CoV-2 vaccination. No Medical History information was reported. On 13-Aug-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 24-Sep-2021, received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to 1 dosage form. On 27-Sep-2021, the patient experienced MYOCARDITIS (Myopericarditis in a patient who recently had the MODERNA Covid vaccine. Blood tests carried out : -CRP 61 - troponin 4700 - serodiagnosis in progress) (seriousness criterion medically significant). At the time of the report, MYOCARDITIS (Myopericarditis in a patient who recently had the MODERNA Covid vaccine. Blood tests carried out : -CRP 61 - troponin 4700 - serodiagnosis in progress) was resolving. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Concomitant product information was not provided. Treatment information was not provided.	17 years old male with unknown medical history who 3 days after the 2nd dose was found to have elevated troponin, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin; a causal relationship cannot be excluded due to the lack of other information.

Case ID	WW Identifier	Narrative	MAH Comment
		Laboratory data was mentioned as on an unknown date patient took blood test and it shows CRP value as 61 and Troponin value as 4700. Company comment: This case concerns a 17 year old male patient with no relevant medical history, who experienced the expected AESI event of myocarditis. The event occurred approximately 44 days after the fist dose and 3 days after the second dose of the Moderna COVID-19 vaccine. The rechallenge was not applicable. The benefit-risk relationship of the Moderna COVID-19 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 14-Oct-2021: Follow-up received contains added Route of administration and Indication for use. On 14-Oct-2021: Translation received on 20-Oct-2021 contains no new information	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 08-Oct-2021 and was forwarded to Moderna on 08-Oct-2021. This regulatory authority case was reported by a physician and describes the occurrence of PERICARDITIS (Acute pericarditis) and MYOCARDITIS (Acute myocarditis) in a 13-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. No Medical History information was reported. On 23-Aug-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 18-Sep-2021, received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. On 22-Sep-2021, the patient experienced PERICARDITIS (Acute pericarditis) (seriousness criteria hospitalization and medically significant) and	

Case ID	WW Identifier	Narrative	MAH Comment
		MYOCARDITIS (Acute myocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, PERICARDITIS (Acute pericarditis) and MYOCARDITIS (Acute myocarditis) was resolving. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. Concomitant medication was not provided Treatment medication was not provided Company Comment: This case concerns a 13-year-old male patient with no reported medical history who experienced the expected events of acute myocarditis and pericarditis. The event occurred 4 days after the second dose of mRNA-1273 (Spikevax). The rechallenge was unknown details about the first dose was not disclosed. Causality for the reported event was not provided by the reporter. Myocarditis and pericarditis are consistent with the current understanding of the mechanism of action of the vaccine. The benefit-risk relationship of Spikevax is not affected by this report. Event assessed as serious per Regulatory authority as the events were noted as medically significant. The events are adverse event of special interest Most recent FOLLOW-UP information incorporated above includes: On 08-Oct-2021: Translation document received on 12OCT2021. Contains non significant information. Dosage text translated to English.	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 14-Oct-2021 and was forwarded to Moderna on 14-Oct-2021. This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myocarditis) in a 15-	

Case ID	WW Identifier	Narrative	MAH Comment
		year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19. No Medical History information was reported. On 23-Sep-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 25-Sep-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Myocarditis) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 28-Sep-2021, Serum ferritin: 133 (normal) 133 ng/mL. On 29-Sep-2021, Troponin I: 243.8 (High) 243.8 pg/ml. On 30-Sep-2021, Troponin I: 67.7 (High) 67.7 pg/ml. On 01-Oct-2021, Troponin I: 32.9 (High) 32.9 pg/ml. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Concomitant information was not provided. Treatment information was not provided. Company comment: The case concerns a 15-year-old-male patient with no relevant medical history, who experienced the expected event of myocarditis. The event occurred approximately 2 days after the first dose of Spikevax, with the highest level of Troponin I on day 4 after the vaccination. The rechallenge was unknown since there's no information about the first dose. The benefit-risk relationship of	

Case ID	WW Identifier	Narrative	MAH Comment
		Spikevax is not affected by this report.	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 14-Oct-2021 and was forwarded to Moderna on 14-Oct-2021. This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myocarditis) in a 17-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3005888) for COVID-19 vaccination. The patient's past medical history included Papillomatosis (Cutaneous Papillomatosis) in July 2020. Concurrent medical conditions included Disorders of refraction and accommodation, other since 2012. On 20-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 23-Sep-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Myocarditis) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 23-Sep-2021, Echocardiogram: abnormal (abnormal) VI non-dilated, non-hypertrophic with preserved SF. Normal global and segmental contractility. Non-dilated aortic root and LA. Structurally preserved mitral valve with good opening and without MI. Non-thickened tricuspid aortic valve with good opening and without aortic insufficiency. Non-dilated right heart cavities with good RV systolic function. Tricuspid valve with normal TI and normal sPAP. Normal pericardium. Non-dilated IVC with adequate inspiratory collapse. Normal diastolic function. Normal aortic arch and normal position of coronary arterial ostia. Normal PA..	17 years old male with medical history of disorders of refraction and accomodation and cutaneous papillomatosis who 3 days after the 2nd dose was diagnosed with myocarditis. ECG and Echo were abnromal. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the abnormal ECG and Echo results; a causal relationship cannot be excluded due to the lack of other information.

Case ID	WW Identifier	Narrative	MAH Comment
		On 24-Sep-2021, Magnetic resonance imaging heart: abnormal (abnormal) VI non-dilated, non-hypertrophic with preserved SF. Normal global and segmental contractility. Non-dilated aortic root and LA. Structurally preserved mitral valve with good opening and without MI. Non-thickened tricuspid aortic valve with good opening and without aortic insufficiency. Non-dilated right heart cavities with good RV systolic function. Tricuspid valve with normal TI and normal sPAP. Normal pericardium. Non-dilated IVC with adequate inspiratory collapse. Normal diastolic function. Normal aortic arch and normal position of coronary arterial ostia. Normal PA.. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. No concomitant medications were provided. No treatment medications were reported. company comment: This case concerns a 17 year-old, male patient with no relevant medical history, who experienced the serious (due to hospitalization) unexpected AESI event of Myocarditis. The event occurred approximately 4 days after the second dose of Spikevax. The rechallenge was not applicable, as the event was reported exclusively after the second dose. The benefit-risk relationship of Spikevax is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 14-Oct-2021: Translation received date 18OCT2021 Medical history comment ,Lab data result , Dosage text updated	
4.1(b) [redacted]	4.1(b) [redacted]	This case was received via European Medicines Agency (Reference number 4.1(b) [redacted]) on 15-Oct-2021 and was forwarded to Moderna on 15-Oct-2021.	

Case ID	WW Identifier	Narrative	MAH Comment
		This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (Myocarditis) in a 16-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 300423) for COVID-19 vaccination. No Medical History information was reported. On 21-Aug-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 25-Sep-2021, received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. On 27-Sep-2021, after starting mRNA-1273 (Spikevax), the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization prolonged and medically significant). At the time of the report, MYOCARDITIS (Myocarditis) had not resolved. Patient had undergone Laboratory tests, echo, ECG, cardiac MRI, results were not provided. No concomitant medication provided. No treatment information mentioned. Company comment: This is a regulatory authority case concerning a 16-year-old male patient with no relevant medical history reported, who experienced serious unexpected event of Myocarditis. The event occurred 2 days after the second dose of mRNA-1273. The rechallenge was not applicable as no additional dosing is expected. The benefit-risk relationship of mRNA-1273 is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 15-Oct-2021: Significant follow-up received, Patient's age updated.	

Case ID	WW Identifier	Narrative	MAH Comment
		On 15-Oct-2021: Translation received on 18-10-2021 contains significant information: lab data was updated in Inarrative supplement.	
4.1(b)	4.1(b)	This case was received via 4.1(b) Pharmaceuticals (Reference number: 4.1(b)) on 11-Oct-2021 and was forwarded to Moderna on 18-Oct-2021. This case, initially reported to the 4.1(b)) by a (physician), was received via the 4.1(b) (Ref, 4.1(b) On an unknown date, the patient received the 1st dose of this vaccine. On 02-Oct-2021, the patient received the 2nd dose of this vaccine. On 04-Oct-2021, chest pain and vomiting developed. On 05-Oct-2021, the patient visited the reporting hospital. The patient was diagnosed with myocarditis due to abnormally high troponin I level. The patient was transported to an advanced treatment hospital and was hospitalized. On 09-Oct-2021, the symptoms were resolving, and the patient was discharged from the hospital. The outcome of myocarditis was reported as resolving. Follow-up investigation will be made. Company Comment: The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	
4.1(b)	4.1(b)	This case was initially received via European Medicines Agency (Reference number 4.1(b)) on 18-Oct-2021. The most recent information was received on 22-Oct-2021 and was forwarded to Moderna on 22-Oct-2021. This regulatory authority case was reported by a consumer and describes the occurrence of CHEST PAIN (Chest pain), ARTHRALGIA (Shoulder pain), TROPONIN I INCREASED (Troponin I increased), PYREXIA (Pyrexia) and MYOCARDITIS (Myocarditis) in a 16-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. No Medical History information was reported.	16 years old male with unknown medical history who next day after dose 1 experienced chest pain, arthalgia, pyrexia, and was diagnosed with myocarditis and elevated troponing. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and a causal relationship cannot be excluded due to the lack of other information.

Case ID	WW Identifier	Narrative	MAH Comment
		In 2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 02-Oct-2021, the patient experienced CHEST PAIN (Chest pain) (seriousness criterion medically significant), ARTHRALGIA (Shoulder pain) (seriousness criterion medically significant), TROPONIN I INCREASED (Troponin I increased) (seriousness criterion medically significant), PYREXIA (Pyrexia) (seriousness criterion medically significant) and MYOCARDITIS (Myocarditis) (seriousness criterion medically significant). At the time of the report, CHEST PAIN (Chest pain), ARTHRALGIA (Shoulder pain), TROPONIN I INCREASED (Troponin I increased), PYREXIA (Pyrexia) and MYOCARDITIS (Myocarditis) was resolving. The action taken with mRNA-1273 (Spikevax) (Unknown) was unknown. No concomitant and treatment medications are provided by the reporter. Company Comment: This case concerns a 16-year-old, male with no reported medical history, who experienced the serious, unexpected events of chest pain, pyrexia, arthralgia and serious, expected and AESI event of myocarditis. Troponin I increased was reported. Time to onset from vaccination was not reported. The event occurred one day 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. Event terms, onset dates, outcomes and seriousness captured per SD from Regulatory Authority reporting. Most recent FOLLOW-UP information incorporated above includes:	

Case ID	WW Identifier	Narrative	MAH Comment
		On 22-Oct-2021: Follow up received on 22-OCT-2021 included: new event added.	
4.1(b)	4.1(b)	This case was received via 4.1(b) Pharmaceuticals (Reference number: 4.1(b) on 12-Oct-2021 and was forwarded to Moderna on 18-Oct-2021. This case, initially reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref, 4.1(b) On an unknown date, the patient received the 1st dose of this vaccine. On an unknown date, body temperature before the vaccination: 36.4 degrees Celsius. On 04-Oct-2021, at 17:00, the patient received the 2nd dose of this vaccine. Pyrexia developed. On 07-Oct-2021, at 06:00, chest discomfort developed. The patient visited the reporting hospital. Echocardiography was performed. Increased myocardial enzyme was noted. The patient was hospitalized with a diagnosis of myocarditis. Fluid replacement and anti-inflammatory analgesics were administered with rest. On 11-Oct-2021, the symptoms were resolving, and the patient was discharged from the hospital. The outcome of pyrexia and myocarditis was reported as resolving. Follow-up investigation will be made. Company Comment: The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 18-Oct-2021 and was forwarded to Moderna on 18-Oct-2021. This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Perimyocarditis) in a 16-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. No medical history was reported. Concurrent medical conditions included Asthma. On 27-Aug-2021, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 21-Sep-2021, after starting mRNA-1273 (Spikevax), the patient experienced MYOCARDITIS	16 years old male with unknown medical historywho 25 days after an unknown dose was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on the temporal association between the use of the product and the start of the events. A causal relationship cannot be excluded due to the lack of other information.

Case ID	WW Identifier	Narrative	MAH Comment
		(Perimyocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Perimyocarditis) had not resolved. The action taken with mRNA-1273 (Spikevax) (Unknown) was unknown. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. No concomitant medication were provided. On an unknown date, laboratory test included COVID-19 virus test and results were not provided. No treatment information were provided. Company Comment: This case concerns a 16-year-old, male patient with no relevant medical history, who experienced the expected event of myocarditis. The event myocarditis occurred 25 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 patient's age and gender remain confounders. 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 Received on 20-Oct-20t21 ,includes Event verbatim translated.	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 19-Oct-2021 and was forwarded to Moderna on 19-Oct-2021. This regulatory authority case was reported by a physician and describes the occurrence of CHEST PAIN (Chest pain) and PERICARDITIS (Pericarditis) in a 13-	

Case ID	WW Identifier	Narrative	MAH Comment
		year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3004959) for COVID-19 vaccination. No Medical History information was reported. On 30-Sep-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 02-Oct-2021, the patient experienced CHEST PAIN (Chest pain) (seriousness criterion medically significant) and PERICARDITIS (Pericarditis) (seriousness criterion medically significant). At the time of the report, CHEST PAIN (Chest pain) and PERICARDITIS (Pericarditis) was resolving. 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 mentioned. No treatment details were reported. Company Comment: This case concerns a 13-year-old, male patient with no relevant medical history, who experienced the unexpected event of Chest pain and expected event of Pericarditis. The events occurred approximately 3 days after the first dose of Spikevax. The rechallenge was not applicable, as the event happened after the first dose. Though events were reported separately, the said chest pain seems a symptoms of pericarditis. The benefit-risk relationship of Spikevax is not affected by this report	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 19-Oct-2021 and was forwarded to Moderna on 19-Oct-2021.	

Case ID	WW Identifier	Narrative	MAH Comment
		This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myocarditis) in a 17-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 3005238 and 3004670) for COVID-19 vaccination. The patient's past medical history included Myocarditis in 2019. On 06-Sep-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 27-Sep-2021, received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. On 28-Sep-2021, after starting mRNA-1273 (Spikevax), the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Myocarditis) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 30-Sep-2021, SARS-CoV-2 test: negative (Negative) Negative. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. No concomitant medications reported by reporter. No treatment medications provided by the reporter. Company Comment: This case concerns a 17 year-old male patient with a history of myocarditis who experienced the expected serious event of myocarditis, an AESI, and the non-serious event of inappropriate schedule of vaccine administered. The event occurred approximately 1 day after the second dose of mRNA-1273, which was administered 22 days after the first	

Case ID	WW Identifier	Narrative	MAH Comment
		dose. The rechallenge was not applicable as no additional dosing will be administered. The medical history of myocarditis and of inappropriate schedule of vaccine administered remain confounders. The benefit-risk relationship of mRNA-1273 (Spikevax) is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 19-Oct-2021: Translation document received on 20-Oct-2021 and event verbatim updated.	
4.1(b)	4.1(b)	This case was received via 4.1(b) Pharmaceuticals (Reference number: 4.1(b) 4.1(b) on 15-Oct-2021 and was forwarded to Moderna on 20-Oct-2021. This case, initially reported to the 4.1(b) by a (physician), was received via the 4.1(b) (Ref, 4.1(b) On an unknown date, the patient received the 1st dose of this vaccine. On 26-Sep-2021, the patient received the 2nd dose of this vaccine. On 27-Sep-2021, pyrexia in the 38 degrees Celsius developed. On 28-Sep-2021, in the morning, acute myocarditis developed. Chest tightness developed. The patient visited a nearby physician. Electrocardiogram showed extensive ST elevation. Blood test showed increased CK, CK-MB, CRP, and WBC. On 29-Sep-2021, the patient was referred to the reporting department. Echocardiography showed no abnormalities, but troponin I was elevated. The patient was hospitalized with a diagnosis of acute myocarditis. On 02-Oct-2021, the symptoms were confirmed as resolved. The outcome of pyrexia and acute myocarditis was reported as resolved. Follow-up investigation will be made. Company Comment: The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 20-Oct-2021 and was forwarded to Moderna on 20-Oct-2021. This regulatory authority case was reported by a physician and describes the occurrence of	16 years old male with unknown medical history who 2 days after an unknown dose experienced chest pain and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as

Case ID	WW Identifier	Narrative	MAH Comment
		MYOCARDITIS (ONSET OF CHEST PAIN WITH INCREASED MYOCARDIAL CYTOLYSIS INDICES 48 HOURS AFTER VACCINE. HOSPITALIZATION FROM 11-sep-2021 to 18/09/2021) in a 16-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3005294) for SARS-CoV-2 vaccination. No Medical History information was reported. On 09-Sep-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) .5 milliliter in total. On 11-Sep-2021, after starting mRNA-1273 (Spikevax), the patient experienced MYOCARDITIS (ONSET OF CHEST PAIN WITH INCREASED MYOCARDIAL CYTOLYSIS INDICES 48 HOURS AFTER VACCINE. HOSPITALIZATION FROM 11-sep-2021 to 18/09/2021) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (ONSET OF CHEST PAIN WITH INCREASED MYOCARDIAL CYTOLYSIS INDICES 48 HOURS AFTER VACCINE. HOSPITALIZATION FROM 11-sep-2021 to 18/09/2021) was resolving. The action taken with mRNA-1273 (Spikevax) (Intramuscular) was unknown. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medication details were provided. Patient done with laboratory test included doppler ultrasound, NMR, and ECG but results were not provided. Patient had experienced onset of chest pain with increased myocardial cytolysis indices 48 hours after the vaccine. Patient was	any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on the temporal association between the use of the product and the start of the events. A causal relationship cannot be excluded due to the lack of other information.

Case ID	WW Identifier	Narrative	MAH Comment
		hospitalized from 11-Sep-2021 to 18-Sep-2021. No treatment information was provided. Company Comment: This case concerns a 16-year-old female patient, with no relevant medical history, who experienced the expected serious event of special interest of myocarditis. The events occurred the day after a dose of Spikevax. The rechallenge was assessed as not applicable as the dose number was unknown. The benefit-risk relationship of Spikevax is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 20-Oct-2021: Translation document received on 21-Oct-2021 included translated event verbatim updated.	
4.1(b)	4.1(b)	This case was received via 4.1(b) Pharmaceuticals (Reference number: 4.1(b)) on 19-Oct-2021 and was forwarded to Moderna on 21-Oct-2021. This case, initially reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref, 4.1(b) Myocarditis was assessed as serious by the MAH. On 11-Sep-2021, the patient received the 1st dose of this vaccination. There was no problem especially. On 09-Oct-2021, the patient received the 2nd dose of this vaccination. On 12-Oct-2021, chest pain developed. On 13-Oct-2021, the patient had a chest pain. On 14-Oct-2021, the patient visited the hospital in the morning. There were no particular findings in echo or electrocardiogram, but troponin increased. The patient was diagnosed with myocarditis. On 18-Oct-2021, the recovery of symptom was confirmed. The outcome of myocarditis was reported as recovered. Follow-up investigation will be made. Company Comment:	

Case ID	WW Identifier	Narrative	MAH Comment
		The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	
4.1(b)	4.1(b)	This case was received via 4.1(b) Pharmaceuticals (Reference number: 4.1(b)) on 19-Oct-2021 and was forwarded to Moderna on 22-Oct-2021. This case, initially reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref, 4.1(b) On an unknown date, the patient received the 1st dose of the vaccine. On 09-Oct-2021, the patient received the 2nd dose of the vaccine. From 10-Oct-2021 to 11-Oct-2021, the patient had pyrexia of 38s degrees Celsius. On 12-Oct-2021, at 03:00, the patient was aware of pain in the left chest for approximately 10 minutes. As chest discomfort sensation persisted thereafter, the patient visited a hospital. An electrocardiogram showed ST elevations in II, III, and aVF, and the result of blood sampling revealed an inflammatory response and elevated cardiac enzymes. Echocardiography showed enhanced pericardium brightness and accumulation of pericardial fluid. The patient was admitted to the hospital for suspected myopericarditis. On an unspecified date, as of the date, any virus that can cause myocarditis had not been detected. Cardiac contrast-enhanced MRI showed findings suggestive of myocarditis. The result of myocardial biopsy showed normal findings of myocardium. After being hospitalized, the patient had no chest pain, cardiac failure, or arrythmia, and the course of the disease was favorable without transformation to fulminant myocarditis. The symptoms had not resolved.	17 years old male with unknown medical history who next day after the 2nd dose of Spikevax developed pyrexia and the next day expereinced chest discomfort and was found to have elevated cardiac enzymes (not especified), abnormal EGC, abnornal Echo with pericardial fluid. Myocardial biopsy showed normal findings. Patient was diagnosed with myopericarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated cardiac enzymes and ECG results; a causal relationship cannot be excluded due to the lack of other information.

Case ID	WW Identifier	Narrative	MAH Comment
		The outcome of pyrexia and myopericarditis was reported as ongoing and unchanged. Follow-up investigation will be made. Company Comment: The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 21-Oct-2021 and was forwarded to Moderna on 21-Oct-2021. This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (4.1(b) in a 17-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 214029) for COVID-19 vaccination. The patient's past medical history included Epilepsy. Concomitant products included LEVETIRACETAM (KEPPRA XR) for an unknown indication. On 02-Oct-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 05-Oct-2021, the patient experienced MYOCARDITIS (4.1(b) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (4.1(b) was resolving. The action taken with mRNA-1273 (Spikevax) (Unknown) was unknown. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. No treatment information was reported.	17 years old male with unknown medical history who 3 days after the 1st dose pain and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events; a causal relationship cannot be excluded due to the lack of other information.

Case ID	WW Identifier	Narrative	MAH Comment
		Company comment: This case concerns a 17-year old, male subject with no relevant medical history, who experienced the serious unexpected event of Myocarditis(AESI). The event, which resulted in hospitalization, occurred 3 days after the first dose of Spikevax. The patient's age and gender remain as confounders. The benefit-risk relationship of Spikevax is not affected by this report.	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 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 MYOCARDITIS (Myocarditis) in a 17-year-old male patient who received mRNA-1273 (Spikevax) (batch no. FH0161) for COVID-19 vaccination. The patient's past medical history included COVID-19 (Had Covid with inpatient care 26-Apr-2021 - 03-May-2021.) from 26-Apr-2021 to 03-May-2021. On 05-Oct-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 08-Oct-2021, after starting mRNA-1273 (Spikevax), the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Myocarditis) was resolving. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. No concomitant medication details was provided. No treatment medication details was provided.	

Case ID	WW Identifier	Narrative	MAH Comment
		Company comment: This case concerns a 17-year-old, male patient with previous relevant medical history of COVID-19 (had COVID with inpatient care 26-Apr-2021 - 03-May-2021), who experienced the expected serious (hospitalization) event of Myocarditis. The event of Myocarditis was also upgraded to serious (Medically Significant) as per Important medical event terms list (MedDRA version 24.0). The event occurred approximately 04 days after the second dose of Spikevax. The rechallenge is not applicable as the AE occurred after the second dose. The medical history of COVID-19 (had COVID with inpatient care 26-Apr-2021 - 03-May-2021) remains a confounder. The event is consistent with the current understanding of the mechanism of action of the vaccine. The benefit-risk relationship of Spikevax is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 22-Oct-2021: Translated document received on 26-OCT-2021 Contains added date of historical condition, added Event verbatim and added dosage text.	
4.1(b)	4.1(b)	This case was received via 4.1(b) Pharmaceuticals (Reference number: 4.1(b) on 15-Oct-2021 and was forwarded to Moderna on 25-Oct-2021. This case, initially reported to the 4.1(b) by a pharmacist, was received via the 4.1(b) (Ref, 4.1(b) On an unknown date, body temperature before the vaccination: 36.3 degrees Celsius. On 05-Oct-2021, the patient received the 1st dose of this vaccine. On 08-Oct-2021, myocarditis developed. Anterior chest pain and numbness of limbs were noted, and the patient was raced to a hospital.	16 years old male with unknown medical history who 3 days after the 1st dose experienced chest pain and numbness of limbs and was found to have elevated troponin, Ck, and abnormal EGC, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and ECG results; a causal relationship cannot be excluded due to the lack of other information.

Case ID	WW Identifier	Narrative	MAH Comment
		Troponin I increased to 0.707 and CK to 354. Acetaminophen 500 mg was intravenously infused for chest pain. Thereafter, the patient was hospitalized. On 09-Oct-2021, 12 lead electrocardiogram showed no changes in ST. Blood test showed troponin positive at 0.053 and CK was 225. Heart rate was 60 to 70 beats/min. Electrocardiogram showed negative T wave in V1 and aVL and early repolarization in V2 to V6. The patient did not have subjective symptoms. On 10-Oct-2021, normalization was confirmed with troponin of 0021 and CK of 125. No subjective symptoms were noted. On 11-Oct-2021, electrocardiogram showed no change in symptoms. On 12-Oct-2021, recovery of the symptoms was noted, and the patient was discharged from the hospital. The outcome of myocarditis and numbness of the limbs was reported as recovered. Follow-up investigation will be made. Company Comment: The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 25-Oct-2021 and was forwarded to Moderna on 25-Oct-2021. This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Perimyocarditis) in a 17-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination.	17 years old male with unknown medical history with unknown TTO who after an unknown dose was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events. A

Case ID	WW Identifier	Narrative	MAH Comment
		No Medical History information was reported. In September 2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 28-Sep-2021, the patient experienced MYOCARDITIS (Perimyocarditis) (seriousness criterion medically significant). At the time of the report, MYOCARDITIS (Perimyocarditis) was resolving. The action taken with mRNA-1273 (Spikevax) (Intramuscular) was unknown. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Concomitant product use was not provided by the reporter No treatment information was provided. Company comment: This is a regulatory case concerning a 17 year-old, male patient with NO clinical history who experienced the expected serious event of MYOCARDITIS (AESI) The event occurred on unknown day after the FIRST dose of Spikevax. The rechallenge is unknown as per no information is available at the time of the report. The benefit-risk relationship of Spikevax is not affected by this report.	causal relationship cannot be excluded due to the lack of other information.
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 27-Oct-2021 and was forwarded to Moderna on 27-Oct-2021. This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myocarditis) in a 14-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 3005696) for COVID-19 vaccination.	

Case ID	WW Identifier	Narrative	MAH Comment
		No Medical History information was reported. On 11-Oct-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 14-Oct-2021, after starting mRNA-1273 (Spikevax), the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Myocarditis) outcome was unknown. 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 provided. Treatment information was not provided.	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b) on 27-Oct-2021 and was forwarded to Moderna on 27-Oct-2021. This regulatory authority case was reported by a consumer and describes the occurrence of PAIN IN EXTREMITY (Pain in arm), PYREXIA (Pyrexia) and PERICARDITIS (Pericarditis) in a 15-year-old female patient who received mRNA-1273 (Spikevax) (batch no. UNKNOWN) for COVID-19 vaccination. No Medical History information was reported. On 08-Oct-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 08-Oct-2021, the patient experienced PAIN IN EXTREMITY (Pain in arm) (seriousness criterion medically significant), PYREXIA (Pyrexia)	15 years old female with unknown medical history who same day after the 1st dose experienced pyrexia and pain in extremities and was diagnosed with pericarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events; a causal relationship cannot be excluded due to the lack of other information.

Case ID	WW Identifier	Narrative	MAH Comment
		(seriousness criterion medically significant) and PERICARDITIS (Pericarditis) (seriousness criterion medically significant). At the time of the report, PAIN IN EXTREMITY (Pain in arm), PYREXIA (Pyrexia) and PERICARDITIS (Pericarditis) was resolving. The action taken with mRNA-1273 (Spikevax) (Intramuscular) was unknown.	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) 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 TROPONIN INCREASED (Troponin increased), CHEST PAIN (Precordial pain) and MYOCARDITIS (Myocarditis) in a 14-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 prophylaxis. No Medical History information was reported. On 08-Oct-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 11-Oct-2021, the patient experienced TROPONIN INCREASED (Troponin increased) (seriousness criterion medically significant), CHEST PAIN (Precordial pain) (seriousness criterion medically significant) and MYOCARDITIS (Myocarditis) (seriousness criterion medically significant). On 17-Oct-2021, TROPONIN INCREASED (Troponin increased), CHEST PAIN (Precordial pain) and MYOCARDITIS (Myocarditis) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):	14 years old male with unknown medical history who 3 days after the 2nd dose experienced chest pain and was found to have elevated troponin, cMRI abnormal, that confirmed the diagnosis of myocarditis. Events, including troponin levels resolved 6 days later. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and cMRI results; a causal relationship cannot be excluded due to the lack of other information.

Case ID	WW Identifier	Narrative	MAH Comment
		On 11-Oct-2021, Troponin: 4000 (High) 4000 and 14000 (High) 14000. On 12-Oct-2021, Troponin: 16000 (High) 16000. On 16-Oct-2021, C-reactive protein: 2 (normal) 2. On an unknown date, Magnetic resonance imaging heart: abnormal (abnormal) It confirmed the diagnosis of the myocarditis.. On an unknown date, Troponin: 1400 (High) 14000. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Concomitant product use was not provided by the reporter. No treatment information was provided. Most recent FOLLOW-UP information incorporated above includes: On 28-Oct-2021: Significant information that include Lab data added.	
4.1(b)	4.1(b)	This case was received via 4.1(b) Pharmaceuticals (Reference number: 4.1(b) on 22-Oct-2021 and was forwarded to Moderna on 29-Oct-2021. This case, reported by a physician, was received by 4.1(b) via Moderna's adverse reaction reporting site 4.1(b) and reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref 4.1(b) Acute myocarditis was assessed as serious by the MAH. On 24-Sep-2021, at 17:00, the patient received the 1st dose of this vaccine. On 17-Oct-2021, at 13:00, the patient received the 2nd dose of this vaccine.	15 years old male with unknown medical history who the next day after the the 2nd dose developed pyrexia and the next day chest pain at rest and was found to have elevated troponin, CK, CK-MB, and abnormal EGC, and Echo and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and ECG and Echo results; a causal relationship cannot be excluded due to the lack of other information.

Case ID	WW Identifier	Narrative	MAH Comment
		On 18-Oct-2021, pyrexia of 39 degrees Celsius developed. On 19-Oct-2021, around 13:15, acute myocarditis developed with chest pain at rest. Improvement was poor, and the patient made an emergency visit at the reporting hospital. ECG showed ST segment elevation in leads 1, 2, aVF, and V3 -6, and ST segment depression in leads V1 and aVR. Echocardiography showed decreased wall motion localized to the apex. Increased cardiac enzymes were noted with CK 263 U/L, CK-MB 20.1 ng/mL, and troponin I 2,234 pg/mL. On 22-Oct-2021, resolving of the symptoms was confirmed. The outcome of acute myocarditis was reported as resolving. Follow-up investigation will be made. Company Comment: The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 29-Oct-2021 and was forwarded to Moderna on 29-Oct-2021. This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (4.1(b) in a 15-year-old male patient who received mRNA-1273 (Spikevax) (batch no. FD9309) for COVID-19 vaccination. Concurrent medical conditions included Milk allergy (4.1(b)) and Grass allergy (4.1(b) Concomitant products included CROMOGLICATE SODIUM (LOMUDAL), MOMETASONE and DESLORATADINE (AERIUS [DESLORATADINE]) for an unknown indication.	15 years old female with unknown medical history who 27 days after the 1st dose was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events; a causal relationship cannot be excluded due to the lack of other information.

Case ID	WW Identifier	Narrative	MAH Comment
		On 30-Jul-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 26-Aug-2021, after starting mRNA-1273 (Spikevax), the patient experienced MYOCARDITIS (4.1(b)) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS 4.1(b)) had not resolved. The action taken with mRNA-1273 (Spikevax) (Unknown) was unknown. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. No treatment medications were reported.	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 29-Oct-2021 and was forwarded to Moderna on 29-Oct-2021. This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myocarditis) and CHEST PAIN (Precordial pain) in a 15-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. No Medical History information was reported. On 08-Oct-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 10-Oct-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). On an unknown date, the patient experienced CHEST PAIN (Precordial pain) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Myocarditis) had not	15 years old male with unknown medical history who 2 days after the 1st dose experienced chest pain and was found to have elevated troponin, Ck, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin; a causal relationship cannot be excluded due to the lack of other information.

Case ID	WW Identifier	Narrative	MAH Comment
		resolved and CHEST PAIN (Precordial pain) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Blood creatine phosphokinase: abnormal (High) ABNORMAL. On an unknown date, Troponin: 24.815,6 (High) 24.815,6 pg/ml. The action taken with mRNA-1273 (Spikevax) (Intramuscular) was unknown. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Concomitant and treatment medications were not reported. Company comment: This is a regulatory case concerning a 15 year-old, male patient with no relevant history, who experienced the unexpected serious events of chest pain, and the expected serious event of myocarditis. The event occurred approximately 3 days after the 1st dose of mRNA-1273 Moderna vaccine. The rechallenge was not applicable (information about 2nd dose was not provided). relevant lab data reported: Blood creatine phosphokinase: abnormal (High), Troponin: 24.815,6 pg/ml (High) The benefit-risk relationship of mRNA-1273 Moderna vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 29-Oct-2021: Follow up received on 29-Oct-2021 contains no new information.	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b) on 29-Oct-2021 and was forwarded to Moderna on 29-Oct-2021.	17 years old female with unknown medical history who 4 days after the 1st dose was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including

Case ID	WW Identifier	Narrative	MAH Comment
		This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myopericarditis) in a 17-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3005698) for COVID-19 vaccination. No Medical History information was reported. On 13-Oct-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form in total. On 17-Oct-2021, after starting mRNA-1273 (Spikevax), the patient experienced MYOCARDITIS (Myopericarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Myopericarditis) 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 and treatment information were reported by the reporter	patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events; a causal relationship cannot be excluded due to the lack of other information.
4.1(b)	4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b)) on 01-Oct-2021 and was forwarded to Moderna on 01-Oct-2021. This regulatory authority case was reported by a pharmacist and describes the occurrence of PALPITATIONS (palpitations), MALAISE (Generally unwell), ELECTROCARDIOGRAM QT PROLONGED (qtc prolonged) and MYOCARDITIS (Myocarditis) in a 37-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for Vaccination.	37 years old male with medical history of anxiety and hypertension who reported having palpitations after the 1st dose and then next day after the 2nd dose with malaise, was hospitalized and was diagnosed with myocarditis. Lab results showed prolonged QTs in the EKG, and hypertension. ELevated troponin, elevated CRP, D-dimer. SARS-CoV-2 test negative. No other information was provided. Important information is missing in the report including patient's medical history, concomitant medications as well as any other laboratory test conducted, including testing for any infectious process. According to the WHO causality

Case ID	WW Identifier	Narrative	MAH Comment
		The patient's past medical history included Anxiety. Family history included Hypertension (Both parents have hypertension.) since an unknown date. On 01-Aug-2021, the patient received first dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 26-Sep-2021, received second dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 27-Sep-2021, after starting mRNA-1273 (Moderna CoviD-19 Vaccine), the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). On an unknown date, the patient experienced PALPITATIONS (palpitations) (seriousness criteria hospitalization and medically significant), MALAISE (Generally unwell) (seriousness criteria hospitalization and medically significant) and ELECTROCARDIOGRAM QT PROLONGED (qtc prolonged) (seriousness criteria hospitalization and medically significant). At the time of the report, PALPITATIONS (palpitations), MALAISE (Generally unwell) and ELECTROCARDIOGRAM QT PROLONGED (qtc prolonged) had resolved and MYOCARDITIS (Myocarditis) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 28-Sep-2021, SARS-CoV-2 test: negative (Negative) No - Negative COVID-19 test. The action taken with mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown) was unknown. For mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown), the reporter did not provide any causality assessments.	assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and abnormal EKG; a causal relationship cannot be excluded due to the lack of other information.

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

Case ID	WW Identifier	Narrative	MAH Comment
		who experienced the unexpected serious event of Palpitations, Malaise, Electrocardiogram QT prolonged and expected serious event myocarditis. Additionally, the unexpected serious event blood pressure increased is also reported. The events occurred on an unknown date after the second dose of Spikevax. The rechallenge was not applicable as the AEs occurred after the second dose and we are not expecting another dose. The medical history hypertension remains a confounder. The benefit-risk relationship of Spikevax is not affected by this report.	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b) on 04-Oct-2021 and was forwarded to Moderna on 04-Oct-2021. This regulatory authority case was reported by a physician and describes the occurrence of PERICARDITIS (4.1(b) in a 21-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 3004959 and 3002616) for Vaccination. No Medical History information was reported. On 09-Aug-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 08-Sep-2021, received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to 1 dosage form. On 09-Sep-2021, the patient experienced PERICARDITIS (4.1(b) (seriousness criteria hospitalization and medically significant). At the time of the report, PERICARDITIS (4.1(b) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 10-Sep-2021, Echocardiogram: normal (normal) No pathological findings..	21 years old male with unknown medical history who next day after the 2nd dose was diagnosed with pericarditis. Laboratory results showed elevated troponinv but normal EKG. No other information was provided. Important information is missing in the report including patient's medical history as well as results for all the laboratory and imaging test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, a causal relationship cannot be excluded due to the lack of other information.

Case ID	WW Identifier	Narrative	MAH Comment
		On 10-Sep-2021, Troponin I: 2236 (abnormal) 2236 ng/L (nanogram per litre). For mRNA-1273 (Spikevax) (Unknown), the reporter considered PERICARDITIS (4.1(b) to be possibly related. Concomitant product use was not provided by the reporter. No treatment information was provided. Company Comment: This case concerns a 21-year-old male patient, with no reported medical history, who experienced the expected event of Pericarditis. The event occurred 1 day after the second dose of mRNA-1273 (Moderna COVID-19 Vaccine). The rechallenge was not applicable as event developed after the second. The event was assessed as related to mRNA-1273 (Moderna COVID-19 Vaccine) by the reporter. The benefit-risk relationship of mRNA-1273 (Moderna COVID-19 Vaccine) was not affected by this report. Event seriousness assessed serious per Regulatory authority as event resulted in hospitalization and is a medical important event. Pericarditis is an adverse event of special interest. Most recent FOLLOW-UP information incorporated above includes: On 04-Oct-2021: Translation received on 06-Oct-2021, contains no new information.	
4.1(b)	4.1(b)	This case was initially received via European Medicines Agency (Reference number: 4.1(b) on 04-Oct-2021. The most recent information was received 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 MYOCARDITIS (Myocarditis) in a 20-year-old male patient who received	20 years old male with medical history of patent ductus arteriosus repair at age 4 who 5 days after the 2nd dose was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as results for all the laboratory and imaging test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this

Case ID	WW Identifier	Narrative	MAH Comment
		mRNA-1273 (Spikevax) (batch no. 3005835) for COVID-19 vaccination. The patient's past medical history included Patent ductus arteriosus repair (operated on at 4 years of age). On 07-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 12-Sep-2021, after starting mRNA-1273 (Spikevax), the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Myocarditis) was resolving. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. No concomitant medications were provided by the reporter. No treatment information was provided by the reporter. Company comment: This case concerns a 20-year-old male patient with relevant medical history of Patent ductus arteriosus repair, who experienced the expected serious AESI event of Myocarditis. The event occurred approximately 5 days after the second dose of Spikevax administration. The rechallenge was not applicable since no events reported after the first dose and no additional dosing was expected. The medical history of Patent ductus arteriosus repair considered as confounder. The benefit-risk relationship is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 22-Oct-2021: Follow up report contains added height and weight of the patient, added batch number.	report is possible based on temporal association between the use of the product and the start of the events, a causal relationship cannot be excluded due to the lack of other information.

Case ID	WW Identifier	Narrative	MAH Comment
		On 22-Oct-2021: Translation received on 26-Oct-2021; medical history comment updated.	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 04-Oct-2021 and was forwarded to Moderna on 04-Oct-2021. This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (4.1(b)) in an 18-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3005835) for COVID-19 vaccination. No Medical History information was reported. On 14-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 17-Sep-2021, the patient experienced MYOCARDITIS (4.1(b)) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (4.1(b)) had not resolved. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. No relevant concomitant medication information provided. No relevant treatment medication information provided. Action taken with mRNA-1273 (Spikevax) was Not Applicable. Company comment: This case concerns a 18 year-old male patient with no reported medical history, who experienced the unexpected serious event of acute myocarditis. The event occurred 4 days after the second dose of mRNA-1273 vaccine. Details of clinical presentation, diagnostic criteria, and clinical course were not provided. Additional information is not expected for this RA case. The benefit-risk	18 years old male with unknown medical history who 3 days after the 2nd dose was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as results for all the laboratory and imaging test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, a causal relationship cannot be excluded due to the lack of other information.

Case ID	WW Identifier	Narrative	MAH Comment
		relationship of mRNA-1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 04-Oct-2021: Translation received on 06-Oct-2021 and included suspect vaccine dose number was added as second. On 14-Oct-2021: Follow-up information included no new information.	
4.1(b) [redacted]	4.1(b) [redacted]	This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 04-Oct-2021 and was forwarded to Moderna on 04-Oct-2021. This regulatory authority case was reported by a physician and describes the occurrence of CHEST PAIN (4.1(b) [redacted] HEART RATE INCREASED (4.1(b) [redacted] COVID-19 IMMUNISATION (4.1(b) [redacted] and PERICARDITIS (4.1(b) [redacted] in a 37-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 3005697) for Vaccination. Previously administered products included for Vaccination: Comirnaty. Past adverse reactions to the above products included Adverse event with Comirnaty. On 25-Aug-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. In 2021, the patient experienced COVID-19 IMMUNISATION (4.1(b) [redacted]) (seriousness criterion hospitalization). On 28-Aug-	37 years old female with unknown medical history, who received as her first dose the Cominarty vaccine at an unknown date, and was seeing in the doctor's office beacuse of reported chest pressure since July, and worsening 3 days after receiving the 2nd dose with Spikevax. At CV examination patient was found to have pericardial fluid, heart rate increased, chest pain, her Echo was abnormal and she was diagnosed with pericarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any laboratory test conducted, including testing for SARS-CoV-2, and any information related to her previous chest pain history. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, a causal relationship cannot be excluded due to the lack of other information.

Case ID	WW Identifier	Narrative	MAH Comment
		2021, the patient experienced CHEST PAIN (4.1(b) [redacted] (seriousness criterion hospitalization) and PERICARDITIS (4.1(b) [redacted] (seriousness criteria hospitalization and medically significant). On 18-Sep-2021, the patient experienced HEART RATE INCREASED (4.1(b) [redacted] (seriousness criterion hospitalization). At the time of the report, CHEST PAIN 4.1(b) [redacted], HEART RATE INCREASED 4.1(b) [redacted] COVID-19 IMMUNISATION 4.1(b) [redacted] and PERICARDITIS (4.1(b) [redacted] was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 31-Aug-2021, Cardiovascular examination: abnormal (abnormal) A 1 cm fluid brake was detected behind the left ventricle. Interpreted as possible pericarditis.. On 18-Sep-2021, C-reactive protein: 5 (Inconclusive) 5. On 18-Sep-2021, Cardiovascular examination: abnormal (abnormal) Approx. 1 cm pericardial fluid brake was detected at the right atrium and approx. 0.5 cm at right ventricle.. On 18-Sep-2021, Red blood cell sedimentation rate: 26 (slightly elevated) (High) 26 (slightly elevated). On 21-Sep-2021, Echocardiogram: abnormal (abnormal) Unchanged amount of pericardial fluid.	

Case ID	WW Identifier	Narrative	MAH Comment
		For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered CHEST PAIN 4.1(b) [redacted]), HEART RATE INCREASED 4.1(b) [redacted] and PERICARDITIS 4.1(b) [redacted] to be possibly related. No further causality assessment was provided for COVID-19 IMMUNISATION 4.1(b) [redacted] No relevant concomitant medications were reported. The Patient was examined on 31 AUG 2021 because she had felt episodic pressure on the chest since July, with worsening on 28 AUG 2021. No treatment information was provided. Company comment: This case concerns a 37-year-old, female patient with no relevant medical history, who experienced, serious unlisted AESI of pericarditis, among other serious events. The event occurred 4 days after the dose of Moderna COVID-19 Vaccine. However, only the second dose was Moderna COVID-19 Vaccine and details of the first dose was not provided. The administration of two different vaccines remains a confounder. The rechallenge was unknown as the event occurred after second vaccine dose. The benefit-risk relationship of Moderna COVID-19 Vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 04-Oct-2021: Translation received on 06-Oct-2021 included updated	

Case ID	WW Identifier	Narrative	MAH Comment
		event related information and updated narrative	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 04-Oct-2021 and was forwarded to Moderna on 04-Oct-2021. This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (4.1(b) and COVID-19 IMMUNISATION (REVACCINATION WITH DIFFERENT COVID-19 VACCINE) in a 31-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3004224) for Vaccination. Previously administered products included for Vaccination: Comirnaty. On 25-Aug-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 17-Sep-2021, the patient experienced MYOCARDITIS (4.1(b) (seriousness criteria hospitalization and medically significant) and COVID-19 IMMUNISATION (REVACCINATION WITH DIFFERENT COVID-19 VACCINE) (seriousness criterion hospitalization). At the time of the report, MYOCARDITIS (4.1(b) and COVID-19 IMMUNISATION (REVACCINATION WITH DIFFERENT COVID-19 VACCINE) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In August 2021, Echocardiogram: findings compatible with perimyocarditis findings compatible with perimyocarditis. In August 2021, Magnetic resonance imaging heart: findings compatible with perimyocarditis findings compatible with perimyocarditis. In August 2021, Troponin: maximum at 1582 Maximum at 1582.	31 years old male with unknown medical history who received Cominarty as the 1st dose of COVID-19 vaccination and 23 days after the 2nd dose of Spikevax was diagnosed with myocardits after laboratory showed elevated troponin, and Echo and cMRI findings compatible with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and Echo and cMRI findings. A causal relationship cannot be excluded due to the lack of other information.

Case ID	WW Identifier	Narrative	MAH Comment
		For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Concomitant product use was not provided by reporter. Treatment information was not provided. Company comment: This case concerns revaccination with different COVID-19 vaccine in a 31 year-old male patient with no reported medical history, who experienced the expected serious event of perimyocarditis. The event occurred 24 days after the dose of mRNA-1273 vaccine, which followed a previous dose of Comirnaty vaccine. Findings on echocardiogram and cardiac MRI were reported to be consistent with perimyocarditis and maximum troponin value was reported to be 1582. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 04-Oct-2021: Translation document received on 06-Oct-2021 as live follow up included NNI.	
4.1(b) [redacted]	4.1(b) [redacted]	This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted] on 04-Oct-2021 and was forwarded to Moderna on 04-Oct-2021. This regulatory authority case was reported by a physician and describes the occurrence of ACUTE PULMONARY OEDEMA (Acute pulmonary edema) and MYOCARDITIS (Myocarditis) in a 37-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3003604) for Vaccination. The occurrence of additional non-serious events is detailed below. Previously administered products included for Vaccination: COMIRNATY.	37 years old male with unknown medical history who received Cominarty as the 1st dose of his COVID-19 vaccination and same day after the 2nd dose with SpikevXexpereinced acute myocardial infarction and was diagnosed with myocarditis. Lab results showed elevated troponin, abnormal catheterizarization and EKG. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and EKG and

Case ID	WW Identifier	Narrative	MAH Comment
		Past adverse reactions to the above products included No adverse reaction with COMIRNATY. On 08-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 11-Sep-2021, the patient experienced ACUTE PULMONARY OEDEMA (Acute pulmonary edema) (seriousness criteria hospitalization and medically significant) and MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). On an unknown date, the patient experienced COVID-19 IMMUNISATION (Revaccination with different COVID-19). On 13-Sep-2021, ACUTE PULMONARY OEDEMA (Acute pulmonary edema) and MYOCARDITIS (Myocarditis) had resolved. At the time of the report, COVID-19 IMMUNISATION (Revaccination with different COVID-19) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 11-Sep-2021, Computerised tomogram thorax: abnormal (abnormal) Changes mostly suspect for interstitial alveolar edema, alt. infection less probable.. On 11-Sep-2021, Ejection fraction: abnormal (abnormal) Left ventricle ejection fraction just below 40 % on admission to hospital and also on 12/Sep/2021. On 13-Sep-2021, Ejection fraction: abnormal (abnormal) Completely normalized. In September 2021, C-reactive protein: 4-126 (abnormal) 4-126. In September 2021, Echocardiogram: abnormal (abnormal) Reduced cardiac function. In September 2021, Troponin T: high (High) Slightly elevated. 118-135-82.. For mRNA-1273 (Spikevax) (Intramuscular), the reporter	catheterization results and a causal relationship cannot be excluded due to the lack of other information.

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

Case ID	WW Identifier	Narrative	MAH Comment
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 04-Oct-2021 and was forwarded to Moderna on 04-Oct-2021. This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (4.1(b) in a 37-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 immunisation. No Medical History information was reported. On 08-Aug-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 milliliter. On 11-Aug-2021, after starting mRNA-1273 (Spikevax), the patient experienced MYOCARDITIS (4.1(b) (seriousness criteria hospitalization and medically significant). On 14-Aug-2021, MYOCARDITIS (4.1(b) had resolved. For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered MYOCARDITIS (4.1(b) to be probably related. No concomitant medications reported by reporter. No treatment medications provided by the reporter. Company Comment: This case concerns a 37 year-old male patient with no reported medical history, who experienced the expected serious event of Myocarditis. The event occurred 3 days after the second dose of mRNA-1273 vaccine. Details of clinical presentation, diagnostic criteria, and clinical course were not provided. Additional information is not expected for this RA case. The benefit-risk relationship of mRNA-	37 years old male with unknown medical history who 3 days after the 2nd dose was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is is possible based on temporal association between the use of the product and the start of the events. A causal relationship cannot be excluded due to the lack of other information.

Case ID	WW Identifier	Narrative	MAH Comment
		1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 04-Oct-2021: Translation document received on 06-Oct-2021 and reporter causality was updated.	
4.1(b)	4.1(b)	This case was initially received via European Medicines Agency (Reference number: 4.1(b)) on 04-Oct-2021. The most recent information was received on 20-Oct-2021 and was forwarded to Moderna on 20-Oct-2021. This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Perimyocarditis) in a 23-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3006273) for COVID-19 vaccination. No Medical History information was reported. On 16-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 19-Sep-2021, the patient experienced MYOCARDITIS (Perimyocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Perimyocarditis) was resolving. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. Concomitant medication use information was not provided by reporter. Treatment medication use information was not provided by reporter. Company comment: This case concerns a 23-year-old, male patient with no relevant medical history, who experienced the expected event of Myocarditis. The event occurred	23 years old male with unknown medical history who 3 days after the 2nd dose was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is is possible based on temporal association between the use of the product and the start of the events. A causal relationship cannot be excluded due to the lack of other information.

Case ID	WW Identifier	Narrative	MAH Comment
		approximately 4 days after the second dose of Spikevax. The rechallenge was not applicable, as the event happened after the second dose. The benefit-risk relationship of Spikevax is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 04-Oct-2021: Translation document received on 07-oct-21 include dosage text. On 14-Oct-2021: Follow-up information included no new information. On 20-Oct-2021: Follow-up document received and product batch number was updated.	
4.1(b)	4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b) on 05-Oct-2021 and was forwarded to Moderna on 05-Oct-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCARDITIS (Myocarditis) and PERICARDITIS (Pericarditis) in a 29-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 048F21A) for COVID-19 vaccination. Concurrent medical conditions included Penicillin allergy. Concomitant products included BUPROPION HYDROCHLORIDE (WELLBUTRIN) for an unknown indication. On 13-Sep-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 15-Sep-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant) and PERICARDITIS (Pericarditis) (seriousness criteria hospitalization and medically significant). The patient was hospitalized on sometime in	29 years old male with unknown medical history and concomitant medication of buproprion HCL who 2 days after the 2nd dose was diagnosed with myperiocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is is possible based on temporal association between the use of the product and the start of the events. A causal relationship cannot be excluded due to the lack of other information.

Case ID	WW Identifier	Narrative	MAH Comment
		September 2021 due to MYOCARDITIS and PERICARDITIS. At the time of the report, MYOCARDITIS (Myocarditis) and PERICARDITIS (Pericarditis) had not resolved. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Patient's treatment was still ongoing. Patient was on frequent ingestion of anti-inflammation medication. Lab test included Blood work on 16-SEP-2021 and Echocardiogram, Cardiac catheter on 17-SEP-2021, however results were not provided. Company comment: This case concerns a 29-year-old, female patient with penicillin allergy, who experienced the unexpected events of myocarditis and pericarditis. The event occurred approximately 3 days after the second dose of Moderna Covid-19 vaccine and resolved after hospitalization. The rechallenge was not applicable, as the event happened after the first dose. The benefit-risk relationship of the vaccine is not affected by this report.	
4.1(b)	4.1(b)	This case was initially received via 4.1(b) (Reference number: 4.1(b)) on 05-Oct-2021. The most recent information was received on 21-Oct-2021 and was forwarded to Moderna on 21-Oct-2021. This regulatory authority case was reported by a physician and describes the occurrence of CHEST PAIN (Chest pain), PAIN IN JAW (Pain in jaw), HEART RATE INCREASED (Heart rate high) and MYOCARDITIS (Acute myocarditis) in a 19-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) (batch no. 3004668) for COVID-19 vaccination and Ill-defined disorder.	19 years old male with unknown medical history who 3 days after the 2nd dose experienced chest pain, pain in jaw, and heart rate increased and was diagnosed with myocarditis. Laboratory values showed elevated troponin, and abnormal cMRI. ECH and Echo were normal. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for any other infectious process that may had explained the cough and the malaise and the previous symptoms he was feeling for a week. According to the WHO causality assessment this report is possible based on temporal association between the use of the

Case ID	WW Identifier	Narrative	MAH Comment
		Concurrent medical conditions included Myocarditis. On 30-Sep-2021, the patient received second dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) .5 ml. On 03-Oct-2021, received dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 03-Oct-2021, after starting mRNA-1273 (Moderna CoviD-19 Vaccine), the patient experienced MYOCARDITIS (Acute myocarditis) (seriousness criteria hospitalization and medically significant). On an unknown date, the patient experienced CHEST PAIN (Chest pain) (seriousness criteria hospitalization and medically significant), PAIN IN JAW (Pain in jaw) (seriousness criteria hospitalization and medically significant) and HEART RATE INCREASED (Heart rate high) (seriousness criteria hospitalization and medically significant). At the time of the report, CHEST PAIN (Chest pain), PAIN IN JAW (Pain in jaw) and HEART RATE INCREASED (Heart rate high) outcome was unknown and MYOCARDITIS (Acute myocarditis) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 03-Oct-2021, Troponin: high (High) Trop 1318 rise to 2370, 3 days after second vaccine. On 04-Oct-2021, Magnetic resonance imaging: abnormal (abnormal) Consultant confirmed myocarditis. On 04-Oct-2021, Troponin: 1700 (Low) Slightly decreased to 1700. On an unknown date, Blood pressure measurement: normal (normal) normal. On an unknown date, Echocardiogram: normal (normal) normal. On an unknown date, Electrocardiogram: normal (normal) normal.	product and the start of the events, as well as the elevated troponin and cMRI results; a causal relationship cannot be excluded due to the lack of other information.

Case ID	WW Identifier	Narrative	MAH Comment
		On an unknown date, Heart rate: inconclusive (Inconclusive) 90s. For mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Concomitant medications was not reported. The patient experienced chest pains and pain in jaw on left side of the body. He went to hospital accident and emergency (a and e) as they suspected a heart attack. The hospital admitted him to the CCU (Coronary care unit) on 03-Oct-2021, placed on unspecified beta blockers 2.5 milligram (mg) to slow heart rate from high 90s, so no more strain was placed on the heart muscle. He had not tested positive for COVID-19 since having the vaccine, and not enrolled in clinical trial. Adverse reaction did not occur as a result of an exposure during pregnancy. Company comment: This case concerns a 19-year-old, male patient with no medical history reported, who experienced serious expected AESI of Myocarditis after second dose of mRNA-1273. The event occurred 5 days after the second dose of mRNA-1273. The re-challenge is unknown as the adverse event occurred after second dose and the outcome is recovering.. The benefit-risk relationship of Moderna covid -19 vaccine, is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 21-Oct-2021: Significant Follow-up Appended, Events, Lab data, Product Information was updated.	
4.1(b)	4.1(b)	This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (4.1(b)) in a 21-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination.	21 years old male with unknown medical history who 3 days after the 2nd dose was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted,

Case ID	WW Identifier	Narrative	MAH Comment
		No Medical History information was reported. On 26-Aug-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 29-Aug-2021, the patient experienced MYOCARDITIS (4.1(b) (seriousness criteria hospitalization prolonged and medically significant). At the time of the report, MYOCARDITIS (4.1(b) outcome was unknown. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. No concomitant product use was reporter. No treatment medication was reporter. Company comment: This case concerns a 21-year-old, male patient with no relevant medical history, who experienced the expected event of Myocarditis. The event occurred approximately 3 days after the second dose of Moderna vaccine. The rechallenge was not applicable as the event occurred only after the second dose. The event was considered related to the product per the reporter's assessment. The event of Myocarditis is consistent with the current understanding of the mechanism of action of the vaccine. The benefit-risk relationship of Moderna Covid-19 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 05-Oct-2021: Translation document received On 07-OCT-2021 and contains updated dosage text.	including testing for SARS-CoV-2. According to the WHO causality assessment this report is is possible based on temporal association between the use of the product and the start of the events. A causal relationship cannot be excluded due to the lack of other information.
4.1(b)	4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b) on 05-Oct-2021 and was forwarded to Moderna on 05-Oct-2021.	24 years old male with medical history of anxiety and depression who 3 days after the 2nd dose experienced pain, and was admitted was found to have elevated troponin,

Case ID	WW Identifier	Narrative	MAH Comment
		This regulatory authority case was reported by an other health care professional and describes the occurrence of PAIN (Pain) and MYOCARDITIS (Myocarditis) in a 24-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 020f21A and 059e21A) for COVID-19 vaccination. The patient's past medical history included Anxiety and Depression. Concomitant products included ESCITALOPRAM OXALATE (LEXAPRO) for an unknown indication. On 15-Sep-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 18-Sep-2021, the patient experienced PAIN (Pain) (seriousness criteria hospitalization and life threatening) and MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization, medically significant and life threatening). The patient was treated with ASA at an unspecified dose and frequency and KETOROLAC TROMETHAMINE (TORADOL) for Pain, at an unspecified dose and frequency. At the time of the report, PAIN (Pain) and MYOCARDITIS (Myocarditis) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 18-Sep-2021, Electrocardiogram: abnormal (abnormal) abnormal. On 18-Sep-2021, Troponin: increased (High) increased. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments.	abnormal ECG and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for any other infectious process. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and ECG results; a causal relationship cannot be excluded due to the lack of other information.

Case ID	WW Identifier	Narrative	MAH Comment
		On 18 Sep 2021 Laboratory Test Blood creatine phosphokinase MB, C-reactive protein, Echocardiogram , Laboratory test, Red blood cell sedimentation rate were performed and results were not reported. Company Comment: This case concerns a 24-year old, male subject with no relevant medical history, who experienced the serious expected event of Myocarditis(AESI) and serious unexpected event of Pain. The events occurred approximately 3 days after the second dose of MODERNA COVID-19 VACCINE. Rechallenge is not applicable as the start date coded for both dose 1 and dose 2 are the same. The benefit-risk relationship of MODERNA COVID-19 VACCINE is not affected by this report. The Regulatory Authority report captured both doses as occurring on same date; this information is retained although there's no mention of this in the case narrative and it is unlikely that this occurred. Date recorded by RA is taken as being of the second dose.	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 05-Oct-2021 and was forwarded to Moderna on 05-Oct-2021. This regulatory authority case was reported by a consumer and describes the occurrence of PERICARDITIS (4.1(b) in a 37-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. No Medical History information was reported. On 16-Jul-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 21-Jul-2021, after starting mRNA-1273 (Spikevax), the patient experienced PERICARDITIS (4.1(b) (seriousness criteria hospitalization, disability, medically	37 years old female with unknown medical history who 5 days after the 2nd dose was diagnosed with pericarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events. A causal relationship cannot be excluded due to the lack of other information.

Case ID	WW Identifier	Narrative	MAH Comment
		significant and life threatening). At the time of the report, PERICARDITIS (4.1(b) was resolving. No concomitant medication was reported by the reporter. No treatment was reported by the reporter. Company comment: This case concerns a 37-year-old, female patient with no relevant medical history, who experienced the serious expected event of Pericarditis(AESI). The event occurred 5 days after the second dose of Spikevax. Rechallenge is not applicable as no information about the first dose is available and no additional dose is expected to be given. The benefit-risk relationship of Spikevax is not affected by this report. Event seriousness assessed as per Regulatory Authority reporting; however, there was no information in the source document supporting that the event resulted in a persistent or permanent disability/incapacity. Most recent FOLLOW-UP information incorporated above includes: On 05-Oct-2021: Translation received 07-OCT-2021 is significant follow up dosage text updated	
4.1(b)	4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b) on 05-Oct-2021 and was forwarded to Moderna on 05-Oct-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of CHEST PAIN (Chest pain), DYSPNOEA (Dyspnoea), EXTRASYSTOLES (Extrasystoles), PALPITATIONS (Palpitations), INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (Inappropriate schedule of product administration) and PERICARDITIS (Pericarditis) in a 28-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination.	28 years old male with unknown medical history who 4 days after the 2nd dose experienced chest pain, extrasystoles, dyspnoea, palpitations, and was diagnosed with pericarditis. Laboratory results showed elevated CRP and abnormal cardiac monitoring. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is is possible based on temporal association between the use of the product and the start of the events. A causal relationship cannot be excluded due to the lack of other information.

Case ID	WW Identifier	Narrative	MAH Comment
		No Medical History information was reported. On 24-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 17-Sep-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 17-Sep-2021, the patient experienced INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (Inappropriate schedule of product administration) (seriousness criterion hospitalization). On 21-Sep-2021, the patient experienced CHEST PAIN (Chest pain) (seriousness criterion hospitalization), DYSPNOEA (Dyspnoea) (seriousness criterion hospitalization), EXTRASYSTOLES (Extrasystoles) (seriousness criterion hospitalization), PALPITATIONS (Palpitations) (seriousness criterion hospitalization) and PERICARDITIS (Pericarditis) (seriousness criteria hospitalization and medically significant). On 17-Sep-2021, INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (Inappropriate schedule of product administration) had resolved. At the time of the report, CHEST PAIN (Chest pain), DYSPNOEA (Dyspnoea), EXTRASYSTOLES (Extrasystoles), PALPITATIONS (Palpitations) and PERICARDITIS (Pericarditis) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 21-Sep-2021, C-reactive protein: increased (High) Increased. On 21-Sep-2021, Cardiac monitoring: abnormal (abnormal) abnormal. On 21-Sep-2021, Red blood cell sedimentation rate: increased (High) Increased. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter	

Case ID	WW Identifier	Narrative	MAH Comment
		did not provide any causality assessments. No concomitant medications were provided. Treatment medications included NSAIDs for pain. The patient experienced significant chest pain and shortness of breath that started 4 days after the vaccine. Additionally, sensation of heart skipping beats and then beating "hard." Pain was better with sitting forward. Determination of acute pericarditis was made by an infectious disease consultant in the hospital. Pain marginally improved with NSAIDs but is still persisting. Company comment: This case concerns a 28-year-old, male patient with no relevant medical history, who experienced the unexpected events of Chest pain, Dyspnea, Extrasystoles, Palpitations, and listed event of Pericarditis. The events occurred approximately 4 days after the second dose of Spikevax. It is noted that the C-reactive protein showed increase and cardiac monitoring was abnormal after the 2nd dose was received. The rechallenge was unknown since no event about the first dose was disclosed. The benefit-risk relationship of Spikevax is not affected by this report.	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 04-Oct-2021 and was forwarded to Moderna on 04-Oct-2021. This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myopericarditis) in a 20-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 3005285 and 3003187) for SARS-CoV-2 vaccination. No Medical History information was reported.	

Case ID	WW Identifier	Narrative	MAH Comment
		On 27-Jul-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 26-Aug-2021, received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to 1 dosage form. On 28-Aug-2021, after starting mRNA-1273 (Spikevax), the patient experienced MYOCARDITIS (Myopericarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Myopericarditis) 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 medications was not provided by the reporter Treatment information was not provided. Company Comment: This case concerns a 20-year-old male patient with no reported medical history who experienced the expected event myocarditis. The event occurred 2 days after the second dose of mRNA-1273 mRNA-1273 (Spikevax) The rechallenge was not applicable as the event occurred after the second dose. Causality assessment 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 is confounded by the patient's underlying thyroid disease as they are known to cause changes in heart function. Event seriousness assessed as serious per Regulatory Authority reporting as event require hospitalization and is an important medical event. Event is an adverse event of special interest Most recent FOLLOW-UP information incorporated above includes:	

Case ID	WW Identifier	Narrative	MAH Comment
		On 04-Oct-2021: Translation received on 07-OCT-2021, first dose information of suspect product updated.	
4.1(b)	4.1(b)	This case was received via 4.1(b) Pharmaceuticals (Reference number: 4.1(b) on 01-Oct-2021 and was forwarded to Moderna on 06-Oct-2021. This case, initially reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref, 4.1(b) On an unknown date, the patient received the 1st dose of this vaccine. On an unknown date, body temperature before vaccination: 36.6 degrees Celsius. On 23-Aug-2021, at 14:17, the patient received the 2nd dose of this vaccine. On 24-Aug-2021, at 01:00, the patient experienced pyrexia and difficulty of breathing and was urgently transported to a hospital. The patient was diagnosed with suspected myocarditis at the hospital where the patient was transported. Afterwards, the patient was spontaneously resolving with follow-up. On 26-Aug-2021, recovery of the symptoms was confirmed. The outcome of pyrexia, difficulty of breathing, and suspected myocarditis was reported as recovered. Follow-up investigation will be made. Company Comment: The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	
4.1(b)	4.1(b)	This case was received via 4.1(b) Reference number: 4.1(b) on 05-Oct-2021 and was forwarded to Moderna on 05-Oct-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of DYSPNOEA (Dyspnoea/Feeling short of breath), CHEST PAIN (Chest pain) and MYOCARDITIS (Myocarditis) in a 33-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 002F21A and 053E21A) for COVID-19 vaccination. No Medical History information was reported.	33 years old male with unknown medical history who same day after the 2nd dose experienced dyspnoea and chest pain and was diagnosed with myocarditis. Laboratory values showed elevated troponin and normal ECH, Echo, and chest x-ray. Patient was admitted to hospital overnight. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events as well as elevated troponin. A causal

Case ID	WW Identifier	Narrative	MAH Comment
		On 20-Sep-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 20-Sep-2021, the patient experienced DYSPNOEA (Dyspnoea/Feeling short of breath) (seriousness criteria hospitalization and life threatening), CHEST PAIN (Chest pain) (seriousness criteria hospitalization and life threatening) and MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization, medically significant and life threatening). The patient was treated with ASPIRIN [ACETYLSALICYLIC ACID] for Chest pain, at an unspecified dose and frequency. On 20-Sep-2021, CHEST PAIN (Chest pain) had resolved. At the time of the report, DYSPNOEA (Dyspnoea/Feeling short of breath) and MYOCARDITIS (Myocarditis) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 20-Sep-2021, Troponin: increased (High) Troponin on arrival was 1.4 and peaked at 2.4.. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medication was given. Laboratory data was mentioned as on 20-Sep-2021 patient took the tests for blood magnesium, blood phosphorus, C-reactive protein, full blood count, lipase, metabolic function test, red blood cell sedimentation rate and SARS-CoV-2 test but the results was not given.	relationship cannot be excluded due to the lack of other information.

Case ID	WW Identifier	Narrative	MAH Comment
		On 20-Sep-2021 Chest X-ray, Echocardiogram and Electrocardiogram were performed and results were normal. Patient had short of breath a few hours later, and chest pain at evening and he was admitted to hospital overnight for myocarditis monitoring. Company comment: This case concerns a 33-year-old male patient, with no reported medical history who experienced the unexpected event of dyspnoea, chest pain, and expected event of myocarditis. The events occurred on the same day after the second dose of mRNA-1273 (Moderna COVID-19 Vaccine). The rechallenge was unknown as no details about the first dose was disclosed. Causality for the reported events were not provided. The event pf myocarditis is consistent with the current understanding of the mechanism of action of the vaccine. The benefit-risk relationship of Moderna COVID-19 Vaccine is not affected by this report. Event assessed as serious per Regulatory authority as event required hospitalization. Myocarditis is an adverse event of special interest.	
4.1(b)	4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b) on 05-Oct-2021 and was forwarded to Moderna on 05-Oct-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of PERICARDITIS (Pericarditis) in a 31-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 052E21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported.	

Case ID	WW Identifier	Narrative	MAH Comment
		On 04-Sep-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 05-Sep-2021, the patient experienced PYREXIA (100 degree fever 24 hours after injection). On 20-Sep-2021, the patient experienced PERICARDITIS (Pericarditis) (seriousness criterion medically significant) and INJECTION SITE PAIN (Injection site pain/ injection site soreness). At the time of the report, PERICARDITIS (Pericarditis), INJECTION SITE PAIN (Injection site pain/ injection site soreness) and PYREXIA (100 degree fever 24 hours after injection) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 20-Sep-2021, Body temperature: 4.1(b) (Inconclusive) 4.1(b) degree fever. On 20-Sep-2021, Electrocardiogram: pericarditis (abnormal) ST greater than.10mV, ant/ lat. On 20-Sep-2021, Heart rate: abnormal (abnormal) abnormal. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No relevant concomitant medications were reported. Treatment information was unknown.	
4.1(b)	4.1(b)	This case was received via 4.1(b) Pharmaceuticals (Reference number: 4.1(b) on 02-Oct-2021 and was forwarded to Moderna on 06-Oct-2021. This case, initially reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref, 4.1(b) On an unknown date, the patient received the 1st dose of this vaccine.	20 years old male with unknown medical history who 3 days after the 2nd dose experienced chest discomfort and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events as well as elevated troponin. A causal

Case ID	WW Identifier	Narrative	MAH Comment
		On an unknown date, body temperature before the vaccination: 36.4 degrees Celsius. On 28-Sep-2021, at 13:30, the patient received the 2nd dose of this vaccine. On 29-Sep-2021, pyrexia of 40 degrees Celsius developed. On 01-Oct-2021, at 07:00, the patient was raced to a hospital for chest discomfort. Since an abnormally high level of troponin I of 1,700 was confirmed, the patient was hospitalized on the same day for suspected myocarditis. The outcome of pyrexia and suspected myocarditis was unknown. Follow-up investigation will be made. Company Comment: The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	relationship cannot be excluded due to the lack of other information.
4.1(b)	4.1(b)	This case was received via 4.1(b) Pharmaceuticals (Reference number: 4.1(b)) on 02-Oct-2021 and was forwarded to Moderna on 06-Oct-2021. This case, initially reported to the 4.1(b) by a (physician), was received via the 4.1(b) (Ref, 4.1(b) On an unknown date, the patient received the 1st dose of this vaccine. On an unknown date, body temperature before vaccination: 36.6 degrees Celsius. On 24-Sep-2021, at 17:00, the patient received the 2nd dose of this vaccine. On 25-Sep-2021, pyrexia of 38.0-38.9 degrees Celsius developed.	28 years old male with unknown medical history who 3 days after the 2nd dose experienced chest pain and respiratory discomfort, and was diagnosed with myocarditis. Laboratory values showed elevated troponin and CK, and abnormal ECGNo other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as elevated troponin and abnormal ECG. A causal relationship cannot be excluded due to the lack of other information.

Case ID	WW Identifier	Narrative	MAH Comment
		On 26-Sep-2021, fever went down to 37 degrees Celsius. At 17:00, myocarditis developed. Chest pain and respiratory discomfort were noted. On 27-Sep-2021, the patient's symptoms did not improve, and the patient visited a nearby physician. ECG showed ST-segment elevation in 1, aVL, and V2. The patient was referred to another hospital, and emergency catheterization was performed. The coronary artery was normal. The patient was hospitalized on the same day. There were no abnormalities in blood pressure and SPO2. Blood test showed increased CK and troponin I. Around 29-Sep-2021, ST tended to improve on ECG. Around 30-Sep-2021, subjective symptoms improved. On 01-Oct-2021, recovery of symptoms was confirmed. The patient was discharged from the hospital. The outcome of pyrexia and myocarditis was reported as recovered. Follow-up investigation will be made. Company Comment: The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	
4.1(b) [redacted]	4.1(b) [redacted]	This case was received via 4.1(b) [redacted] (Reference number: 4.1(b) [redacted]) on 05-Oct-2021 and was forwarded to Moderna on 05-Oct-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of PERICARDITIS (Pericarditis) in a 40-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 053E21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Eczema. Concurrent medical conditions included Drug hypersensitivity (Sulfa). Concomitant products included DUPILUMAB (DUPIXENT) and LEVONORGESTREL (MIRENA) for an unknown indication.	

Case ID	WW Identifier	Narrative	MAH Comment
		On 10-Sep-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 13-Sep-2021, the patient experienced PERICARDITIS (Pericarditis) (seriousness criterion medically significant), DYSPNOEA EXERTIONAL (Dyspnoea exertional) and CHEST PAIN (Chest pain). The patient was treated with IBUPROFEN at an unspecified dose and frequency and COLCHICINE for Pericarditis, at an unspecified dose and frequency. At the time of the report, PERICARDITIS (Pericarditis), DYSPNOEA EXERTIONAL (Dyspnoea exertional) and CHEST PAIN (Chest pain) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 15-Sep-2021, Blood test: normal (normal) Blood work within normal limits. On 15-Sep-2021, Chest X-ray: normal (normal) Chest X-ray clear. On 15-Sep-2021, Electrocardiogram: abnormal (abnormal) abnormal. On 16-Sep-2021, Fibrin D dimer: normal (normal) Within normal limits. On 16-Sep-2021, Oxygen saturation: decreased (Low) Drop in O2 saturation level. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Company comment: This case concerns a 40-year-old, female patient with no relevant medical history, who experienced the serious expected event (AESI) of Pericarditis. The event occurred three days after the second dose of mRNA-1273. The rechallenge was not applicable as no information about the first dose was provided. The benefit-risk relationship of mRNA-1273 is not affected by this report.	
4.1(b)	4.1(b)	This case was received via 4.1(b) Pharmaceuticals (Reference number: 4.1(b)) on 02-Oct-2021 and was forwarded to Moderna on 06-Oct-2021. This case, initially reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref, 4.1(b) The patient had an allergic history of food (buckwheat, pear, peach, cherry, and various fish eggs) On an unknown date, the patient received the 1st dose of this vaccine. On an unknown date, body temperature before the vaccination: 36.3 degrees Celsius. On 26-Sep-2021, during the medical interview, the patient complained of a sort of chest discomfort. The patient received the 2nd dose of this vaccine. On 27-Sep-201, pyrexia of 39.0-39.9 degrees Celsius developed. On 28-Sep-2021, around 10:00, chest pain developed. It was exacerbated, and the patient visited a medical institution. There were findings of acute myocarditis, and the patient was raced to the reporting hospital. The patient was hospitalized.	

Case ID	WW Identifier	Narrative	MAH Comment
		On an unknown date, after acute myocarditis, cardiomyopathy was noted as a sequela. The outcome of pyrexia was unknown. The outcome of acute myocarditis was reported as sequela. Follow-up investigation will be made. Company Comment: The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	
4.1(b)	4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b) on 05-Oct-2021 and was forwarded to Moderna on 05-Oct-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of ACUTE MYOCARDIAL INFARCTION (Acute myocardial infarction), MYOCARDIAL INFARCTION (Myocardial infarction), CHEST PAIN (Chest pain), DYSPNOEA (Dyspnoea), TROPONIN INCREASED (Troponin increased) and MYOCARDITIS (Myocarditis) in a 25-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. Concurrent medical conditions included Allergy to vaccine (Pertussis Toxoid). On 17-Sep-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 17-Sep-2021, the patient experienced ACUTE MYOCARDIAL INFARCTION (Acute myocardial infarction) (seriousness criteria hospitalization and medically significant) and MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). 17-Sep-2021, the patient experienced MYOCARDIAL INFARCTION (Myocardial infarction) (seriousness criteria hospitalization and medically	25 years old male with unknown medical history who same day after the 2nd doseexpereinced acute myocardial infarction and was diagnosed with myocarditis. Lab results showed elevated troponin, abnormal catheterizarization and EKG. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and EKG and catheterization results and a causal relationship cannot be excluded due to the lack of other information.

Case ID	WW Identifier	Narrative	MAH Comment
		significant), CHEST PAIN (Chest pain) (seriousness criterion hospitalization), DYSPNOEA (Dyspnoea) (seriousness criterion hospitalization) and TROPONIN INCREASED (Troponin increased) (seriousness criterion hospitalization). The patient was hospitalized on 19-Jul-2021 due to TROPONIN INCREASED, then on 19-Sep-2021 due to ACUTE MYOCARDIAL INFARCTION, CHEST PAIN, DYSPNOEA, MYOCARDIAL INFARCTION and MYOCARDITIS. At the time of the report, ACUTE MYOCARDIAL INFARCTION (Acute myocardial infarction), MYOCARDIAL INFARCTION (Myocardial infarction), CHEST PAIN (Chest pain), DYSPNOEA (Dyspnoea), TROPONIN INCREASED (Troponin increased) and MYOCARDITIS (Myocarditis) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 19-Sep-2021, Electrocardiogram: st elevation (abnormal) ST elevation consider inferolateral injury or acute infarct. On 19-Sep-2021, Troponin: 869 (High) 869. On 20-Sep-2021, Catheterisation cardiac: acute st-elevation mi (abnormal) Acute ST-elevation myocardial infarction (MI). This appears to be related to myocarditis.. On 20-Sep-2021, Troponin: 1799 (High) 1799. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Concomitant product use was not provided by the reporter. No treatment information was provided.	

Case ID	WW Identifier	Narrative	MAH Comment
		Patient reported worsening chest pain (8 out of 10) and shortness of breath. On 17 Sep 2021, echocardiogram and magnetic resonance imaging heart was performed (results were pending). Company comment: This case concerns a 25-year-old, male patient with no previous relevant medical history reported, who experienced the unexpected events of acute myocardial infarction, myocardial infarction, chest pain, dyspnoea, myocarditis and troponin increased. The events occurred the same day after the second dose of mRNA-1273. The rechallenge was not applicable since the events happened after the second dose. The benefit-risk relationship of mRNA-1273 is not affected by this report.	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 06-Oct-2021 and was forwarded to Moderna on 06-Oct-2021. This regulatory authority case was reported by a physician and describes the occurrence of HYPERHIDROSIS (Sweating attack), DIZZINESS (Light headedness), PALPITATIONS (Heart racing), CHEST DISCOMFORT (Pressure chest) and MYOCARDITIS (Myocarditis) in a 27-year-old male patient who received mRNA-1273 (Spikevax) for Prophylactic vaccination. Previously administered products included for COVID-19 vaccination: COVID-19 Vaccine Moderna (COVID-19 Vaccine Moderna dispersion for injectionCOVID-19 mRNA Vaccine (nucleoside modified)SpykeVax) in June 2021. Past adverse reactions to the above products included No adverse reaction with COVID-19 Vaccine Moderna.	

Case ID	WW Identifier	Narrative	MAH Comment
		In June 2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 01-Jul-2021, received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. On 05-Jul-2021, the patient experienced HYPERHIDROSIS (Sweating attack) (seriousness criterion medically significant), DIZZINESS (Light headedness) (seriousness criterion medically significant), PALPITATIONS (Heart racing) (seriousness criterion medically significant), CHEST DISCOMFORT (Pressure chest) (seriousness criterion medically significant) and MYOCARDITIS (Myocarditis) (seriousness criterion medically significant). At the time of the report, HYPERHIDROSIS (Sweating attack), DIZZINESS (Light headedness), PALPITATIONS (Heart racing), CHEST DISCOMFORT (Pressure chest) and MYOCARDITIS (Myocarditis) had resolved. For mRNA-1273 (Spikevax) (Unknown), 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 case concerns a 27-year-old male patient with no relevant medical history, who experienced the unexpected, serious (medically significant) events of myocarditis, hyperhidrosis, dizziness, palpitations and chest discomfort. The events occurred approximately 1 month after the first dose of mRNA-1273 and 4 days after the second dose of mRNA-1273. At the time of the event onset, myocarditis was considered an unexpected event. The rechallenge was not applicable. The benefit-risk relationship of mRNA-1273 is not affected by this report.	

Case ID	WW Identifier	Narrative	MAH Comment
4.1(b)	4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b)) on 06-Oct-2021 and was forwarded to Moderna on 06-Oct-2021. This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDIAL INFARCTION (heart attack), ELECTROCARDIOGRAM NORMAL (ECG normal) and MYOCARDITIS (Myocarditis) in a 19-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) (batch no. 3004668) for COVID-19 vaccination. No Medical History information was reported. On 30-Sep-2021, the patient received second dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 03-Oct-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). On an unknown date, the patient experienced MYOCARDIAL INFARCTION (heart attack) (seriousness criteria hospitalization and medically significant) and ELECTROCARDIOGRAM NORMAL (ECG normal) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDIAL INFARCTION (heart attack) and ELECTROCARDIOGRAM NORMAL (ECG normal) had resolved and MYOCARDITIS (Myocarditis) was resolving. The action taken with mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown) was unknown. No concomitant medication was provided by reporter.	19 years old male with unknown medical history who 3 days after the 2nd dose experienced chest pain and pain was found to have elevated troponin, cMRI abnormal, that confirmed the diagnosis of myocarditis, with normal ECH and normal Echo. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and cMRI results; a causal relationship cannot be excluded due to the lack of other information.

Case ID	WW Identifier	Narrative	MAH Comment
		Patient experienced chest pain and pain in jaw on left side of the body. Doctor advised to go to hospital as doctor suspected a heart attack. Patient was admitted to coronary care unit on 03-Oct-2021. The ECG, echocardiogram and blood pressure was normal; Troponin was 1318 which then increased to more than 2000. Patient was placed on beta blockers 2.5mg to slow heart rate from high 90 so no more strain was placed on the heart muscle. Troponin level on 04-Oct-2021 was 1700. The MRI on 04-Oct-2021, the myocarditis was confirmed. No treatment drug was provided by reporter. Company Comment: This case concerns a 19-year-old, male patient with no relevant medical history, who experienced the unexpected events of Myocardial infarction, Electrocardiogram normal and the expected event of Myocarditis. The event of Myocarditis occurred approximately 3 days after the second dose of Moderna vaccine. The rechallenge was unknown as no information was provided about the first dose. The events were considered related to the product per the reporter's assessment. The event of Myocarditis is consistent with the current understanding of the mechanism of action of the vaccine. The benefit-risk relationship of Moderna Covid-19 vaccine is not affected by this report.	
4.1(b)	4.1(b)	This case was initially received via 4.1(b) Pharmaceuticals (Reference number: 4.1(b) on 01-Oct-2021. The most recent information was received on 06-Oct-2021 and was forwarded to Moderna on 19-Oct-2021. This case, reported by a pharmacist, was received by 4.1(b) via Moderna's adverse reaction reporting site 4.1(b) and reported to the 4.1(b) by a	21 years old male with unknown medical history who 3 days after the 2nd dose experienced chest pain and was found to have elevated troponin, Ck, NT-proBNP, abnormal EGC, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal

Case ID	WW Identifier	Narrative	MAH Comment
		pharmacist, was received via the 4.1(b) (Ref, 4.1(b) On 06-Oct-2021, follow-up information, initially reported by a pharmacist, was received by 4.1(b) via Moderna's adverse reaction reporting site (4.1(b) On 07-Oct-2021, follow-up information, initially reported to the 4.1(b) by a pharmacist, was received via the 4.1(b) (Ref, 4.1(b) On 31-Aug-2021, the patient received the 1st dose of this vaccine. On 28-Sep-2021, the patient received the 2nd dose of this vaccine. On 30-Sep-2021, severe chest pain developed. It was considered that acute myocarditis developed. On 01-Oct-2021, the patient visited a medical institution. Electrocardiogram showed extensive ST elevation, and echocardiography showed decreased wall hypokinesia. CK: 698, CK-MB: 52, TnT: 0.818, NT-proBNP: 148, which increased. Myocarditis after the vaccination with this vaccine was suspected. The patient was hospitalized in the reporting hospital. On an unknown date, after the hospitalization, follow-up was performed, and CK and NT-proBNP levels returned to normal. On 04-Oct-2021, the recovery was confirmed, and the patient was discharged from the hospital. The outcome of acute myocarditis was reported as recovered. No follow-up investigation will be made. Follow-up received on 06-OCT-2021	association between the use of the product and the start of the events, as well as the elevated troponin and ECG results; a causal relationship cannot be excluded due to the lack of other information.

Case ID	WW Identifier	Narrative	MAH Comment
		Updated: Lab Data, Product Information, Event Information, Narrative Company Comment: The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 06-Oct-2021 and was forwarded to Moderna on 06-Oct-2021. This regulatory authority case was reported by a physician and describes the occurrence of PERICARDITIS (SUSPICION OF DRY PERICARDITIS) in a 30-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. No Medical History information was reported. On 19-Aug-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 01-Sep-2021, the patient experienced PERICARDITIS (SUSPICION OF DRY PERICARDITIS) (seriousness criterion medically significant). At the time of the report, PERICARDITIS (SUSPICION OF DRY PERICARDITIS) outcome was unknown. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. As per source document event as reported by primary source was SUSPICION OF DRY PERICARDITIS. No concomitant medication was reported. No treatment medication was reported.	

Case ID	WW Identifier	Narrative	MAH Comment
		Company Comment: This case concerns a 30-year-old, female patient with no medical history reported, who experienced the expected event of pericarditis. The event occurred approximately 13 days after the second dose of Moderna COVID-19 Vaccine. As reported per source document there was a suspicion of dry pericarditis. The rechallenge was not applicable as events occurred after second dose and no further dosing was reported or planned, based on information provided. The benefit-risk relationship of Moderna COVID-19 Vaccine is not affected by this report. Event seriousness assessed as per Regulatory Authority reporting. Most recent FOLLOW-UP information incorporated above includes: On 06-Oct-2021: Translation document received on 08-OCT-2021, contains updated event term reported by primary source.	
4.1(b)	4.1(b)	This case was received via 4.1(b) Pharmaceuticals (Reference number: 4.1(b) on 04-Oct-2021 and was forwarded to Moderna on 08-Oct-2021. This case, initially reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref 4.1(b) On an unknown date, the patient received the 1st dose of this vaccine. On 20-Sep-2021, around 19:00, the patient received the 2nd dose of this vaccine. On 21-Sep-2021, pyrexia of 38.0 degrees Celsius developed and persisted for two days. On 22-Sep-2021, at 19:00, as chest pain developed and did not disappear with oral administration of loxoprofen sodium hydrate but slightly improving, the patient visited the reporting	22 years old male with unknown medical history who next days after the 2nd dose experienced pyrexia, and the following day experienced chest pain, patient went to the hospital and was found to have elevated troponin, CK, abnormal EGC, abnormal cMRIand was diagnosed with myocarditis and acute epicarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and cMRI and ECG results; a causal relationship cannot be excluded due to the lack of other information.

Case ID	WW Identifier	Narrative	MAH Comment
		hospital. ST elevation on ECG and increase of in TnT, CK, and CKMB on blood test were observed. The patient was hospitalized with a diagnosis of acute epicarditis and myocarditis. CK/CKMB was 367/35 at the peak. On 23-Sep-2021, the symptoms were resolving, and ST tended to decrease. On 25-Sep-2021, T wave was negative, and electrocardiogram normalized. On 28-Sep-2021, MRI showed findings of myocarditis (delayed imaging on a plaque in the middle of the left ventricular wall). On 29-Sep-2021, the patient recovered from the symptoms and was discharged from the hospital. The outcome of pyrexia, acute epicarditis, and myocarditis was reported as recovered. Follow-up investigation will be made. Reporter comments continuation: Since myocardial enzyme elevation, ST elevation on ECG, and findings of myocarditis on MRI are present, pericarditis and myocarditis are also definite diagnosis. Company Comment: The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 07-Oct-2021 and was forwarded to Moderna on 07-Oct-2021. This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (Retrosternal pain / chest pain) in a 27-year-old male patient who received mRNA-1273	27 years old male with medical history of cholecystectomy who 21 days after the 2nd dose experienced retrosternal chest pain and was found to have elevated troponin, and abnormal cMRI, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted,

Case ID	WW Identifier	Narrative	MAH Comment
		(Spikevax) for Prophylactic vaccination. The patient's past medical history included Cholecystectomy. Concurrent medical conditions included Drug allergy (Mivacurium allergy). On 16-Jun-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 30-Jul-2021, received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. On 20-Aug-2021, after starting mRNA-1273 (Spikevax), the patient experienced MYOCARDITIS (Retrosternal pain / chest pain) (seriousness criteria hospitalization and medically significant). The patient was hospitalized from 20-Aug-2021 to 24-Aug-2021 due to MYOCARDITIS. At the time of the report, MYOCARDITIS (Retrosternal pain / chest pain) was resolving. No relevant concomitant medications were reported. Patient was discharged with pain medication. Patient had consulted with the primary care physician due to chest pain/ heart palpitations. Physician determined patient had positive troponin levels in evening. In hospital patient had MRI which diagnosed Myocarditis. Patient was hospitalized on 20-AUG-2021. Patient was discharged on 24-AUG-2021 with subjective well-being. Company comment: This case concerns a 27 year old male with no relevant history who experienced the serious, expected event of Myocarditis 24 days after the second dose of Spikevax. Re-challenge is unknown for dose 1 as no information is reported and not applicable for dose 2 as no further dosing is expected. Benefit-risk relationship of Spikevax is not affected by this report.	including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and cMRI results; a causal relationship cannot be excluded due to the lack of other information.

Case ID	WW Identifier	Narrative	MAH Comment
		Most recent FOLLOW-UP information incorporated above includes: On 07-Oct-2021: Translation received on 12-OCT-2021 contains: Event Verbatim Updated and Sender's comment which contains information about allergy, pre-existing condition, treatment medication and event information updated in narrative.	
4.1(b) [redacted]	4.1(b) [redacted]	This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted] on 07-Oct-2021 and was forwarded to Moderna on 07-Oct-2021. This regulatory authority case was reported by a physician and describes the occurrence of PERICARDITIS (Acute pericarditis) in a 29-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3004498) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Previously administered products included for Vaccination: Comirnaty. Past adverse reactions to the above products included No adverse event with Comirnaty. On 25-Aug-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 23-Sep-2021, the patient experienced PERICARDITIS (Acute pericarditis) (seriousness criteria hospitalization and medically significant). On an unknown date, the patient experienced COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine). At the time of the report, PERICARDITIS (Acute pericarditis) was resolving and COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):	

Case ID	WW Identifier	Narrative	MAH Comment
		In September 2021, Echocardiogram: abnormal (abnormal) showed pericardial effusion. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Concomitant product use was not provided by the reporter. Treatment medication was not provided by the reporter. Company comment This case concerns a 29-year-old male patient with no relevant medical history, who experienced the expected serious AESI event of Pericarditis. The event occurred approximately 30 days after the second dose of Spikevax administration. The rechallenge was not applicable since no information available on the first dose and no additional dosing was expected. The benefit-risk relationship is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 07-Oct-2021: Translation received 08-OCT-2021 contains no new information.	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 07-Oct-2021 and was forwarded to Moderna on 07-Oct-2021. This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (Myocarditis) in a 22-year-old male patient who received mRNA-1273 (Spikevax) for Prophylactic vaccination. No Medical History information was reported. On 12-Aug-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form.	

Case ID	WW Identifier	Narrative	MAH Comment
		On an unknown date, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 15-Aug-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization prolonged and medically significant). At the time of the report, MYOCARDITIS (Myocarditis) was resolving. Concomitant product use was not provided by the reporter. Had inpatient treatment in hospital for myocarditis. No treatment information was provided. Company comment- This case concerns a 22-year-old male patient with no relevant medical history, who experienced the expected serious event of Myocarditis. The event occurred approximately 04 days after the second dose of Spikevax. The patient had inpatient treatment in hospital for myocarditis. The rechallenge was unknown as there's no information available about the first dose. The event is consistent with the current understanding of the mechanism of action of the vaccine. The benefit-risk relationship of Spikevax is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 07-Oct-2021: Translation document received on 11-Oct-2021 and narrative was updated.	
4.1(b)	4.1(b)	This case was received via 4.1(b) Pharmaceuticals (Reference number: 4.1(b) on 01-Oct-2021 and was forwarded to Moderna on 08-Oct-2021. This case was reported by a physician via a medical representative. Myocarditis was assessed as serious by the MAH. On an unknown date, the patient received the 1st dose of the vaccine. On 28-Sep-2021, the patient received the 2nd dose of the vaccine.	

Case ID	WW Identifier	Narrative	MAH Comment
		On 30-Sep-2021, myocarditis developed. In the morning, chest pain was noted when the patient was examined at the reporting hospital, and examinations were performed. Elevations in CPK and ST were observed. The outcome of myocarditis was unknown. Follow-up investigation will be made. Company Comment: The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	
4.1(b)	4.1(b)	This case was received via 4.1(b) Pharmaceuticals (Reference number: 4.1(b) on 04-Oct-2021 and was forwarded to Moderna on 08-Oct-2021. This case, reported by a pharmacist, was received by 4.1(b) via Moderna's adverse reaction reporting site 4.1(b) and reported to the 4.1(b) by a pharmacist, was received via the 4.1(b) (Ref, 4.1(b) On 02-Sep-2021, the patient received the 1st dose of this vaccine. On 30-Sep-2021, at 10:00, the patient received the 2nd dose of this vaccine. On 01-Oct-2021, the patient was aware of chest pain and breathlessness. On 03-Oct-2021, at 11:09, the patient visited a nearby physician. Electrocardiogram showed ST elevation. The patient was referred to the reporting hospital. Blood test showed increased troponin, and echocardiography showed decreased lower wall motion. The patient was admitted to the hospital with a diagnosis of acute myocarditis. On 04-Oct-2021, the symptoms were ongoing. The outcome of acute myocarditis was reported as ongoing and unchanged.	20 years old male with unknown medical history who 2 days after the 2nd dose experienced chest pain and SOB was found to have elevated troponin, and abnormal EGC, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and ECG results; a causal relationship cannot be excluded due to the lack of other information.

Case ID	WW Identifier	Narrative	MAH Comment
		Follow-up investigation will be made. Company Comment: The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 07-Oct-2021 and was forwarded to Moderna on 07-Oct-2021. This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (Myocarditis) in a 19-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 3004233 and 214007) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 23-Jul-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 20-Aug-2021, received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. On 22-Aug-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criterion medically significant), TACHYCARDIA (Tachycardia) and CHEST DISCOMFORT (Complaints of retrosternal pressure). On 26-Aug-2021, MYOCARDITIS (Myocarditis), TACHYCARDIA (Tachycardia) and CHEST DISCOMFORT (Complaints of retrosternal pressure) had resolved. Treatment information was not provided. 3 days after the second vaccination, Patient developed complaints of retrosternal pressure, tachycardia (206/min).	19 years old male with unknown medical history who 2 days after the 2nd dose experienced chest discomfort and was found to have elevated troponin, Ck, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin ECG results; a causal relationship cannot be excluded due to the lack of other information.

Case ID	WW Identifier	Narrative	MAH Comment
		The laboratory data's were reported as creatine kinase, Creatine kinase-MB, C-reactive protein, with unknown results and troponin TR showed elevation and result of D-dimer was reported as neg. After three days the c-reactive protein level showed elevation. . Fast progression, inconspicuous heart echo were also reported. Company Comment: This case concerns a 19 year old male with no medical history who experienced the serious listed event of Myocarditis 2 days after the second dose of Spikevax. Re-challenge is unknown for dose 1 as no information is reported and not applicable for dose 2 as no further dosing is expected. Benefit-risk relationship of Spikevax is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 07-Oct-2021: Translation received on 11-OCT-2021 contain significant information that include event verbatim updated and I narrative updated.	
4.1(b)	4.1(b)	This case was received via 4.1(b) Pharmaceuticals (Reference number: 4.1(b)) on 05-Oct-2021 and was forwarded to Moderna on 09-Oct-2021. This case, reported by a physician, was received by 4.1(b) via Moderna's adverse reaction reporting site (4.1(b) and reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref, 4.1(b) On 08-Sep-2021, the patient received the 1st dose of this vaccine. On 29-Sep-2021, at 18:00, the patient received the 2nd dose of this vaccine. Vomiting developed 3 times. On 30-Sep-2021, at 00:00, pyrexia of 38.0-38.9 degrees Celsius and chest	24 years old male with unknown medical history who 1 days after the 2nd dose experienced vomiting, pyrexia, chest discomfort, malaise, and was found to have elevated troponin, and abnormal EGC, and was diagnosed with myopericarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and ECG results; a causal relationship cannot be excluded due to the lack of other information.

Case ID	WW Identifier	Narrative	MAH Comment
		discomfort developed. The patient experienced increased malaise and difficulty in moving, and an emergency call was made. At the time of transport, the patient had pyrexia of 37.9 degrees Celsius and slightly increased CRP of 2.82. There was no increase in troponin I, but there was ST elevation in V4-6 of electrocardiogram. PCR for coronavirus was negative. On 01-Oct-2021, pericarditis and myocarditis developed. The patient was hospitalized for pericarditis after the vaccination. On 05-Oct-2021, recovery was confirmed. The outcome of vomiting, pyrexia, malaise, pericarditis, and myocarditis was reported as resolved. Follow-up investigation will be made. Company Comment: The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	
4.1(b)	4.1(b)	This case was received via 4.1(b) Pharmaceuticals (Reference number: 4.1(b)) on 06-Oct-2021 and was forwarded to Moderna on 11-Oct-2021. This case, reported by a physician, was received by 4.1(b) via Moderna's adverse reaction reporting site (4.1(b) and reported to the 4.1(b)) by a physician, was received via the 4.1(b) (Ref, 4.1(b) Myocarditis was assessed as serious by the MAH. On an unknown date, the patient received the 1st dose of this vaccine. On 21-Sep-2021, the patient received the 2nd dose of this vaccine.	22 years old male with unknown medical history who next days after the 2nd dose experienced chest pain and was found to have elevated troponin, and abnormal EGC, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and ECG results; a causal relationship cannot be excluded due to the lack of other information.

Case ID	WW Identifier	Narrative	MAH Comment
		On 22-Sep-2021, at 20:00, chest pain developed. There were ECG changes and elevated troponin I, and the patient was diagnosed with myocarditis. On 04-Oct-2021, recovery of symptoms was confirmed. The outcome of myocarditis was reported as recovered. Follow-up investigation will be made. Company Comment: The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 08-Oct-2021 and was forwarded to Moderna on 08-Oct-2021. This regulatory authority case was reported by a physician and describes the occurrence of VENTRICULAR DYSFUNCTION (Myocarditis occuring two days after the second dose of vaccine,with associated left ventricular dysfunction.) and MYOCARDITIS (Myocarditis occuring two days after the second dose of vaccine,with associated left ventricular dysfunction.) in a 21-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 immunisation. The patient's past medical history included Smoker. On 23-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to .5 milliliter in total. On an unknown date, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) .5 ml. On 25-Sep-2021, the patient experienced VENTRICULAR DYSFUNCTION (Myocarditis occuring two days after the second dose of vaccine,with	21 years old male with unknown medical history who 2 days after the 2nd dose was found to have ventricular dysfunction and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the ventricular dysfunction and myocarditis diagnosis; a causal relationship cannot be excluded due to the lack of other information.

Case ID	WW Identifier	Narrative	MAH Comment
		associated left ventricular dysfunction.) (seriousness criterion hospitalization) and MYOCARDITIS (Myocarditis occuring two days after the second dose of vaccine,with associated left ventricular dysfunction.) (seriousness criterion hospitalization). At the time of the report, VENTRICULAR DYSFUNCTION (Myocarditis occuring two days after the second dose of vaccine,with associated left ventricular dysfunction.) and MYOCARDITIS (Myocarditis occuring two days after the second dose of vaccine,with associated left ventricular dysfunction.) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 26-Sep-2021, Troponin I: 21704 (High) 21704 ng. On 26-Sep-2021, White blood cell count: 16840 (High) 16840 INTERNATIONAL UNIT(S)-(UNDER 100). On 27-Sep-2021, C-reactive protein: 6 (normal) 6 mg. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Concomitant medications was not reported. Treatment history was not reported. This case concerns a 21-year-old male patient with no reported relevant medical history, who experienced the expected serious AESI event of Myocarditis and the unexpected serious event of Ventricular dysfunction. The events occurred approximately 3 days after the second dose of Spikevax administration. The rechallenge was not applicable since no events were reported after the first dose and no additional dosing was expected. The benefit-risk relationship is not affected by this report.	

Case ID	WW Identifier	Narrative	MAH Comment
		Most recent FOLLOW-UP information incorporated above includes: On 08-Oct-2021: Follow up received contains No new information On 08-Oct-2021: Translated document received on 12-OCT-2021 contains updated event verbatim and relevant past drug name as reported and updated Narrative.	
4.1(b) [redacted]	4.1(b) [redacted]	This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 08-Oct-2021 and was forwarded to Moderna on 08-Oct-2021. This regulatory authority case was reported by a physician and describes the occurrence of DYSPNOEA (DYSPNEA) and MYOCARDITIS (MYOCARDITIS) in a 25-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3004224) for Vaccination. No Medical History information was reported. On 21-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 26-Sep-2021, the patient experienced DYSPNOEA (DYSPNEA) (seriousness criterion hospitalization) and MYOCARDITIS (MYOCARDITIS) (seriousness criteria hospitalization and medically significant). At the time of the report, DYSPNOEA (DYSPNEA) and MYOCARDITIS (MYOCARDITIS) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 26-Sep-2021, Echocardiogram: no signs of pericardial fluid, normal ventricular (normal) No signs of pericardial fluid, normal ventricular function. For mRNA-1273 (Spikevax) (Intramuscular), the reporter	25 years old male with unknown medical history who 5 days after the 2nd dose experienced dyspnoea and was found to have elevated troponin, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin; a causal relationship cannot be excluded due to the lack of other information.

Case ID	WW Identifier	Narrative	MAH Comment
		considered DYSPNOEA (DYSPNEA) and MYOCARDITIS (MYOCARDITIS) to be possibly related. Concomitant product use was not provided by the reporter. Treatment information was not provided. On 26-Sep-2021, Troponin T: 401 (normal) Maximum measured value: 401 ng/L. Company comment: This case concerns a 25-year-old male patient with no reported medical history who experienced the unexpected events of dyspnea and expected event of myocarditis. The events occurred 5 days after the second dose of mRNA-1273 (Spikevax). The rechallenge was unknown no details about the first dose was provided. The reported assessed the reported evens as related to the product use. Myocarditis is consistent with the current understanding of the mechanism of action of the vaccine. The benefit-risk relationship of Spikevax is not affected by this report. Event assessed as serious per Regulatory authority as the events were noted as medically significant. Myocarditis is an adverse event of special interest Most recent FOLLOW-UP information incorporated above includes: On 08-Oct-2021: Translation received on 12-Oct-2021, contains no new information.	
4.1(b) [redacted]	4.1(b) [redacted]	This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 08-Oct-2021 and was forwarded to Moderna on 08-Oct-2021. This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (Myocarditis) in a 24-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3004671) for Prophylactic vaccination.	

Case ID	WW Identifier	Narrative	MAH Comment
		No Medical History information was reported. On 18-Aug-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 25-Aug-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). The patient was hospitalized for 7 days due to MYOCARDITIS. At the time of the report, MYOCARDITIS (Myocarditis) had not resolved. Concomitant product use was not provided by the reporter. Patient was allergic to amoxicillin. Patient was hospitalized for 1 week, signed off sick since hospitalization, no final examination yet. No treatment information was provided. Company Comment: This case concerns a 24-year-old male subject, with no relevant medical history, who experienced the serious, expected, AESI event of Myocarditis. The event occurred approximately 8 days after the second dose of Spikevax. The rechallenge is not applicable, as no additional dose will be given. The benefit-risk relationship of Spikevax is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 08-Oct-2021: Translation received on 12-OCT-2021 in which sender's comment and event verbatim were updated. On 25-Oct-2021: Follow-up received contains no new information.	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on	

Case ID	WW Identifier	Narrative	MAH Comment
		08-Oct-2021 and was forwarded to Moderna on 08-Oct-2021. This regulatory authority case was reported by a consumer and describes the occurrence of PERICARDITIS (Pericardial irritation) in an 18-year-old female patient who received mRNA-1273 (Spikevax) (batch nos. 3004217 and 3003609) for COVID-19 vaccination. No Medical History information was reported. On 18-Jul-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 15-Aug-2021, received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. On 18-Aug-2021, after starting mRNA-1273 (Spikevax), the patient experienced PERICARDITIS (Pericardial irritation) (seriousness criteria hospitalization and medically significant). On 01-Sep-2021, PERICARDITIS (Pericardial irritation) had not resolved. No concomitant medications were mentioned. No treatment details were reported. It was reported that patient investigation included increased hs-TNT 3 times. fluoride,myocarditis, ischemia, infection investigations were excluded. Company comment: This case concerns a 18-year-old, female patient with no relevant medical history, who experienced the expected event of pericarditis. The event pericarditis occurred 3 days after the second dose of mRNA-1273 vaccine administration. The rechallenge was unknown as there's no information available about the first dose. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. The RA SD contain conflicting information, the RA SD captured the end date of	

Case ID	WW Identifier	Narrative	MAH Comment
		the event pericarditis as 1 September 2021 but the outcome of event pericarditis at the time of last observation is not recovered/not resolved/ongoing. RA SD coding was captured and maintained. Most recent FOLLOW-UP information incorporated above includes: On 08-Oct-2021: Translation received on 13 OCT 2021 contains significant information, Event verbatim was updated, Sender's comment was updated.	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 08-Oct-2021 and was forwarded to Moderna on 08-Oct-2021. This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Acute myocarditis) in a 20-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 prophylaxis. No Medical History information was reported. On 20-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 23-Sep-2021, the patient experienced MYOCARDITIS (Acute myocarditis) (seriousness criterion medically significant). On 27-Sep-2021, MYOCARDITIS (Acute myocarditis) had resolved. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. No concomitant product use was provided by the reporter. No treatment medication was provided.	

Case ID	WW Identifier	Narrative	MAH Comment
		Company comment: This case concerns a 20-year-old, male patient, with no disclosed medical history, who experienced the serious, expected, AESI event of myocarditis. The event occurred on an unknown day after second dose of Spikevax. The rechallenge is unknown as no details on the first dose was given. The benefit-risk relationship of Spikevax is not affected by this report.	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 11-Oct-2021 and was forwarded to Moderna on 11-Oct-2021. This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (myocarditis) in a 20-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 3002335 and 3002335) for COVID-19 vaccination. No Medical History information was reported. In May 2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 27-Jun-2021, received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to 1 dosage form. On 29-Jun-2021, after starting mRNA-1273 (Spikevax), the patient experienced MYOCARDITIS (myocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (myocarditis) had not resolved. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medications were reported. No treatment details were reported.	

Case ID	WW Identifier	Narrative	MAH Comment
		This case concerns a 20-year-old male patient with no relevant medical history who experienced serious expected event of Myocarditis. The event occurred approximately two days after the second dose of Spikevax. The rechallenge was not applicable as the event occurred following the second dose. Very limited information regarding clinical course of the 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 11-Oct-2021: Translation document received on 13-Oct-2021 included no new information.	
4.1(b) [redacted]	4.1(b) [redacted]	This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 11-Oct-2021 and was forwarded to Moderna on 11-Oct-2021. This regulatory authority case was reported by a physician and describes the occurrence of PERICARDITIS (Pericarditis) in a 23-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3003604) for Vaccination. No Medical History information was reported. On 08-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 27-Sep-2021, the patient experienced PERICARDITIS (Pericarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, PERICARDITIS (Pericarditis) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):	

Case ID	WW Identifier	Narrative	MAH Comment
		In September 2021, Echocardiogram: normal (normal) Normal findings. In September 2021, Electrocardiogram: consistent with pericarditis, no pericardial fluid (abnormal) Findings from clinical examination and ECG consistent with pericarditis, no pericardial fluid or specific sound (2/4 criteria for pericarditis fullfilled).. In September 2021, Laboratory test: normal (normal) Normal results. In September 2021, Physical examination: consistent with pericarditis, no pericardial fluid (abnormal) Findings from clinical examination and ECG consistent with pericarditis, no pericardial fluid or specific sound (2/4 criteria for pericarditis fullfilled).. For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered PERICARDITIS (Pericarditis) to be possibly related. No relevant concomitant medications were reported. No treatment information was provided. Company comment This case concerns a 23 year old male patient, with no medical history reported, who experienced serious expected event of pericarditis (AESI) after second dose of mRNA-1273. The event occurred 20 days after second dose of mRNA-1273. The re-challenge is not applicable because further dose is not expected. The event 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 11-Oct-2021: Translation received on 13-Oct-2021 included no new information	

Case ID	WW Identifier	Narrative	MAH Comment
4.1(b)	4.1(b)	This case was initially received via European Medicines Agency (Reference number: 4.1(b)) on 11-Oct-2021. The most recent information was received on 11-Oct-2021 and was forwarded to Moderna on 13-Oct-2021. This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (Myocarditis) in a 38-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. No Medical History information was reported. On 10-Aug-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 14-Aug-2021, after starting mRNA-1273 (Spikevax), the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Myocarditis) outcome was unknown. Concomitant medication was not provided. Treatment information was not provided. Patient Initial 4.1(b) and MRI of patient was confirmed CHD was ruled out. company comment: This case concerns a 38-year-old male patient with no reported medical history, who experienced the expected event of myocarditis. The event occurred 4 days after the second dose of mRNA-1273 (Spikevax). The rechallenge was unknown as no details about the first dose was disclosed. Causality for the reported event 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	

Case ID	WW Identifier	Narrative	MAH Comment
		is not affected by this report. Events assessed as medically significant per regulatory authority reporting and required hospitalization. Myocarditis is an adverse event of special interest. Most recent FOLLOW-UP information incorporated above includes: On 11-Oct-2021: Translation received on 13-OCT-21 and it included Patient Initial 4.1(b) and MRI result added in narrative.	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 11-Oct-2021 and was forwarded to Moderna on 11-Oct-2021. This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myocarditis) in a 23-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 214021 and 3004738) for COVID-19 vaccination. No Medical History information was reported. On 14-Aug-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 04-Sep-2021, received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to 1 dosage form. On 07-Sep-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Myocarditis) had not resolved. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Concomitan and treatment medication was not provided. Company comment: This case concerns a 23-year-old male patient with no relevant medical history, who	

Case ID	WW Identifier	Narrative	MAH Comment
		experienced the expected serious AESI event of Myocarditis. The events occurred approximately 5 days after the second dose of Spikevax administration. The rechallenge was not applicable since no events were reported after the first dose and no additional dosing was expected. Additional administrative event of inappropriate vaccination schedule was considered. The benefit-risk relationship is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 11-Oct-2021: Translation received on 14-OCT-2021: Contains no new information.	
4.1(b) [redacted]	4.1(b) [redacted]	This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 12-Oct-2021 and was forwarded to Moderna on 12-Oct-2021. This regulatory authority case was reported by a physician and describes the occurrence of PERICARDITIS (PERICARDITIS) in a 32-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3004498) for Vaccination. No Medical History information was reported. On 06-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 07-Sep-2021, the patient experienced PERICARDITIS (PERICARDITIS) (seriousness criteria hospitalization and medically significant). At the time of the report, PERICARDITIS (PERICARDITIS) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):	

Case ID	WW Identifier	Narrative	MAH Comment
		On 07-Sep-2021, Echocardiogram: abonormal (abnormal) No pleural effusion. On 07-Sep-2021, Electrocardiogram: abnormal (abnormal) ECG changes.. For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered PERICARDITIS (PERICARDITIS) to be possibly related. Concomitant product use was not provided by the reporter. No treatment information was provided. Company Comment: This case concerns a 32-year-old, male patient with no relevant medical history, who experienced the expected event of pericarditis. The event, which resulted in hospitalization, occurred 1 day after administration of the second dose of Spikevax. The rechallenge was not applicable as no additional dosing will be given. The patient's gender remains a confounder. 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 document received on 15-Oct-2021 with Sender's comments, dosage form text translated and updated.	
4.1(b) [redacted]	4.1(b) [redacted]	This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 12-Oct-2021 and was forwarded to Moderna on 12-Oct-2021. This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Acute myocarditis) and PERICARDITIS (Acute pericarditis) in a 24-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3003604) for Vaccination. The occurrence of	24 years old male with unknown medical history and Cominarty as the 1st dose of COVID019 vaccine who 28 days after the 2nd dose was found to have elevated troponin, and abnormal EGC, and was diagnosed with myopericarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal

Case ID	WW Identifier	Narrative	MAH Comment
		additional non-serious events is detailed below. Previously administered products included for Vaccination: COMIRNATY. On 02-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. In 2021, the patient experienced COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine). On 30-Sep-2021, the patient experienced MYOCARDITIS (Acute myocarditis) (seriousness criteria hospitalization and medically significant) and PERICARDITIS (Acute pericarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Acute myocarditis) and PERICARDITIS (Acute pericarditis) was resolving and COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In 2021, C-reactive protein: crp elevation (High) CRP elevation.. In 2021, Electrocardiogram: abnormal (abnormal) Acute pericarditis with typical symptoms, ECG changes and CRP elevation.. In 2021, Troponin I: 7000 (High) Approx. 7000 at the highest. For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered MYOCARDITIS (Acute myocarditis), PERICARDITIS (Acute pericarditis) and COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine) to be possibly related. Concomitant product use was not provided by the reporter.	association between the use of the product and the start of the events, as well as the elevated troponin and ECG results; a causal relationship cannot be excluded due to the lack of other information.

Case ID	WW Identifier	Narrative	MAH Comment
		No treatment information was provided. Company Comment: This case concerns a 24-year-old male subject with no relevant medical history reported, who experienced the serious unexpected and AESI events of MYOCARDITIS and PERICARDITIS 29 days receiving the second dose of spikevax. Time to onset for the first dose is unknown, and this dose was a dose of COMIRNATY. Rechallenge is not applicable since the events occurred after the second dose and no further doses will be given. Previous vaccination with comirnaty remains as a counfounder/co-suspect for this event. The benefit-risk relationship of spikevax is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 12-Oct-2021: Translated document received on 15-Oct-2021. Translation Document contains no new information	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 12-Oct-2021 and was forwarded to Moderna on 12-Oct-2021. This regulatory authority case was reported by a physician and describes the occurrence of CONGESTIVE CARDIOMYOPATHY (Dilated cardiomyopathy) and MYOCARDITIS (Myocarditis) in a 29-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 immunisation. No Medical History information was reported. On 27-May-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 08-Jul-2021, received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. On 11-	

Case ID	WW Identifier	Narrative	MAH Comment
		Jul-2021, the patient experienced CONGESTIVE CARDIOMYOPATHY (Dilated cardiomyopathy) (seriousness criterion medically significant) and MYOCARDITIS (Myocarditis) (seriousness criterion medically significant). At the time of the report, CONGESTIVE CARDIOMYOPATHY (Dilated cardiomyopathy) and MYOCARDITIS (Myocarditis) had not resolved. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. No Treatment informations were reported. Company Comment: This case concerns Inappropriate schedule of vaccine administration in a 29 year-old male patient with no reported medical history, who experienced the expected serious event of Myocarditis (AESI) and the unexpected serious event of Dilated cardiomyopathy. The events occurred 3 days after the second dose of mRNA-1273 vaccine. Details of clinical presentation, diagnostic criteria, and clinical course were not provided. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.	
4.1(b)	4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b) on 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 MYOCARDITIS (Myocarditis) in a 39-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. On 05-Feb-2021, the patient received second dose of mRNA-1273	

Case ID	WW Identifier	Narrative	MAH Comment
		(Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 08-Feb-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). The patient was hospitalized for 4 days due to MYOCARDITIS. At the time of the report, MYOCARDITIS (Myocarditis) had resolved. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter considered MYOCARDITIS (Myocarditis) to be possibly related. No concomitant medications were provided. Treatment for the events were not provided. Company Comment: This case concerns a 39-year-old, male patient with no relevant medical history, who experienced the expected event of myocarditis. The event, which resulted in hospitalization, occurred 3 days after administration of the second dose of the Moderna COVID-19 Vaccine. The rechallenge was not applicable as no additional dosing will be given. The patient's gender remains a confounder. The benefit-risk relationship of Moderna COVID-19 Vaccine is not affected by this report.	
4.1(b)	4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b) on 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 PERICARDITIS (Pericarditis with pericardial effusion) and PERICARDIAL EFFUSION (Pericarditis with pericardial effusion) in a 26-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination.	

Case ID	WW Identifier	Narrative	MAH Comment
		Concurrent medical conditions included Peanut allergy. Concomitant products included TESTOSTERONE CIPIONATE (TESTOSTERONE CYPIONATE), OXYCODONE HYDROCHLORIDE, PARACETAMOL (PERCOCET [OXYCODONE HYDROCHLORIDE;PARACETAMOL]), MELOXICAM and ACETYLSALICYLIC ACID (ASPRIN) for an unknown indication. On 01-Jan-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 11-Sep-2021, the patient experienced PERICARDITIS (Pericarditis with pericardial effusion) (seriousness criteria hospitalization and medically significant) and PERICARDIAL EFFUSION (Pericarditis with pericardial effusion) (seriousness criteria hospitalization and medically significant). At the time of the report, PERICARDITIS (Pericarditis with pericardial effusion) and PERICARDIAL EFFUSION (Pericarditis with pericardial effusion) had not resolved. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. No treatment information was provided by the reporter. On 11-Sep-2021, the patient had undergone computerized tomogram and echocardiogram tests. Company comment -This case concerns a 26-year old, male subject with a medical history of concomitant use of testosterone cypionate, who experienced the serious (Seriousness criteria-caused hospitalization, medically significant) expected event of Pericarditis(AESI) and serious unexpected event of Pericardial	

Case ID	WW Identifier	Narrative	MAH Comment
		effusion. The events occurred approximately 8 months after the second dose of MODERNA COVID-19 VACCINE. Rechallenge is not applicable as no information about the first dose is available and no additional dose is expected to be given. The patient's concomitant use of testosterone cypionate remains a confounder. The benefit-risk relationship of MODERNA COVID-19 VACCINE is not affected by this report.	
4.1(b) [redacted]	4.1(b) [redacted]	This spontaneous case was reported by a consumer and describes the occurrence of DYSPNOEA (could not breath), CHEST DISCOMFORT (pressure over the chest) and MYOCARDITIS (heart muscle inflammation) in a 19-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. Previously administered products included for an unreported indication: PFIZER BIONTECH COVID-19 VACCINE (First dose Pfizer on 21Jul2021) on 21-Jul-2021. On 08-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 08-Sep-2021, the patient experienced RHINORRHOEA (maybe a runny nose), PYREXIA (fever) and INTERCHANGE OF VACCINE PRODUCTS (First dose Pfizer on 21Jul2021 & Second dose Moderna on 08Sep2021). On 09-Sep-2021, the patient experienced MYOCARDITIS (heart muscle inflammation) (seriousness criterion medically significant). On an unknown date, the patient experienced DYSPNOEA (could not breath) (seriousness criteria hospitalization and medically significant), CHEST DISCOMFORT (pressure over the chest) (seriousness criterion hospitalization) and DEPRESSED MOOD (was not	

Case ID	WW Identifier	Narrative	MAH Comment
		good during those two weeks). The patient was hospitalized from 09-Sep-2021 to 09-Sep-2021 due to CHEST DISCOMFORT and DYSPNOEA. The patient was treated with IBUPROFEN at an unspecified dose and frequency. On 08-Sep-2021, INTERCHANGE OF VACCINE PRODUCTS (First dose Pfizer on 21Jul2021 & Second dose Moderna on 08Sep2021) had resolved. At the time of the report, DYSPNOEA (could not breath), CHEST DISCOMFORT (pressure over the chest) and MYOCARDITIS (heart muscle inflammation) had not resolved and RHINORRHOEA (maybe a runny nose), DEPRESSED MOOD (was not good during those two weeks) and PYREXIA (fever) outcome was unknown. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. No Concomitant medications were reported. They performed tests and they mentioned to patient that he has heart muscle inflammation and he received a sick leave for 2 weeks. Patient not good during those two weeks, so he went to the healthcare center and they told him that he still has the heart muscle inflammation and extended the sick leave with another month. Patient still experiences the pressure on the chest and the breathlessness during physical activity. Company comment: This case of vaccine interchange concerning a 19-year-old male patient, who had prior administration of Pfizer Biontech Covid-vaccine and with no other reported medical history, who experienced the expected event of heart muscle inflamed (myocarditis) and unexpected events of dyspnoea and chest discomfort. The events occurred 1 day after the second	

Case ID	WW Identifier	Narrative	MAH Comment
		dose of mRNA-1273 (COVID-19 Vaccine Moderna). The rechallenge was not applicable as the events 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. Myocarditis is consistent with the current understanding of the mechanism of action of the vaccine. Events were assessed as serious as both chest discomfort and dyspnoea resulted in hospitalization. Heart muscle inflamed was noted as medically significant and is an adverse event of special interest.	
4.1(b)	4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b) on 12-Oct-2021 and was forwarded to Moderna on 12-Oct-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of ASTHENIA (Asthenia), CHEST DISCOMFORT (Chest discomfort), CHEST PAIN (Chest pain), INFLUENZA LIKE ILLNESS (Influenza like illness), CHILLS (Chills), PRESYNCOPE (Presyncope), VOMITING (Vomiting) and MYOCARDITIS (Myocarditis) in a 33-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 002F21A) for COVID-19 vaccination. No Medical History information was reported. On 20-Sep-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 21-Sep-2021, the patient experienced ASTHENIA (Asthenia) (seriousness criterion hospitalization), CHEST DISCOMFORT (Chest discomfort) (seriousness criterion hospitalization), CHEST PAIN (Chest pain) (seriousness criterion hospitalization), INFLUENZA LIKE ILLNESS	33 years old male with unknown medical history who next day after the 2nd dose experienced chest discomfort, chest pain, influenza like-illness, chills, presyncope, vomiting, and was found to have elevated troponin, and abnormal EGC, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and ECG results; a causal relationship cannot be excluded due to the lack of other information.

Case ID	WW Identifier	Narrative	MAH Comment
		(Influenza like illness) (seriousness criterion hospitalization), CHILLS (Chills) (seriousness criterion hospitalization), PRESYNCOPE (Presyncope) (seriousness criterion hospitalization), VOMITING (Vomiting) (seriousness criterion hospitalization) and MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). The patient was hospitalized from 23-Sep-2021 to 24-Sep-2021 due to ASTHENIA, CHEST DISCOMFORT, CHEST PAIN, CHILLS, INFLUENZA LIKE ILLNESS, MYOCARDITIS, PRESYNCOPE and VOMITING. At the time of the report, ASTHENIA (Asthenia), CHEST DISCOMFORT (Chest discomfort), CHEST PAIN (Chest pain), INFLUENZA LIKE ILLNESS (Influenza like illness), CHILLS (Chills), PRESYNCOPE (Presyncope), VOMITING (Vomiting) and MYOCARDITIS (Myocarditis) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 21-Sep-2021, Troponin: increased (High) Increased. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Laboratory data on 21-Sep-2021 included C-reactive protein, Chest X-ray, Echocardiogram, Electrocardiogram, Full blood count, Metabolic function test, Red blood cell sedimentation rate with unknown results. On 23-Sep-2021 admitted for chest pain w/detectable troponin. his troponin quickly trended down and chest pain felt second to probable myocarditis presumed from COVID vaccine.	

Case ID	WW Identifier	Narrative	MAH Comment
		Patient developed flu-like symptoms approximately 12 hr. after vaccine which included, chills, rigors, emesis x4-5, weakness, near syncope, and chest pain. His pain was initially mild but then became moderate, was centrally located, sharp and tight. Patient was presented to the ER dur to the degree of pain. This case concerns a 33-year-old, male patient with no relevant medical history, who experienced the unexpected events of Asthenia, Chest discomfort, Chest pain, Influenza like illness, Chills, Presyncope, Vomiting, and the expected event of Myocarditis. The events of vomiting and chills are unexpected as they are retained as serious per the source document Authority reporting. The events occurred 1 day after the second dose of Spikevax. Laboratory data included troponin increased. The rechallenge was not applicable as no additional dose is expected to be given, and no details were provided about the first dose. The benefit-risk relationship of Spikevax is not affected by this report.	
4.1(b)	4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b) on 12-Oct-2021 and was forwarded to Moderna on 12-Oct-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of CHEST DISCOMFORT (Chest discomfort), CHILLS (Chills), COUGH (Cough), DYSPNOEA (Dyspnoea), FATIGUE (Fatigue/ tiredness), PYREXIA (Pyrexia) and MYOCARDITIS (Myocarditis) in a 35-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 004F21A and 046C21A) for COVID-19 vaccination. Concomitant products included FLUTICASONE PROPIONATE (FLONASE [FLUTICASONE PROPIONATE]) for an unknown indication.	

Case ID	WW Identifier	Narrative	MAH Comment
		On 20-Sep-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 21-Sep-2021, the patient experienced CHEST DISCOMFORT (Chest discomfort) (seriousness criteria hospitalization and disability), CHILLS (Chills) (seriousness criteria hospitalization and disability), COUGH (Cough) (seriousness criteria hospitalization and disability), DYSPNOEA (Dyspnoea) (seriousness criteria hospitalization and disability), FATIGUE (Fatigue/ tiredness) (seriousness criteria hospitalization and disability), PYREXIA (Pyrexia) (seriousness criteria hospitalization and disability) and MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization, disability and medically significant). At the time of the report, CHEST DISCOMFORT (Chest discomfort), CHILLS (Chills), COUGH (Cough), DYSPNOEA (Dyspnoea), FATIGUE (Fatigue/ tiredness), PYREXIA (Pyrexia) and MYOCARDITIS (Myocarditis) 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. The patient had shortness of breath, chest pressure and tightness, chills, fever, fatigue, tiredness, cough, chest tightness when stand and outcome was myocarditis. No treatment information was provided.	

Case ID	WW Identifier	Narrative	MAH Comment
		Company Comment: This case concerns a 35-year-old male patient, with no relevant details on medical history provided, who experienced the serious expected AESI of MYOCARDITIS. The event occurred one day after receiving the second dose of SPIKEVAX. The rechallenge is not applicable since no additional dose of Spikevax will be administered. The benefit-risk relation of Spikevax is not affected by this report. Seriousness criteria was assessed as per Regulatory Authority report, even if there is no evidence confirming the events met the disability criteria.	
4.1(b)	4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b) on 12-Oct-2021 and was forwarded to Moderna on 12-Oct-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of ANAPHYLACTIC REACTION (Anaphylactic reaction) and MYOCARDITIS (Myocarditis) in a 40-year-old female 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. The patient's past medical history included Childhood asthma (History of childhood asthma). Concurrent medical conditions included Drug allergy (Allergic to Sulfa). Concomitant products included MULTIVITAMINS [VITAMINS NOS], CALCIUM, ZINC and VITAMIN C [ASCORBIC ACID] for an unknown indication. On 01-Jan-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)	

Case ID	WW Identifier	Narrative	MAH Comment
		(unknown route) 1 dosage form. On 03-Feb-2021, the patient experienced ANAPHYLACTIC REACTION (Anaphylactic reaction) (seriousness criterion medically significant), MYOCARDITIS (Myocarditis) (seriousness criterion medically significant), BRONCHOSPASM (Bronchospasm) and HYPOTENSION (Hypotension). On an unknown date, the patient experienced CHEST PAIN (chest pain), PALPITATIONS (palpitations), DYSPNOEA (shortness of breath), VERTIGO (vertigo) and HEADACHE (Headaches). The patient was treated with COLCHICINE for Myocarditis, at an unspecified dose and frequency. At the time of the report, ANAPHYLACTIC REACTION (Anaphylactic reaction), MYOCARDITIS (Myocarditis), BRONCHOSPASM (Bronchospasm) and HYPOTENSION (Hypotension) had resolved and CHEST PAIN (chest pain), PALPITATIONS (palpitations), DYSPNOEA (shortness of breath), VERTIGO (vertigo) and HEADACHE (Headaches) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 03-Feb-2021, Blood pressure measurement: 64/40 (Low) severe hypotension. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Patient reported full cardiac work up, ekg, echocardiogram, chest Vt, chest X-ray, etc. On 03-FEB-2021 Lab data included Cardiovascular examination, Chest X-ray, Computerized tomogram thorax, Echocardiogram, Electrocardiogram and results were not reported. First dose: patient had chest pain, palpitations, shortness of breath, Headaches and vertigo symptoms.	

Case ID	WW Identifier	Narrative	MAH Comment
		After 2nd: dose, patient had anaphylactic reaction with associated sxs bronchospasm and severe hypotension, 64/40. Later developed myopericarditis requiring treatment with colchicine. This case concerns a 40 year-old female patient with history of childhood asthma, who experienced the expected serious events of Anaphylactic reaction and Myocarditis (AESI). The events occurred approximately one month after the second dose of mRNA-1273 vaccine. The patient's history of asthma remains a confounder for the non-serious event of bronchospasm reported as an associated symptom of anaphylaxis. Regarding the event of Myocarditis, patient reported full cardiac workup, however the details of clinical presentation, results of assessments/diagnostic criteria, and clinical course were not provided. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.	
4.1(b)	4.1(b)	This case was received via 4.1(b) Pharmaceuticals (Reference number: 4.1(b)) on 05-Oct-2021 and was forwarded to Moderna on 13-Oct-2021. This case, reported by a physician, was received by 4.1(b) via Moderna's adverse reaction reporting site (4.1(b) and reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref, 4.1(b) On 14-Jul-2021, the patient received the 1st dose of this vaccine. On an unknown date, body temperature before the vaccination: 36.2 degrees Celsius. On 11-Aug-2021, at 16:00, the patient received the 2nd dose of this vaccine. At night, headache developed. On 12-Aug-2021, in the morning, chest pain developed. Headache persisted. On 13-Aug-2021, pyrexia of 38.4 degrees Celsius developed, and the patient took loxoprofen sodium hydrate. On 14-Aug-2021, the symptoms were exacerbated in the early morning, and the patient was hospitalized. Suspected myocarditis was diagnosed. On 18-Aug-2021, the symptoms were resolving, and the patient was discharged from the hospital.	

Case ID	WW Identifier	Narrative	MAH Comment
		On 02-Sep-2021, the symptoms resolved. The outcome of pyrexia, chest pain, headache, and suspected myocarditis was reported as resolved. Follow-up investigation will be made. Company Comment: The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	
4.1(b) [redacted]	4.1(b) [redacted]	This spontaneous case was reported by a consumer and describes the occurrence of MYOCARDITIS (Myocarditis) in a 24-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 022C21A and 022C21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 31-Aug-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 01-Oct-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 05-Oct-2021, after starting mRNA-1273 (Moderna COVID-19 Vaccine), the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). In October 2021, the patient experienced IMPAIRED WORK ABILITY (cannot do strenuous work or exercise for a month). The patient was hospitalized from sometime in October 2021 to sometime in October 2021 due to MYOCARDITIS. At the time of the report, MYOCARDITIS (Myocarditis) was resolving and IMPAIRED WORK ABILITY (cannot do strenuous work or exercise for a month) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):	

Case ID	WW Identifier	Narrative	MAH Comment
		In October 2021, Electrocardiogram: normal (normal) EKG looked normal. In October 2021, Troponin: high (High) High troponin levels. No concomitant medications were provided. Patient had no prior history for the symptoms nor a history of COVID-19 infection. He had no medical or family history for myocarditis/pericarditis. Patient experienced strong chest pain in the morning. He would rate the pain about 7 out of 10; 10 being the strongest pain. Walking or stretching would not make it better or worse. It was a constant stable pain. It was quite noticeable. The pain lasted 2-3 hours. The symptoms started on 05 Oct 2021 from 7 AM to 10:30 AM. The symptoms repeated everyday. On 06 Oct 2021, at about 9 AM to10:30 AM, the pain was less than on 05 Oct 2021. On 07 Oct 2021, it was less noticeable, but he could still feel the pain. Patient was kept under observation for a day and then they discharged him. He felt better and he did not have any symptoms now. He could not do strenuous work or exercise for a month. The hospital summary suspected the second dose of Moderna COVID-19 vaccine as the cause. Patient received an injection in his belly that made his blood flow better. He was given a blood thinner injection. He reported that the hospital told him he could take Tylenol but he never did. Company Comment : This case concerns a 24-year-old male patient with no relevant medical history, who experienced the serious expected event of Myocarditis. The event occurred approximately 5 days after the Moderna COVID-19 Vaccine. The patient had high troponin levels and EKG was normal. The patient was under observation for a day then got discharged. The rechallenge was not applicable as the event occurred after	

Case ID	WW Identifier	Narrative	MAH Comment
		the second dose. The patient received the second dose approximately a month after the first dose. The benefit-risk relationship of COVID-19 Vaccine is not affected by this report.	
4.1(b)	4.1(b)	This case was received via 4.1(b) Pharmaceuticals (Reference number: 4.1(b)) on 06-Oct-2021 and was forwarded to Moderna on 14-Oct-2021. This case, initially reported to the 4.1(b)) by a (physician), was received via the 4.1(b) (Ref, 4.1(b) On an unknown date, the patient received the 1st dose of this vaccine. On an unknown date, body temperature before the vaccination: 36.2 degrees Celsius. On 29-Sep-2021, at 11:00, the patient received the 2nd dose of this vaccine. At around 23:00, pyrexia developed. On 30-Sep-2021, at around 03:00, chest pain developed. The symptom did not improve, and the patient visited a hospital. Breathlessness or oedema was not observed. The patient was diagnosed with acute pericarditis based on chest pain and PR depression on an electrocardiogram. The patient was hospitalized. On 03-Oct-2021, the symptoms were resolving, and the patient was discharged from the hospital. The outcome of pyrexia, chest pain, and acute pericarditis was reported as resolving. Follow-up investigation will be made. Company Comment: The events developed after the administration of COVID-19 vaccine	18 years old female with unknown medical history who next day after the 2nd dose experienced chest pain and was found to have and abndormal ECG and was diagnosed with pericarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events as well as the abnormal ECG. A causal relationship cannot be excluded due to the lack of other information.

Case ID	WW Identifier	Narrative	MAH Comment
		mRNA (mRNA 1273) and there is temporal relationship.	
4.1(b)	4.1(b)	This case was received via 4.1(b) Pharmaceuticals (Reference number: 4.1(b)) on 07-Oct-2021 and was forwarded to Moderna on 14-Oct-2021. This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Acute myocarditis) in an 18-year-old male patient who received mRNA-1273 (COVID 19 Vaccine Moderna) for COVID-19 vaccination. No Medical History information was reported. On 27-Sep-2021, the patient received second dose of mRNA-1273 (COVID 19 Vaccine Moderna) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (COVID 19 Vaccine Moderna) (Intramuscular) 1 dosage form. On 29-Sep-2021, after starting mRNA-1273 (COVID 19 Vaccine Moderna), the patient experienced MYOCARDITIS (Acute myocarditis) (seriousness criteria hospitalization and medically significant). On 06-Oct-2021, MYOCARDITIS (Acute myocarditis) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 29-Sep-2021, Alanine aminotransferase: 56 enzyme unit per litre 56. On 29-Sep-2021, Aspartate aminotransferase: 88 enzyme unit per litre 88. On 29-Sep-2021, Blood creatine phosphokinase: 770 Test Result:770. On 29-Sep-2021, Blood lactate dehydrogenase: 246 enzyme unit per litre 246. On 29-Sep-2021, Brain natriuretic peptide: 20.6 picogram per millilitre 20.6.	18 years old male with unknown medical history who 2 days after the 2nd dose experienced have elevated troponin, CRP, abnormal ECG, SARS-ColoV-2 negative, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and ECH results; a causal relationship cannot be excluded due to the lack of other information.

Case ID	WW Identifier	Narrative	MAH Comment
		On 29-Sep-2021, C-reactive protein increased: 1.17 milligram per decilitre 1.17. On 29-Sep-2021, Echocardiogram: preserved ef, no asynergy, no valvular disease, an Echocardiography showed preserved EF, no asynergy, no valvular disease, and no pericardial and pleural effusion. On 29-Sep-2021, Electrocardiogram: st elevation in v2-6 Electrocardiogram showed ST elevation in V2-6.. On 29-Sep-2021, Polymerase chain reaction: negative (Negative) PCR test for SARS-CoV-2 was negative.. On 29-Sep-2021, Troponin: 10.2922 milliliter 10.2922. On 29-Sep-2021, White blood cell count: 6200 u/l U/L Test Result: 6,200 U/L. On 30-Sep-2021, Blood creatine phosphokinase: 988 Test Result:988 (CK-MB 84.2). For mRNA-1273 (COVID 19 Vaccine Moderna) (Intramuscular), the reporter considered MYOCARDITIS (Acute myocarditis) to be possibly related. This case refers to a 18-year-old male patient with no known medical history who experienced the expected event of Myocarditis approximately 1 day after the second dose of Moderna COVID-19 Vaccine. Rechallenge was assessed as not applicable. The event was considered related to the vaccine per the reporter's assessment. The benefit-risk relationship of Moderna COVID-19 Vaccine is not affected by this report.	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 14-Oct-2021 and was forwarded to Moderna on 14-Oct-2021. This regulatory authority prospective pregnancy case was reported by a physician and describes the occurrence of MYOCARDITIS (Myocarditis) and MATERNAL	

Case ID	WW Identifier	Narrative	MAH Comment
		EXPOSURE DURING PREGNANCY (Maternal exposure during pregnancy) in a 29-year-old female patient who received mRNA-1273 (Spikevax) (batch nos. 3004955 and 214001) for COVID-19 vaccination. The patient's past medical history included Myocarditis in 2018. On 15-Jul-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 31-Aug-2021, received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. Last menstrual period and estimated date of delivery were not provided. On 01-Oct-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization prolonged and medically significant). On an unknown date, the patient experienced MATERNAL EXPOSURE DURING PREGNANCY (Maternal exposure during pregnancy) (seriousness criterion hospitalization prolonged). The patient was hospitalized on 01-Oct-2021 due to MYOCARDITIS. At the time of the report, MYOCARDITIS (Myocarditis) and MATERNAL EXPOSURE DURING PREGNANCY (Maternal exposure during pregnancy) was resolving. 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) (Unknown), the reporter did not provide any causality assessments. No concomitant and treatment medication were provided Gestation period when reaction/event was observed in the fetus was 15 weeks	

Case ID	WW Identifier	Narrative	MAH Comment
		This case concerns a 29 year old female patient, with medical history of myocarditis 3 years ago, who experienced serious expected event of myocarditis and unexpected event of maternal exposure during pregnancy. The patient received the second dose of vaccine at 11 weeks of gestation. The event myocarditis occurred at 15 weeks of gestation (1 month after second dose of mRNA-1273). The re-challenge is not applicable since no information is available. Patient´s past medical history of myocarditis remains a confounder. The benefit-risk relationship of Spikevax in not affected by this report. Events seriousness captured as per Regulatory Authority assessment in the Source Document. Most recent FOLLOW-UP information incorporated above includes: On 14-Oct-2021: Translation document received on 15-Oct-2021 include NNI On 15-Oct-2021: Follow up received on 15-Oct-2021 it contains no new information	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 14-Oct-2021 and was forwarded to Moderna on 14-Oct-2021. This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myocarditis) in a 33-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3004217) for Prophylactic vaccination. No Medical History information was reported. On 12-Jul-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 23-Aug-2021, received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. On 24-Aug-2021, the patient experienced	

Case ID	WW Identifier	Narrative	MAH Comment
		MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization, medically significant and life threatening). At the time of the report, MYOCARDITIS (Myocarditis) outcome was unknown. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. There is an Inappropriate schedule of vaccine administered as the gap between the doses was 42 days. No concomitant medications reported by reporter. No treatment medications provided by the reporter. Company comment: This case concerns a 33 year old male with no reported history who experienced the serious, listed event of Myocarditis the day after the second dose of Spikevax. Re-challenge is not applicable as this was dose 2. Benefit-risk relationship of Spikevax is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 14-Oct-2021: Translation received on 18-OCT-2021: Contains No new information.	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 14-Oct-2021 and was forwarded to Moderna on 14-Oct-2021. This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myocarditis) in a 34-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3005238) for COVID-19 vaccination. No Medical History information was reported.	

Case ID	WW Identifier	Narrative	MAH Comment
		On 23-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 30-Sep-2021, after starting mRNA-1273 (Spikevax), the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Myocarditis) was resolving. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. Concomitant product use was not provided by the reporter. Treatment information was not provided. Company comment: This case concerns a 34-year-old, male patient with no relevant medical history, who experienced the expected serious event of Myocarditis. The event occurred approximately 08 days after the second dose of Spikevax. The rechallenge was not applicable. The event is consistent with the current understanding of the mechanism of action of the vaccine. The benefit-risk relationship of Spikevax is not affected by this report. Event term, onset date, outcome and seriousness captured per SD from Regulatory Authority reporting. Most recent FOLLOW-UP information incorporated above includes: On 14-Oct-2021: Translation document received on 16-OCT-2021, contains translated event verbatim, and product dose information.	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 14-Oct-2021 and was forwarded to Moderna on 14-Oct-2021. This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Perimyocarditis), CHEST PAIN (Chest discomfort after	29 years old male with unknown medical history who same day after the 2nd dose experienced chest pain and malaise and was found to have elevated troponin and CRP, ECG abnormal, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as

Case ID	WW Identifier	Narrative	MAH Comment
		the 2nd vaccination) and MALAISE (Malaise after the 2nd vaccination) in a 29-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 3004954 and 3004954) for COVID-19 immunisation. No Medical History information was reported. On 23-Aug-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 20-Sep-2021, received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to 1 dosage form. On 20-Sep-2021, the patient experienced MYOCARDITIS (Perimyocarditis) (seriousness criteria hospitalization and medically significant), CHEST PAIN (Chest discomfort after the 2nd vaccination) (seriousness criterion hospitalization) and MALAISE (Malaise after the 2nd vaccination) (seriousness criterion hospitalization). At the time of the report, MYOCARDITIS (Perimyocarditis) had not resolved and CHEST PAIN (Chest discomfort after the 2nd vaccination) and MALAISE (Malaise after the 2nd vaccination) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 23-Sep-2021, C-reactive protein: 18 (abnormal) 18 Unit not specified. On 23-Sep-2021, Electrocardiogram: unknown (abnormal) Compatible with perimyocarditis. On 23-Sep-2021, Troponin T: 243-465 (High) Increasing, unit not specified. On 23-Sep-2021, White blood cell count: 5.8 (abnormal) 5.8 Unit not specified. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medication provided.	any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and ECG results; a causal relationship cannot be excluded due to the lack of other information.

Case ID	WW Identifier	Narrative	MAH Comment
		No treatment information mentioned. Company comment: This case concerns a 29-year-old, male patient with no relevant medical history, who experienced the serious unexpected events of Chest pain and Malaise and the serious expected (AESI) of Myocarditis. The events occurred on the same day after the 2nd dose of mRNA-1273. Relevant labs like ECG result was suggestive of perimyocarditis, other lab results include an increase in Troponin T, abnormal C-reactive protein, and an abnormal leukocyte count. The rechallenge was not applicable since the event occurred after the second dose. The benefit-risk relationship of mRNA-1273 is not affected by this report. Event seriousness assessed as per Regulatory Authority reporting and retained for consistency with the RA report.	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b) on 14-Oct-2021 and was forwarded to Moderna on 14-Oct-2021. This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (acute myocarditis) in a 37-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. Concurrent medical conditions included Ulcer peptic, Alcohol use (1 glass per week), 4.1(b) use (1 4.1(b)/3 days), Tabaquism (3 cigarettes per day) and Obesity (BMI = 30.5). Concomitant products included ESOMEPRAZOLE for an unknown indication. On 24-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 25-Sep-2021, the patient experienced MYOCARDITIS (acute myocarditis) (seriousness criteria hospitalization and medically	

Case ID	WW Identifier	Narrative	MAH Comment
		significant). At the time of the report, MYOCARDITIS (acute myocarditis) was resolving. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No treatment medication was provided. The patient received vaccine on unknown deltoid. Company Comment: This case concerns a 37-year-old, male patient with relevant medical history of Alcohol use, 4.1(b) use, Tabaquism and Obesity, who experienced the unexpected AESI event of Myocarditis. The event occurred approximately 1 day after the second dose of Spikevax, which resulted in an outcome of Hospitalization. The rechallenge was unknown since no information about the events of the first dose was disclosed. The patient's medical history of Alcohol use, 4.1(b) use, Tabaquism and Obesity remain as confounders for the occurrence of the event. The benefit-risk relationship of Moderna CoviD-19 Vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 14-Oct-2021: Translated document received on 18-Oct-2021 included suspect product route of administration updated and relevant medical history, concurrent conditions related and comments updated.	
4.1(b)	4.1(b)	This case was received via 4.1(b) Pharmaceuticals (Reference number: 4.1(b)) on 08-Oct-2021 and was forwarded to Moderna on 14-Oct-2021. This case, initially reported to the 4.1(b) by a pharmacist, was received via the 4.1(b) (Ref, 4.1(b)	18 years old male with unknown medical history who dveloped fever the same day after the 2nd dose of the vaccine and 3 days later experienced chest pain and was found to have abnormal ECG. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to

Case ID	WW Identifier	Narrative	MAH Comment
		On an unknown date, the patient received the 1st dose of this vaccine. On 28-Sep-2021, the patient received the 2nd dose of this vaccine. Only on the same day, the patient had low-grade fever. On 01-Oct-2021, at 06:30, myocarditis developed. The patient felt pressure in the precordium after waking up. Because the symptoms persisted for about 1 hour and a half, the patient visited a medical institution. The symptoms had disappeared by the time the patient left home. The negative T wave of V1 was noted in the electrocardiogram. The patient had no medical or medication history and had no problems with other collagen diseases. The patient was hospitalized. On 05-Oct-2021, the symptoms were resolving, and the patient was discharged from the hospital. The outcome of low-grade fever was reported as recovered. The outcome of myocarditis was reported as resolving. Follow-up investigation will be made. Company Comment: The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the ECG results; a causal relationship cannot be excluded due to the lack of other information.
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 14-Oct-2021 and was forwarded to Moderna on 14-Oct-2021. This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myocarditis) in an 18-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination.	

Case ID	WW Identifier	Narrative	MAH Comment
		Concurrent medical conditions included Strength training with creatine supplementation. On 31-Aug-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 01-Sep-2021, after starting mRNA-1273 (Spikevax), the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Myocarditis) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 04-Sep-2021, SARS-CoV-2 test: negative (Negative) Negative. For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered MYOCARDITIS (Myocarditis) to be possibly related. No concomitant medication was reported. Treatment medication was not provided by the reporter. Patient was under strength training with creatine supplementation. Company Comment: This case concerns an 18-year-old, male patient with no relevant medical history, who experienced the expected serious event of myocarditis. The event, which resulted in hospitalization, occurred 1 day after administration of the second dose of the Moderna COVID-19 Vaccine. The rechallenge was not applicable as no additional dosing will be given. The benefit-risk relationship of the Moderna COVID-19 Vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 14-Oct-2021: Translation document was received on 15-Oct-	

Case ID	WW Identifier	Narrative	MAH Comment
		2021 which contains text for relevant medical history and concurrent conditions was translated.	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 14-Oct-2021 and was forwarded to Moderna on 14-Oct-2021. This regulatory authority case was reported by a physician and describes the occurrence of PERICARDITIS 4.1(b)) in a 25-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3003604) for COVID-19 vaccination. Previously administered products included for Vaccination: Spikevax. On 27-Aug-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 29-Sep-2021, the patient experienced PERICARDITIS (4.1(b)) (seriousness criteria hospitalization and medically significant). At the time of the report, PERICARDITIS (4.1(b)) was resolving. For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered PERICARDITIS (4.1(b)) to be possibly related. No relevant concomitant and treatment medications were reported. Company Comment: This case concerns a 25-year-old male patient with no reported medical history, who experienced the expected event of pericarditis. The event occurred I month 2 days after the second dose of mRNA-1273 (Spikevax). The rechallenge was unknown as no details about the first dose was disclosed. Causality for the reported event was assessed as related by the reporter. Pericarditis 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 assessed as medically significant per regulatory authority reporting. Pericarditis is an adverse event of special interest. Most recent FOLLOW-UP information incorporated above includes: On 14-Oct-2021: Translation of follow up document received on 18-OCT-2021, which contains no new information On 22-Oct-2021: Non-significant follow up	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 14-Oct-2021 and was forwarded to Moderna on 14-Oct-2021. This regulatory authority case was reported by a consumer and describes the occurrence of PERICARDITIS (Pericarditis), CHEST PAIN (Chest pains) and HOSPITALISATION (hospitalised) in a 25-year-old female patient who	

Case ID	WW Identifier	Narrative	MAH Comment
		received mRNA-1273 (Spikevax) for Vaccination. Concurrent medical conditions included Abstains from alcohol and Non-smoker. Concomitant products included DROSPIRENONE, ETHINYLESTRADIOL (YASMIN) for Contraception. On 01-Sep-2021 at 12:00 PM, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 03-Sep-2021, the patient experienced PERICARDITIS (Pericarditis) (seriousness criteria hospitalization, medically significant and life threatening) and CHEST PAIN (Chest pains) (seriousness criteria hospitalization and medically significant). On an unknown date, the patient experienced HOSPITALISATION (hospitalised) (seriousness criterion hospitalization). At the time of the report, PERICARDITIS (Pericarditis) was resolving and CHEST PAIN (Chest pains) and HOSPITALISATION (hospitalised) outcome was unknown. No treatment medication details was reported. On 03 Sep 2021, the patient developed acute chest pain. She was hosptalised with acute pericarditis. Company comment: This case concerns a 25 year-old female patient with a reported medical history of non-tobacco, non-alcohol use, on drospirenone and ethinyl lestradiol who experienced the unexpected serious events of pericarditis, which is an AESI, chest pain and hospitalization. The events occurred approximately 2 days after the second dose of mRNA-1273 (Spikevax). The rechallenge was not applicable as no additional dosing will be administered. The benefit-risk	

Case ID	WW Identifier	Narrative	MAH Comment
		relationship of mRNA-1273 (Spikevax) is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 14-Oct-2021: Translation document received on 18 Oct 2021 and event verbatims was translated.	
4.1(b)	4.1(b)	This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myocarditis) in a 31-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination. No Medical History information was reported. On 23-Aug-2021, the patient received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 200 microgram. On 27-Aug-2021, after starting mRNA-1273 (COVID-19 Vaccine Moderna), the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). On 31-Aug-2021, MYOCARDITIS (Myocarditis) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 28-Aug-2021, Blood creatine phosphokinase: 297 u/ml (High) 297 U/ml. On 28-Aug-2021, Troponin: 581 ng/l (High) 581 ng/l. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered MYOCARDITIS (Myocarditis) to be possibly related. Concomitant product use was not provided by reporter. Treatment information was not provided.	

Case ID	WW Identifier	Narrative	MAH Comment
		Company comment: This case concerns a 31-year-old, male patient, with no disclosed medical history, who experienced the serious, expected, AESI event of Myocarditis. The events occurred 4 days after second dose of Moderna vaccine. The event was considered related to the product per the reporter's assessment. The rechallenge is not applicable as a third dose is not expected. The benefit-risk relationship of Moderna vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 14-Oct-2021: Translated document received on 18-Oct-2021 included Updated Event Verbatim, Updated lab data from initial version.	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 15-Oct-2021 and was forwarded to Moderna on 15-Oct-2021. This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myopericarditis) in a 23-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 214020 and 214010) for COVID-19 vaccination. No Medical History information was reported. On 18-Jul-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 15-Aug-2021, received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. On 17-Aug-2021, the patient experienced MYOCARDITIS (Myopericarditis) (seriousness criterion medically significant). At the time of the report, MYOCARDITIS (Myopericarditis) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):	

Case ID	WW Identifier	Narrative	MAH Comment
		On 18-Aug-2021, Troponin T (0-14): 160 pg/ml (High) 160 pg/ml. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. Concomitant product use was not provided by the reporter. Treatment information was not provided. Most recent FOLLOW-UP information incorporated above includes: On 15-Oct-2021: Translation received on 18 Oct 2021 included: Event as reported by primary source has changed, dosage text updated.	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) 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 MYOCARDITIS (I had the second dose of the Moderna vaccine on 22-Jun-2021 and 3 4 days I started having symptoms (final diagnosis, acute perimyocarditis). Admitted to hospital for 1 month) in a 37-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 214003) for COVID-19 immunization. No Medical History information was reported. On 22-Jun-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form in total. On 26-Jun-2021, after starting mRNA-1273 (Spikevax), the patient experienced MYOCARDITIS (I had the second dose of the Moderna vaccine on 22-Jun-2021 and 3 4 days I started having symptoms (final diagnosis, acute perimyocarditis). Admitted to hospital for 1 month) (seriousness criteria hospitalization and medically significant). At the time of the report,	

Case ID	WW Identifier	Narrative	MAH Comment
		MYOCARDITIS (I had the second dose of the Moderna vaccine on 22-Jun-2021 and 3 4 days I started having symptoms (final diagnosis, acute perimyocarditis). Admitted to hospital for 1 month) had not resolved. Concomitant product use was not provided by the reporter. Treatment medication was not provided by the reporter. Before the second dose the patient was in good health, and was sporty and used to play basketball. This case concerns a 37-year-old male patient with no relevant medical history, who experienced the expected serious AESI event of Myocarditis. The event occurred approximately 5 days after the second dose of Spikevax administration. The rechallenge was not applicable since no events were reported after the first dose and no additional dosing was expected. The benefit-risk relationship is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 15-Oct-2021: Translation received on 18-Oct-2021, included significant information (Event verbatim translated). On 29-Oct-2021: follow up received on 29-OCT-2021 contains no new information	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) 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 MYOCARDITIS (Pressure on the chest, increased inspiratory, perimyocarditis) in an 18-year-old male patient who received mRNA-	

Case ID	WW Identifier	Narrative	MAH Comment
		1273 (Spikevax) for Prophylactic vaccination. No Medical History information was reported. On 23-Aug-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 26-Aug-2021, the patient experienced MYOCARDITIS (Pressure on the chest, increased inspiratory, perimyocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Pressure on the chest, increased inspiratory, perimyocarditis) was resolving. Concomitant medication information was not provided by the reporter. Treatment information was not provided by the reporter. Patient has allergies to Strawberry or Apple. It was reported that inpatient admission to the hospital, as part of the diagnostics (TTE / laboratory / MR) then evidence of peri myocarditis. Most recent FOLLOW-UP information incorporated above includes: On 15-Oct-2021: Translation received on 19-Oct-2021 contains Significant Information. Reaction/event as reported by primary source is updated. Sender's comments is updated.	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 15-Oct-2021 and was forwarded to Moderna on 15-Oct-2021.	

Case ID	WW Identifier	Narrative	MAH Comment
		This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myopericarditis) in an 18-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. No Medical History information was reported. On 23-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 25-Sep-2021, the patient experienced MYOCARDITIS (Myopericarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Myopericarditis) was resolving. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. No concomitant medications was reported. No treatment information was provided. Company Comment: This case concerns an 18-year-old male patient with no relevant medical history who experienced serious expected event of Myocarditis. The event occurred two days after the patient had received the second dose of Spikevax. Except that the event was resolving at the time of the report, no further information was provided regarding the clinical course of the event. The rechallenge is not applicable as the event occurred after the second dose of Spikevax. The benefit-risk relationship of Spikevax is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 15-Oct-2021: Translation received on 20-OCT-2021 included Event verbatim translated.	

Case ID	WW Identifier	Narrative	MAH Comment
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 15-Oct-2021 and was forwarded to Moderna on 15-Oct-2021. This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Perimyocarditis) in a 33-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 3004730 and 3004959) for COVID-19 immunisation. No Medical History information was reported. On 21-Aug-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 02-Oct-2021, received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to 1 dosage form. On 04-Oct-2021, after starting mRNA-1273 (Spikevax), the patient experienced MYOCARDITIS (Perimyocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Perimyocarditis) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In October 2021, Ejection fraction: low (Low) Decreased LVEF. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. On OCT-2021 patient went through Blood test and Echocardiography with unknown results No relevant concomitant and treatment medications were reported Company Comment: This authority report concerns a 33 year old male patient with no relevant medical history who experienced a serious expected event of peri myocarditis.	

Case ID	WW Identifier	Narrative	MAH Comment
		The event occurred 2 days after the second dose and nearly 1.5 months after the first dose of mRNA-1273 respectively. The patient was administered second dose 42 days (which is more than the 25-35 days window period) after the first dose of mRNA-1273. Hence, an additional non-serious event of inappropriate schedule of vaccine administration was considered. As per the report, the patient was hospitalized for the event and was noted to have decreased left ventricular ejection fraction. The report also states that blood tests and echocardiography were performed but the results were not provided. Re-challenge is not applicable as the event happened after the second dose and no additional dosing will be given. The patient had not recovered from the event at the time of the report. The benefit-risk relationship of mRNA-1273 is not affected by this report.	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 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 CARDIAC DISORDER (HEART INFLAMMATION) and PERICARDITIS (INFLAMMATION OF THE PERICARDIUM) in a 21-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 3005242 and 3003659) for COVID-19 vaccination. The patient's past medical history included Adverse reaction to antibiotics. Concurrent medical conditions included Taste loss, COVID-19 since 30-Dec-2020, Intestinal inflammation, Smell loss and General physical condition decreased. On 07-Jul-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form.	

Case ID	WW Identifier	Narrative	MAH Comment
		On 29-Aug-2021, received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. On 15-Sep-2021, the patient experienced CARDIAC DISORDER (HEART INFLAMMATION) (seriousness criteria hospitalization, disability and life threatening) and PERICARDITIS (INFLAMMATION OF THE PERICARDIUM) (seriousness criteria hospitalization, disability, medically significant and life threatening). At the time of the report, CARDIAC DISORDER (HEART INFLAMMATION) and PERICARDITIS (INFLAMMATION OF THE PERICARDIUM) was resolving. Concomitant product use was not provided by reporter. Treatment information was not provided. Most recent FOLLOW-UP information incorporated above includes: On 15-Oct-2021: Translated document received on 18-Oct-2021, included Dose information (Dosage text) translated and event verbatim translated.	
4.1(b)	4.1(b)	This case was received via 4.1(b) Pharmaceuticals (Reference number: 4.1(b)) on 08-Oct-2021 and was forwarded to Moderna on 15-Oct-2021. This case, initially reported to the 4.1(b) by a (physician), was received via the 4.1(b) (Ref, 4.1(b) On 03-Sep-2021, the patient received the 1st dose of the vaccine. On an unknown date, body temperature before the vaccination: 36.4 degrees Celsius.	18 years old male with unknown medical history who developed pyrexia the same day after receiving the 2nd dose of Spikevax and 3 days later experienced chest pain and was found to have elevated troponin, CK, and CKMB, ECG abnormal, and was diagnosed with myopericarditis. Patient had a myocardial biopsy doen that showed mild lymphocyte inflitration. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and

Case ID	WW Identifier	Narrative	MAH Comment
		On 01-Oct-2021, at 15:00, the patient received the 2nd dose of the vaccine. At night, pyrexia developed. On 02-Oct-2021, fever subsided. On 03-Oct-2021, the patient had chest pain. On 04-Oct-2021, the symptom was aggravated, and the patient was emergently transported to hospital. There were elevated cardiac enzymes as troponin T was positive (1.300 ng/mL) with CK of 762 U/L and CKMB of 72 U/L. Diffuse hypokinesis in the wall was shown by echocardiography (left ventricular ejection fraction: 46%). The patient was diagnosed with perimyocarditis and was hospitalized. Steroid pulse therapy was started on the same day. On 05-Oct-2021, mild lymphocyte infiltration was found by myocardial biopsy, which led to definitive diagnosis of myocarditis. On 07-Oct-2021, steroid therapy was effective, and CK/CKMB were normalized with a decrease in troponin T to 0.551 ng/mL. The general condition of the patient was stable, and relief of the symptom was confirmed. The patient was to be discharged from the hospital after troponin T was normalized, and an ambulant follow was scheduled. The outcome of pyrexia and perimyocarditis was reported as resolving. Follow-up investigation will be made. Reporter comments continuation: In addition, considering the favorable response to steroid therapy (steroid therapy is less effective in viral myocarditis), the event was likely to be caused by administration of this vaccine. As other contributing factors, viral myocarditis should be distinguished, but administration of	the start of the events, as well as all the other well documented information; a causal relationship cannot be excluded due to the lack of other information.

Case ID	WW Identifier	Narrative	MAH Comment
		this vaccine is considered as highly possible cause of the event based on the timing of onset. Company Comment: The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b) on 15-Oct-2021 and was forwarded to Moderna on 15-Oct-2021. This regulatory authority case was reported by a consumer and describes the occurrence of COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine), CONCOMITANT DISEASE AGGRAVATED (Concomitant disease aggravated), CHEST DISCOMFORT (Chest pressure) and PERICARDITIS (Pericarditis) in a 39-year-old male patient who received mRNA-1273 (Spikevax) for Vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Emergency care examination (No findings.), Chest pressure on 12-Jul-2021 and Chest discomfort on 12-Jul-2021. Previously administered products included for Vaccination: COMIRNATY. On 13-Aug-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 23-Sep-2021, the patient experienced PERICARDITIS (Pericarditis) (seriousness criterion medically significant). On an unknown date, the patient experienced COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine) (seriousness criterion medically significant), CONCOMITANT	39 years old male with medical history of chest discomfort and chest pressure a month before receiving the 2nd dose of Spikevax and his first dose was Cominarty who 41 days after the 2nd dose aggravation of his chest discomfort, and dizziness, and was admitted and found to have abnormal ultrasound scan and normal Echo. He was diagnosed with Pericarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted. This case is heavily confounded by the use of Cominarty as the 1st dose. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and Echo results; a causal relationship cannot be excluded due to the lack of other information.

Case ID	WW Identifier	Narrative	MAH Comment
		DISEASE AGGRAVATED (Concomitant disease aggravated) (seriousness criterion medically significant), CHEST DISCOMFORT (Chest pressure) (seriousness criterion medically significant) and DIZZINESS (Dizziness). At the time of the report, COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine), CONCOMITANT DISEASE AGGRAVATED (Concomitant disease aggravated) and DIZZINESS (Dizziness) outcome was unknown and CHEST DISCOMFORT (Chest pressure) and PERICARDITIS (Pericarditis) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In September 2021, Emergency care examination: normal (normal) Normal No findings. On 23-Sep-2021, Ultrasound scan: abnormal (abnormal) Abnormal Diagnosed with PERICARDITIS.. On an unknown date, Electrocardiogram: normal (normal) Normal No findings. No concomitant medication was reported. No treatment medication was reported. Company Comment: This is a case of revaccination with different Covid -19 vaccine for this 39-year-old, male patient with relevant medical history of chest pressure and chest discomfort and relevant vaccine history of receiving other brand of Covid 19 vaccine (Comirnaty), who experienced the unexpected events of concomitant disease aggravated and chest discomfort and expected event of pericarditis. The event pericarditis occurred 42 days after a dose of mRNA-1273 vaccine administration while the occurrence of the events concomitant disease aggravated and chest discomfort exact occurrence	

Case ID	WW Identifier	Narrative	MAH Comment
		unknown but stated that the events occurred after the administration of mRNA-1273 vaccine administration. The rechallenge is not applicable because the patient received other brand of Covid-19 vaccine (Comirnaty), prior to receiving mRNA-1273 vaccine. The medical history of chest pressure and chest discomfort and vaccine history of receiving other brand of Covid 19 vaccine (Comirnaty) remains confounders. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. This case was linked to 4.1(b) [redacted] E2B Linked Report). Most recent FOLLOW-UP information incorporated above includes: On 15-Oct-2021: Translation document received on 19-OCT-2021 contains no new information.	
4.1(b) [redacted]	4.1(b) [redacted]	This case was received via 4.1(b) Pharmaceuticals (Reference number: 4.1(b) [redacted] on 09-Oct-2021 and was forwarded to Moderna on 15-Oct-2021. This case, initially reported to the 4.1(b) [redacted] by a (physician), was received via the 4.1(b) (Ref, 4.1(b) [redacted] Acute pericarditis was assessed as serious by the MAH. On an unknown date, the patient received the 1st dose of this vaccine. On 18-Sep-2021, the patient received the 2nd dose of this vaccine. On 19-Sep-2021, at 12:00, symptoms of respiratory discomfort and chest pain were noted. On 20-Sep-2021, the patient visited the reporting hospital. Although no elevation of cardiac enzymes was noted, ST decreased in 2, 3, aVF, and V2-5 leads was found. The physician made the diagnosis of acute pericarditis based on symptoms and examination findings. On 30-Sep-2021, symptoms were confirmed to be improving. The outcome of acute pericarditis was reported as resolving. Follow-up investigation will be made. Company Comment: The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	
4.1(b) [redacted]	4.1(b) [redacted]	This case was received via 4.1(b) Pharmaceuticals (Reference number: 4.1(b) [redacted] on 09-Oct-2021 and was forwarded to Moderna on 15-Oct-2021.	

Case ID	WW Identifier	Narrative	MAH Comment
		This case, initially reported to the 4.1(b) by a nurse, was received via the 4.1(b) (Ref, 4.1(b) On 31-Aug-2021, the patient received the 1st dose of the vaccine. On an unknown date, body temperature before the vaccination: 36.4 degrees Celsius. On 28-Sep-2021, at 16:30, the patient received the 2nd dose of the vaccine. On 29-Sep-2021, at 18:00, median chest discomfort persisted intermittently from the early evening. On 01-Oct-2021, around 05:30, the patient woke up with intense median chest discomfort. The symptom persisted for slightly less than 10 minutes, and thus the patient visited a hospital. As the symptom had been alleviated when an electrocardiography was performed, no change was showed in the electrocardiographic waveform. However, elevated cardiac enzymes were found in a blood test. The patient was transported to a medical institution. Elevated cardiac enzymes and ST elevation in aVL and V4-6 in electrocardiogram were revealed. The patient was hospitalized with a diagnosis of myopericarditis. On 08-Oct-2021, improvements in cardiac enzymes and ST waveform in electrocardiogram were shown. No problems were found in the results of cardiac MRI and echocardiography, and resolution of the symptom was confirmed. The patient was discharged from the hospital. The outcome of chest discomfort and myopericarditis was reported as resolving. Follow-up investigation will be made. Company Comment: The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b) on 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 ASTHENIA (Weakness), CHEST PAIN (Chest pain), GAIT DISTURBANCE (Difficulty in walking), PERIPHERAL COLDNESS (Ice cold feet), PALPITATIONS (Strong heart pounding), CHILLS (Chills), PYREXIA (Fever), NAUSEA (Nausea) and MYOCARDITIS (Heart muscle inflammation) in a 34-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3005697) for COVID-19 vaccination. Concurrent medical conditions included Asthma.	

Case ID	WW Identifier	Narrative	MAH Comment
		On 27-Aug-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 27-Aug-2021, the patient experienced PERIPHERAL COLDNESS (Ice cold feet) (seriousness criterion life threatening), CHILLS (Chills) (seriousness criterion life threatening) and PYREXIA (Fever) (seriousness criterion life threatening). On 28-Aug-2021, the patient experienced ASTHENIA (Weakness) (seriousness criterion life threatening), CHEST PAIN (Chest pain) (seriousness criterion life threatening), GAIT DISTURBANCE (Difficulty in walking) (seriousness criterion life threatening), PALPITATIONS (Strong heart pounding) (seriousness criterion life threatening), NAUSEA (Nausea) (seriousness criterion life threatening) and MYOCARDITIS (Heart muscle inflammation) (seriousness criteria medically significant and life threatening). On 28-Aug-2021, PERIPHERAL COLDNESS (Ice cold feet), CHILLS (Chills), PYREXIA (Fever) and NAUSEA (Nausea) had resolved. On 29-Aug-2021, ASTHENIA (Weakness), CHEST PAIN (Chest pain), GAIT DISTURBANCE (Difficulty in walking), PALPITATIONS (Strong heart pounding) and MYOCARDITIS (Heart muscle inflammation) had resolved. Concomitant product use was not provided by the reporter. Treatment information was not provided. Company comment: This case concerns a 34-year-old, male patient with no relevant medical history, who experienced the serious unexpected events of Asthenia, Chest pain, Gait disturbance, Peripheral coldness,	

Case ID	WW Identifier	Narrative	MAH Comment
		Palpitations, Chills, Pyrexia and Nausea and serious expected AESI of Myocarditis. The events of Peripheral coldness, Chills and pyrexia occurred on the same day after the second dose of mRNA-1273, while the events of Asthenia, Chest pain, Gait disturbance, Palpitations, Nausea and Myocarditis occurred one day after the second dose of mRNA-1273. The rechallenge is not applicable as the event occurred after the second dose. The benefit-risk relationship of mRNA-1273 is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 15-Oct-2021: Translated document received on 18-Oct-2021, included translated event verbatim and updated the dose number	
4.1(b)	4.1(b)	This regulatory authority case was reported by a physician and describes the occurrence of PERICARDITIS (Pericarditis) in a 25-year-old female patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination. Concurrent medical conditions included Endometriosis, Asthma (bronchial asthma) and Hypothyroidism. On 11-Aug-2021, the patient received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form. On 12-Aug-2021, after starting mRNA-1273 (COVID-19 Vaccine Moderna), the patient experienced PERICARDITIS (Pericarditis) (seriousness criteria hospitalization and medically significant). The patient was hospitalized from 13-Aug-2021 to 14-Aug-2021 due to PERICARDITIS. At the time of the report, PERICARDITIS (Pericarditis) had not resolved.	

Case ID	WW Identifier	Narrative	MAH Comment
		DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Electrocardiogram: typical ecg changes (abnormal) Typical ECG changes. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered PERICARDITIS (Pericarditis) to be possibly related. Concomitant medications were not provided. No Treatment Information was provided. Lab data included Elevated inflammatory parameters. Company comment -This case concerns a 25 year old female with no relevant history who experienced the serious, listed AESI of Pericarditis the day after the second dose of mRNA-1273. Re-challenge is not applicable as this was dose 2 and the event is not reported for dose 1. Benefit-risk relationship of mRNA-1273 is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 15-Oct-2021: Translation recived on 18-Oct-21- Age of the patient was updated. Medical history was added, Laboratory tests added in the I-narrative, Sender's comment, Reporter's comments added. Event verbatim term translated and hospitalization dates were updated. Dosing details of the vaccine was updated.	
4.1(b)	4.1(b)	This regulatory authority case was reported by a physician and describes the occurrence of PERICARDITIS (Pericarditis) in a 33-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for SARS-CoV-2 immunisation. No Medical History information was reported. On 02-Aug-2021, the patient received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form. On *02-Aug-2021, after*	

Case ID	WW Identifier	Narrative	MAH Comment
		starting mRNA-1273 (COVID-19 Vaccine Moderna), the patient experienced PERICARDITIS (Pericarditis) (seriousness criterion medically significant). At the time of the report, PERICARDITIS (Pericarditis) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 08-Aug-2021, Chest X-ray: normal (normal) Non-pathological, no pneumothorax. On 08-Aug-2021, Electrocardiogram: abnormal (abnormal) PR descending in DII, DIII and AVF, no repolarization disorders.. On 08-Aug-2021, Troponin T (Unknown-< 14): < 3 (abnormal) Troponin T- hs < 3 ng/L. On 10-Aug-2021, Echocardiogram: abnormal (abnormal) minimal pericardial effusion. On 10-Aug-2021, Ejection fraction: normal (normal) Normal. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered PERICARDITIS (Pericarditis) to be probably related. Lab tests C-reactive protein, Leucocyte count was done on 8-AUG-2021. The patient had good health, athletic, active smoker. Patient received 1st dose in July 2021, precise date unknown and the 2nd dose of the on Aug 2, 2021. In the night, a few hours after the vaccination, he was woken by a hot-cold sensation and intermittent oppressive chest pain for around 1 hour 30 minutes which decreased with anteflexion of the trunk. From slight unusual dyspnea during intense exercise. The chest pain almost disappeared. In the night of Aug 07, 2021, he was again woken by oppressive chest pain that lasted 2 hours before spontaneously resolving. A sitting position helped alleviate the pain. On Aug 8, 2021, he went to the emergency room with a feeling of very slight tightness in the chest. His vitals are within normal, the ECG shows no pathologies, same for the chest radiography. Troponins are negative (troponin T hs <3 ng/L, normal <14 ng/L). The cardiological status shows that the sounds are normal without murmur or perceived pericardial friction. The patient was in less pain with anteflexion of the trunk. Faced with the typical clinical case, a diagnosed with acute pericarditis, treatment with ibuprofen and dextromethorphan was started the same day. On Aug 10, 2021 during the cardiological exam, he described the disappearance of the retrosternal pains but the persistence of the cough and orthopnea. The transthoracic ultrasound showed a slight pericardial effusion. A regressive treatment of colchicine for 3 months and NSAIDs was introduced. This case refers to a 33-year-old male patient with no known medical history who experienced the expected event of Pericarditis on the same day after receiving the second dose of Moderna COVID-19 Vaccine. Rechallenge was assessed as not applicable. The event was considered related to the vaccine per the reporter's assessment. The benefit-risk relationship of Moderna COVID-19 Vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 15-Oct-2021: Translation received on 19-OCT-2021. Lab data added. Event verbatim updated. Narrative supplement updated.	
4.1(b)	4.1(b)	This case was received via 4.1(b) Pharmaceuticals (Reference number: 4.1(b) on 11-Oct-2021 and was forwarded to Moderna on 18-Oct-2021.	

Case ID	WW Identifier	Narrative	MAH Comment
		This case was reported by a hospital personnel and physician via a medical representative. On an unknown date, the patient received the 1st dose of this vaccination. On 09-Oct-2021, the patient received the 2nd dose of this vaccination. On 10-Oct-2021, the patient had a pyrexia of around 39 degrees Celsius. On 11-Oct-2021, around 12:00, chest pain developed, and the patient was requested an emergency transport, because the patients condition that cannot take a meal continued. The patient was hospitalized with a diagnosis of myocarditis on the same day. The outcome of pyrexia and myocarditis was reported as unknown. Follow-up investigation will be made. Company Comment: The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship..	
4.1(b)	4.1(b)	This case was received via 4.1(b) Pharmaceuticals (Reference number: 4.1(b)) on 11-Oct-2021 and was forwarded to Moderna on 18-Oct-2021. This case, initially reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref 4.1(b) On an unknown date, the patient received the 1st dose of the vaccine. On 05-Oct-2021, the patient received the 2nd dose of the vaccine. On 06-Oct-2021, pyrexia developed. On 07-Oct-2021, at 02:00, chest pain developed, and an emergency call was made. As ST elevation was shown by electrocardiogram and cardiac effusion was showed by CT, the patient was diagnosed with myocarditis. On an unspecified date, the patient was hospitalized. The outcome of pyrexia and myocarditis was unknown. Follow-up investigation will be made.	

Case ID	WW Identifier	Narrative	MAH Comment
		Company Comment: The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	
4.1(b)	4.1(b)	This case was received via 4.1(b) Pharmaceuticals (Reference number: 4.1(b) on 12-Oct-2021 and was forwarded to Moderna on 18-Oct-2021. This case, initially reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref, 4.1(b) Suspected myocarditis was assessed as serious by the MAH. On an unknown date, the patient received the 1st dose of this vaccine. On 03-Oct-2021, the patient received the 2nd dose of this vaccine. The patient had pyrexia of 38.0-38.9 degrees Celsius. On 05-Oct-2021, around 00:00, left precordial pain persisted for 2 hours, and dyspnea also developed. Body temperature was 37 degrees Celsius at this time. On 06-Oct-2021, in the morning, the patient had chest pain and palpitations for 30 minutes. The patient visited the reporting hospital because the patient was suffered from the symptoms. At the time of medical consultation, although the patient had mild precordial pain, but had no pyrexia, and there was no problem in cardiopulmonary physical findings. SpO2 98% and pulse 74/min. Chest X-ray was normal. Elevations in ST, 1, 2, and V2-6 were noted on ECG. Blood test showed elevated levels including GOT 44, GPT 47, CK 362, and CRP 4.7. Myocarditis was suspected. No medication was prescribed. On 07-Oct-2021, subjective symptoms subsided. The symptoms were confirmed to be resolving. The outcome of pyrexia, left precordial pain, dyspnoea, palpitations, and suspected myocarditis was reported as resolving. Follow-up investigation will be made. Company Comment: The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	
4.1(b)	4.1(b)	This case was received via 4.1(b) Pharmaceuticals (Reference number: 4.1(b) on 13-Oct-2021 and was forwarded to Moderna on 18-Oct-2021. This case, initially reported to the 4.1(b) by a (physician), was received via the 4.1(b) (Ref, 4.1(b) On 10-Sep-2021, the patient received the 1st dose of this vaccine. On 08-Oct-2021, the patient received the 2nd dose of this vaccine.	

Case ID	WW Identifier	Narrative	MAH Comment
		On 09-Oct-2021, pyrexia developed. On 10-Oct-2021, around 08:30, Chest pain appeared, and the patient called for emergency medical assistance and was rushed to our hospital. The patient was diagnosed with suspected myocarditis at the emergency department. The outcome of pyrexia, chest pain, suspected myocarditis was unknown. Follow-up investigation will be made. Company Comment: The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	
4.1(b)	4.1(b)	This case was received via 4.1(b) Pharmaceuticals (Reference number: 4.1(b) on 12-Oct-2021 and was forwarded to Moderna on 18-Oct-2021. This case, reported by a physician, was received by 4.1(b) via Moderna's adverse reaction reporting site (4.1(b) and reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref, 4.1(b) Myocarditis was assessed as a serious by the MAH. The patient had a history of pyrexia with Japanese encephalitis vaccination. On 07-Sep-2021, at 16:45, the patient received the 1st dose of this vaccination. On 05-Oct-2021, at 16:45, the patient received the 2nd dose of this vaccination. On 07-Oct-2021, at 09:00, myocarditis developed. Chest pain, dyspnea, and feeling of fatigue were observed. On 11-Oct-2021, the symptoms resolved. The outcome of myocarditis was reported as resolving. Follow-up investigation will be made. Company Comment: The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b) on 18-Oct-2021 and was forwarded to Moderna on 18-Oct-2021. This regulatory authority case was reported by a physician and	

Case ID	WW Identifier	Narrative	MAH Comment
		describes the occurrence of VENTRICULAR EXTRASYSTOLES (Ventricular extrasystoles) and MYOCARDITIS (Acute myocarditis) in a 19-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. No Medical History information was reported. On 06-Jul-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 03-Aug-2021, received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. In July 2021, the patient experienced VENTRICULAR EXTRASYSTOLES (Ventricular extrasystoles) (seriousness criterion medically significant). On 03-Aug-2021, the patient experienced MYOCARDITIS (Acute myocarditis) (seriousness criterion medically significant). At the time of the report, VENTRICULAR EXTRASYSTOLES (Ventricular extrasystoles) and MYOCARDITIS (Acute myocarditis) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 03-Aug-2021, Magnetic resonance imaging heart: abnormal (abnormal) myocarditis. On 12-Aug-2021, Troponin: negative (Negative) negative. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. No concomitant medications provided. No treatment medications provided.	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b) on 18-Oct-2021 and was forwarded to Moderna on 18-Oct-2021. This regulatory authority case was reported by a physician and	

Case ID	WW Identifier	Narrative	MAH Comment
		describes the occurrence of MYOCARDITIS (Perimyocarditis) in a 31-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. No Medical History information was reported. On 06-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 08-Sep-2021, the patient experienced MYOCARDITIS (Perimyocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Perimyocarditis) was resolving. 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 31-year-old, male patient with no medical history reported, who experienced the expected event of myocarditis which required hospitalization. The event occurred approximately 2 days after the second dose of Moderna COVID-19 Vaccine. The rechallenge was not applicable as event occurred after second dose and no further dosing was reported or planned, based on information provided. No information regarding patient's symptoms or diagnostic findings was provided. The benefit-risk relationship of Moderna COVID-19 Vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 18-Oct-2021: Translation document received on 20-Oct-2021 contains event as reported by primary	

Case ID	WW Identifier	Narrative	MAH Comment
		source updated and Dosage text translated.	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 18-Oct-2021 and was forwarded to Moderna on 18-Oct-2021. This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Perimyocarditis) in an 18-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. Concurrent medical conditions included Pollen allergy and Asthma. On 10-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 23-Sep-2021, after starting mRNA-1273 (Spikevax), the patient experienced MYOCARDITIS (Perimyocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Perimyocarditis) was resolving. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. Concomitant medications were not reported. Treatment medications were not reported. Company Comment: This case concerns a 18-year-old, male with no relevant medical history, who experienced the serious, expected and AESI event of myocarditis. The events occurred 13 days after second dose of Spikevax. The rechallenge was not applicable, as no additional dosing will be given. The benefit-risk relationship of Spikevax is not affected by this report.	

Case ID	WW Identifier	Narrative	MAH Comment
		Most recent FOLLOW-UP information incorporated above includes: On 18-Oct-2021: Translation received on 19-OCT-2021 contains: Dose number of vaccination added and Event verbatim updated.	
4.1(b)	4.1(b)	This case was received via 4.1(b) Pharmaceuticals (Reference number: 4.1(b)) on 13-Oct-2021 and was forwarded to Moderna on 18-Oct-2021. This case, initially reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref, 4.1(b) Suspected cardiac failure and myocarditis was assessed as serious by the MAH. On an unknown date, the patient received the 1st dose of this vaccine. On 29-Aug-2021, at 14:00, the patient received the 2nd dose of this vaccine. On 27-Sep-2021, at 07:00, generalized malaise and oedema of the lower limbs developed. Myocarditis was considered to developed. On 30-Sep-2021, the patient visited the reporting hospital. In X-ray, mild bilateral congestion was found. Cardiac failure was suspected. Combined with the echocardiographic findings, viral myocarditis or myocarditis due to this vaccine was considered. On 07-Oct-2021, the course of the symptoms was unknown. The outcome of suspected cardiac failure and myocarditis was unknown. Follow-up investigation will be made. Company Comment: The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	
4.1(b)	4.1(b)	This case was received via 4.1(b) Pharmaceuticals (Reference number: 4.1(b)) on 13-Oct-2021 and was forwarded to Moderna on 18-Oct-2021. This case, initially reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref, 4.1(b) Myocarditis was assessed as serious by the MAH. On an unknown date, the patient received the 1st dose of this vaccine. On an unknown date, body temperature before vaccination: 35.8 degrees Celsius. On 28-Sep-2021, the patient received the 2nd dose of this vaccine.	

Case ID	WW Identifier	Narrative	MAH Comment
		On 01-Oct-2021, in the morning, the patient had left chest pain and visited the hospital. No abnormalities in the chest X-ray, double master stress electrocardiogram, and echocardiography were noted. Blood test showed increases with CRP 2.46, high-sensitivity troponin I 1,938, and CK 446. The patient was diagnosed with myocarditis after vaccination with this vaccine. On 02-Oct-2021, left chest pain showed a tendency of improvement at return visit. On 07-Oct-2021, the patient visited another hospital. On an unknown date, the improvement of symptom was confirmed. The outcome of myocarditis was reported as resolving. Follow-up investigation will be made. Company Comment: The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	
4.1(b)	4.1(b)	This case was received via 4.1(b) Pharmaceuticals (Reference number: 4.1(b)) on 14-Oct-2021 and was forwarded to Moderna on 19-Oct-2021. This case, initially reported to the 4.1(b) by a (physician), was received via the 4.1(b) (Ref, 4.1(b) On an unknown date, the patient received the 1st dose of this vaccine. On an unknown date, body temperature before the vaccination: 36.3 degrees Celsius. On 05-Oct-2021, the patient received the 2nd dose of this vaccine. On 07-Oct-2021, around 19:00, chest pain developed, and the patient visited the reporting hospital. The patient was hospitalized with a diagnosis of acute myocarditis based on extensive ST elevation in electrocardiogram and elevation of cardiac enzymes in blood test. On an unknown date, there was no symptom of cardiac failure, and various examination findings improved. On 13-Oct-2021, the symptoms were resolving, and the patient was discharged from the hospital. The outcome of acute myocarditis was reported as resolving. Follow-up investigation will be made. Company Comment: The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	

Case ID	WW Identifier	Narrative	MAH Comment
4.1(b)	4.1(b)	This case was received via 4.1(b) Pharmaceuticals (Reference number: 4.1(b) on 14-Oct-2021 and was forwarded to Moderna on 19-Oct-2021. This case, initially reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref, 4.1(b) On an unknown date, the patient received the 1st dose of the vaccine. On an unknown date, body temperature before the vaccination: 36.4 degrees Celsius. On 09-Oct-2021, the patient received the 2nd dose of the vaccine. On 10-Oct-2021, pyrexia of 39.0-39.9 degrees Celsius developed. On 11-Oct-2021, around 12:00, pericarditis and myocarditis developed. Chest pain was noted, and thus an emergency call was made. The patient was transported to the reporting hospital. An electrocardiogram showed ST elevations in I, II, aVL, aVF, and V2-6. Echocardiography showed mild encircling hypokinesis. Blood test showed an increase in troponin. The patient was hospitalized with a diagnosis of pericarditis and myocarditis. The outcome of pericarditis and myocarditis was unknown. Follow-up investigation will be made. Company Comment: The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	20 years old male with unknown medical history who developed fever the next day afetr the 2nd dose of the vaccine and the next day experienced chest pain, was admitted was found to have elevated troponin, abnormal Echo and ECG. He was diagnosed with myopericarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and ECG and Echo results; a causal relationship cannot be excluded due to the lack of other information.
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 19-Oct-2021 and was forwarded to Moderna on 19-Oct-2021.	

Case ID	WW Identifier	Narrative	MAH Comment
		This regulatory authority case was reported by a physician and describes the occurrence of PERICARDITIS (Pericarditis, acute inflammatory reaction post-vaccination) and INFLAMMATION (Pericarditis, acute inflammatory reaction post-vaccination) in a 20-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3002545) for SARS-CoV-2 vaccination. No Medical History information was reported. On 26-May-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) .5 milliliter. On 30-Jun-2021, received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to .5 milliliter. On 10-Jul-2021, the patient experienced PERICARDITIS (Pericarditis, acute inflammatory reaction post-vaccination) (seriousness criteria hospitalization and medically significant) and INFLAMMATION (Pericarditis, acute inflammatory reaction post-vaccination) (seriousness criterion hospitalization). At the time of the report, PERICARDITIS (Pericarditis, acute inflammatory reaction post-vaccination) and INFLAMMATION (Pericarditis, acute inflammatory reaction post-vaccination) had resolved. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medications were mentioned. No treatment details were reported. Reported that Intramuscular administration of the second dose, deltoid. time of administration: 01:13 p.m.	

Case ID	WW Identifier	Narrative	MAH Comment
		Company comment: This case concerns a 20-year-old, male patient with no relevant medical history, who experienced the unexpected events of Pericarditis and Acute Inflammatory Reaction post-vaccination. The events occurred approximately 11 days after the second dose of Spikevax. The rechallenge was not applicable since evets occurred after second dose. The benefit-risk relationship of Spikevax is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 19-Oct-2021: Translation received on 21-OCT-2021 contained translated event verbatim term , Reporters comment translated, time and anatomical position of injection has been updated.	
4.1(b) [redacted]	4.1(b) [redacted]	This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 19-Oct-2021 and was forwarded to Moderna on 19-Oct-2021. This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myocarditis) and PERICARDITIS (Pericarditis) in a 23-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 immunisation. The patient's past medical history included Chronic diarrhoea and Ferropenic anaemia. On 19-Aug-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 milliliter. On 27-Sep-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant) and PERICARDITIS (Pericarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Myocarditis) and	

Case ID	WW Identifier	Narrative	MAH Comment
		PERICARDITIS (Pericarditis) was resolving. For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered MYOCARDITIS (Myocarditis) and PERICARDITIS (Pericarditis) to be possibly related. No concomitant medication details was reported. No treatment medication details was reported. Company comment: This case concerns a 23 year old female patient with no relevant medical history reported, who experienced serious expected AESI of myocarditis and pericarditis after second dose of mRNA-1273. The events occurred 40 days after second dose of mRNA-1273. The re-challenge is unknown as the events occurred after second dose and the outcome is recovering at the time of report. The benefit risk relationship of vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 19-Oct-2021: Translation received on 20-OCT-2021 contains significant information that include all event description as reported updated and suspected product dose text updated. On 20-Oct-2021: Follow-up received and added other relevant medical history.	
4.1(b) [redacted]	4.1(b) [redacted]	This case was received via an unknown source (no reference has been entered for a health authority or license partner) on 19-Oct-2021 and was forwarded to Moderna on 19-Oct-2021. This regulatory authority case was reported by a physician and describes the occurrence of CARDIAC FAILURE (Cardiac Insufficiency), MYOCARDITIS (Acute myocarditis) and PERICARDITIS (Pericarditis) in a 22-year-old male patient who received mRNA-1273	

Case ID	WW Identifier	Narrative	MAH Comment
		(Spikevax) (batch no. 3005885) for COVID-19 immunisation. No Medical History information was reported. On 27-Jul-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 ml. On 29-Jul-2021, the patient experienced CARDIAC FAILURE (Cardiac Insufficiency) (seriousness criteria hospitalization and medically significant), MYOCARDITIS (Acute myocarditis) (seriousness criteria hospitalization and medically significant) and PERICARDITIS (Pericarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, CARDIAC FAILURE (Cardiac Insufficiency), MYOCARDITIS (Acute myocarditis) and PERICARDITIS (Pericarditis) was resolving. For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered MYOCARDITIS (Acute myocarditis) to be probably related. No further causality assessments were provided for CARDIAC FAILURE (Cardiac Insufficiency) and PERICARDITIS (Pericarditis). No concomitant medications were reported. Treatment information was not provided. Company Comment: This is a Regulatory case concerning a 22-year-old male patient with no relevant medical history who experienced serious unexpected event of Cardiac failure and serious expected events of Myocarditis and Pericarditis (AESI). The events occurred approximately two days after the second dose of Spikevax. The rechallenge was not applicable as the events occurred following the second dose. Very limited information regarding clinical course of the	

Case ID	WW Identifier	Narrative	MAH Comment
		events 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 19-Oct-2021: Translation document received on 20-Oct-2021, added dose number of vaccine, updated event verbatim and causality of acute myocarditis changed to probable. On 20-Oct-2021: Follow up received contains No-new information.	
4.1(b)	4.1(b)	This case was received via 4.1(b) Pharmaceuticals (Reference number: 4.1(b) on 14-Oct-2021 and was forwarded to Moderna on 20-Oct-2021. This case, initially reported to the 4.1(b) by a (physician), was received via the 4.1(b) (Ref, 4.1(b) On an unknown date, the patient received the 1st dose of this vaccine. On an unknown date, body temperature before the vaccination: 36.6 degrees Celsius. On 11-Oct-2021, at 10:00, the patient received the 2nd dose of this vaccine. Pyrexia of BT 37.5 degrees Celsius developed in the early evening. Since the body temperature rose to 38.3 degrees Celsius, the patient took over-the-counter aspirin. On 12-Oct-2021, after waking up, the patient's body temperature was in the 39 degrees Celsius range. At 12:00, the patient took aspirin. At the same time, respiratory discomfort, throbbing chest pain, chest tightness, and cough developed. Around 18:00, because the symptoms persisted, an emergency call was made. The patient was transported with BP of 99/64, HR of 155, Sat of 98 (room air), and eardrum temperature of 37.2 degrees	24 years old male with unknown medical history who developed 3 days after the 2nd dose experienced chest pain and was found to have elevated troponin, Ck, NT-proBNP, abnormal EGC, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and ECG results; a causal relationship cannot be excluded due to the lack of other information.

Case ID	WW Identifier	Narrative	MAH Comment
		Celsius. After arriving, 12 lead electrocardiogram showed negative T waves in 2, 3 and aVf, and there was no arrhythmia. No previous ECG was recorded. Vital signs were stable with BP of 134/83, HR of 90, Sat of 98 (room air), and axillary BT of 38.5 degrees Celsius. The patient was raced to a hospital due to persistent symptoms and abnormal electrocardiogram. After transport, 12 lead electrocardiogram, blood sampling, chest Xp, and echocardiography were performed. Echocardiography showed pericardial effusion, and the patient was diagnosed with suspected acute pericarditis based on the clinical course and electrocardiographic findings and was hospitalized. Afterwards, the symptoms were resolving. On 13-Oct-2021, respiratory discomfort remained but tended to improve. The outcome of pyrexia, suspected acute pericarditis, respiratory discomfort, throbbing chest pain, chest tightness, cough, and pericardial effusion was reported as resolving. Follow-up investigation will be made . Company Comment: The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	
4.1(b)	4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b) on 19-Oct-2021 and was forwarded to Moderna on 19-Oct-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCARDITIS	

Case ID	WW Identifier	Narrative	MAH Comment
		(Myocarditis) in a 27-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 010D9A) for COVID-19 vaccination. No Medical History information was reported. On 03-Oct-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 04-Oct-2021, after starting mRNA-1273 (Moderna COVID-19 Vaccine), the patient experienced MYOCARDITIS (Myocarditis) (seriousness criterion medically significant). At the time of the report, MYOCARDITIS (Myocarditis) had not resolved. For mRNA-1273 (Moderna COVID-19 Vaccine) (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: This case concerns a 27-year-old, female patient with no relevant medical history, who experienced the expected event of myocarditis. The event myocarditis occurred 1 day after the second dose of mRNA-1273 vaccine administration. The rechallenge was unknown as there's no information available about the first dose. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.	
4.1(b)	4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b) on 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	

Case ID	WW Identifier	Narrative	MAH Comment
		occurrence of CHEST PAIN (Chest pain) and MYOCARDITIS (Myocarditis) in an 18-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 038C21A) for COVID-19 vaccination. No Medical History information was reported. On 23-Jul-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 25-Jul-2021, the patient experienced CHEST PAIN (Chest pain) (seriousness criterion hospitalization) and MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). The patient was hospitalized on 25-Jul-2021 due to CHEST PAIN and MYOCARDITIS. The patient was treated with IBUPROFEN for Chest pain, at an unspecified dose and frequency. At the time of the report, CHEST PAIN (Chest pain) had resolved and MYOCARDITIS (Myocarditis) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 25-Jul-2021, Magnetic resonance imaging heart: abnormal (abnormal) visualized regions of epicardial delayed gadolinium enhancement consistent with myocarditis. On 25-Jul-2021, Pain assessment: 7/10 (High) Stabbing chest pain rated it a 7/10 on the pain scale.. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments.	

Case ID	WW Identifier	Narrative	MAH Comment
		Concomitant medications was not reported. On an unknown date, after receiving the first dose, 2 weeks later patient received the TDAP (tetanus, diphtheria, and pertussis) and typhoid vaccines. On 25-Jul-2021, the patient developed stabbing chest pain rated it as 7/10 on the pain scale at which point the patient went to the local ER (emergency room) and was transported to another medical facility for further evaluation and management due to concerns for myocarditis. Cardiology visualized regions of epicardial delayed gadolinium enhancement consistent with myocarditis. The patient had follow-up with cardiology in 2-3 weeks. Company comment This case concerns a 18-year-old, male with no reported medical history, who experienced the serious, unexpected event of chest pain and serious, expected and AESI event of myocarditis. The events occurred 2 days after second dose of Spikevax. The rechallenge was not applicable, as no additional dosing will be given. Previous vaccination with TDAP and Typhoid vaccines could be potentially confounders. The benefit-risk relationship of Spikevax is not affected by this report.	
4.1(b)	4.1(b)	This case was received via 4.1(b) Reference number: 4.1(b) on 19-Oct-2021 and was forwarded to Moderna on 19-Oct-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCARDITIS (Myocarditis), PRESYNCOPE (Presyncope), CHEST PAIN (Chest pain), DIZZINESS (Dizziness), DYSPNOEA (Dyspnoea) and FEELING ABNORMAL (Feeling abnormal) in a 37-year-old female patient who received mRNA-1273	

Case ID	WW Identifier	Narrative	MAH Comment
		(Moderna COVID-19 Vaccine) for COVID-19 vaccination. Concurrent medical conditions included Hashimoto's thyroiditis and Hypocalcemia. Concomitant products included LEVOTHYROXINE, LIOTHYRONINE (NP THYROID), OMEPRAZOLE (4.1(b) [OMEPRAZOLE]), VITAMIN D3, CALCIUM, MAGNESIUM OXIDE and CALCITRIOL for an unknown indication. On 31-Aug-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 03-Sep-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant), PRESYNCOPE (Presyncope) (seriousness criterion hospitalization), CHEST PAIN (Chest pain) (seriousness criterion hospitalization), DIZZINESS (Dizziness) (seriousness criterion hospitalization), DYSPNOEA (Dyspnoea) (seriousness criterion hospitalization) and FEELING ABNORMAL (Feeling abnormal) (seriousness criterion hospitalization). The patient was hospitalized for 3 days due to CHEST PAIN, DIZZINESS, DYSPNOEA, FEELING ABNORMAL, MYOCARDITIS and PRESYNCOPE. At the time of the report, MYOCARDITIS (Myocarditis), PRESYNCOPE (Presyncope), CHEST PAIN (Chest pain), DIZZINESS (Dizziness), DYSPNOEA (Dyspnoea) and FEELING ABNORMAL (Feeling abnormal) had not resolved. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. No treatment information was provided.	

Case ID	WW Identifier	Narrative	MAH Comment
		On 03-Sep-2021, Multiple EKG, Angiogram, CT chest, X-rays, laboratory test, ECHO, ultrasound scan were performed. Results not provided.	
4.1(b)	4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b) on 19-Oct-2021 and was forwarded to Moderna on 19-Oct-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of CHEST DISCOMFORT (Chest discomfort), CHEST PAIN (Chest pain), DYSPNOEA (Dyspnoea), EJECTION FRACTION DECREASED (Ejection fraction decreased), MYOCARDIAL OEDEMA (Myocardial oedema), MYOCARDITIS (Myocarditis), PAIN (Pain), PAIN IN JAW (Pain in jaw), PERICARDIAL EFFUSION (Pericardial effusion), PYREXIA (Pyrexia), SLEEP DISORDER (Sleep disorder), VENTRICULAR HYPOKINESIA (Ventricular hypokinesia) and PERICARDITIS (Pericarditis) in a 21-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 939901) for COVID-19 vaccination. Concomitant products included FENTANYL for Pain, ACETYLSALICYLIC ACID (ASPIRIN (E.C.)), COLCHICINE, IBUPROFEN and METOPROLOL SUCCINATE for an unknown indication. On 24-Aug-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 23-Sep-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 24-Sep-2021, the patient experienced CHEST DISCOMFORT (Chest discomfort) (seriousness criterion hospitalization), CHEST PAIN (Chest pain) (seriousness criterion hospitalization), DYSPNOEA	21 years old male with unknown medical history who next day after the 2nd dose experienced chest pain, chest discomfort, dyspnoea, and was found to have elevated troponin, pericardial effussion, ventricular hypokynesia, and abnormal EGC, and was diagnosed with myopericarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and ECG results; a causal relationship cannot be excluded due to the lack of other information.

Case ID	WW Identifier	Narrative	MAH Comment
		(Dyspnoea) (seriousness criterion hospitalization), EJECTION FRACTION DECREASED (Ejection fraction decreased) (seriousness criterion hospitalization), MYOCARDIAL OEDEMA (Myocardial oedema) (seriousness criteria hospitalization and medically significant), MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant), PAIN (Pain) (seriousness criterion hospitalization), PAIN IN JAW (Pain in jaw) (seriousness criterion hospitalization), PERICARDIAL EFFUSION (Pericardial effusion) (seriousness criteria hospitalization and medically significant), PYREXIA (Pyrexia) (seriousness criterion hospitalization), SLEEP DISORDER (Sleep disorder) (seriousness criterion hospitalization), VENTRICULAR HYPOKINESIA (Ventricular hypokinesia) (seriousness criteria hospitalization and medically significant) and PERICARDITIS (Pericarditis) (seriousness criteria hospitalization and medically significant). The patient was hospitalized from 27-Sep-2021 to 29-Sep-2021 due to CHEST DISCOMFORT, CHEST PAIN, DYSPNOEA, EJECTION FRACTION DECREASED, MYOCARDIAL OEDEMA, MYOCARDITIS, PAIN, PERICARDIAL EFFUSION, PERICARDITIS, PYREXIA, SLEEP DISORDER and VENTRICULAR HYPOKINESIA. At the time of the report, CHEST DISCOMFORT (Chest discomfort), CHEST PAIN (Chest pain), DYSPNOEA (Dyspnoea), EJECTION FRACTION DECREASED (Ejection fraction decreased), MYOCARDIAL OEDEMA (Myocardial oedema), MYOCARDITIS (Myocarditis), PAIN (Pain), PAIN IN JAW (Pain in jaw), PERICARDIAL EFFUSION (Pericardial effusion), PYREXIA (Pyrexia), SLEEP DISORDER (Sleep disorder), VENTRICULAR HYPOKINESIA (Ventricular hypokinesia) and PERICARDITIS (Pericarditis) had resolved.	

Case ID	WW Identifier	Narrative	MAH Comment
		DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 24-Sep-2021, Blood potassium: decreased (Low) decreased. On 24-Sep-2021, Cardiac imaging procedure: abnormal (abnormal) abnormal. On 27-Sep-2021, Electrocardiogram: st elevations (abnormal) ST elevations and st elevations (abnormal) ST elevations. On 27-Sep-2021, Troponin: 5ng/ml (High) 5ng/ml, 10.6 ng/ml (High) 10.6 ng/ml, 9.5 ng/ml (High) 9.5 ng/mL, 10.5 ng/ml (High) 10.5 ng/mL and 25.9 ng/ml (High) 25.9 ng/ml. On 28-Sep-2021, Magnetic resonance imaging heart: normal lv cavity si (abnormal) Normal LV cavity si. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. On 24-SEP-2021 Chest x ray,Echocardiogram normal, Electrocardiogram ST segment elevation,Magnetic resonance imaging heart, Right ventricular ejection fraction decreased,SARS-CoV-2 test,Troponin increased was performed, results not reported however outcome is reported as recovered/resolved. ON 27-SEP-2021 at 06.32 Chest X-Raywas done ,On same day at 10.56 Covid PCR was done,results not provided. It wa reported that the patient also received (see continuation) 40 mEq of potassium to replete electrolytes (potassium level upon arrival 3.4 mmol/L). No treatment medications were provided. Company Comment: This case concerns a 21-year-old, male patient with no relevant medical	

Case ID	WW Identifier	Narrative	MAH Comment
		history, who experienced the unexpected events of Chest discomfort, Chest pain, Dyspnea, Ejection fraction decreased, Myocardial edema, Myocarditis, Pain, Pain in jaw, Pericardial effusion, Pyrexia, Sleep disorder, Ventricular hypokinesia, and Pericarditis. The events occurred approximately 2 days after the second dose of mRNA-1273 (Moderna Covid-19 vaccine). The rechallenge was not applicable as events occurred after the second dose. The benefit-risk relationship of mRNA-1273 (Moderna Covid-19 vaccine) is not affected by this report.	
4.1(b)	4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b) on 19-Oct-2021 and was forwarded to Moderna on 19-Oct-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of BACK PAIN (Back pain), CHEST PAIN (Chest pain), DYSPNOEA (Dyspnoea), PAIN (Pain), PAIN IN EXTREMITY (Pain in extremity) and MYOCARDITIS (Myocarditis) in a 19-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 048F21A) for COVID-19 vaccination. No Medical History information was reported. On 28-Sep-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 29-Sep-2021, the patient experienced BACK PAIN (Back pain) (seriousness criterion hospitalization), CHEST PAIN (Chest pain) (seriousness criterion hospitalization), DYSPNOEA (Dyspnoea) (seriousness criterion hospitalization), PAIN (Pain) (seriousness criterion hospitalization), PAIN IN EXTREMITY (Pain in extremity) (seriousness criterion hospitalization) and MYOCARDITIS (Myocarditis) (seriousness criteria	

Case ID	WW Identifier	Narrative	MAH Comment
		hospitalization and medically significant). The patient was hospitalized on sometime in September 2021 due to BACK PAIN, CHEST PAIN, DYSPNOEA, MYOCARDITIS, PAIN and PAIN IN EXTREMITY. At the time of the report, BACK PAIN (Back pain), CHEST PAIN (Chest pain), DYSPNOEA (Dyspnoea), PAIN (Pain), PAIN IN EXTREMITY (Pain in extremity) and MYOCARDITIS (Myocarditis) had resolved. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No concomitant product was provided by the reporter. No treatment medication was provided. Chest pain started at 5am, approximately 19 hours after vaccination. Patient's symptoms mimicked those of a hear attack. Patient taken to the hospital on Thursday morning after shortness of breath developed. Pain was radiating down his arm and to his back. Patient was admitted on Thursday after being at the ER. Company Comment: This case concerns a 19-year-old, male patient, with no relevant medical history, who experienced the serious, expected, AESI event of myocarditis and other serious unexpected events of back pain, chest pain, dyspnea, pain and pain in extremity. The events occurred 1 day after second dose of Moderna vaccine. The rechallenge is not applicable as a third dose is not expected. The benefit-risk relationship of Moderna vaccine is not affected by this report.	
4.1(b)	4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b) on 19-Oct-2021 and was forwarded to Moderna on 19-Oct-2021.	

Case ID	WW Identifier	Narrative	MAH Comment
		This regulatory authority case was reported by an other health care professional and describes the occurrence of ARTHRALGIA (Arthralgia), BACK PAIN (Back pain), CHEST PAIN (Chest pain), HYPOPNOEA (Hypopnoea), MUSCULOSKELETAL PAIN (Musculoskeletal pain), PAIN (Pain), PAINFUL RESPIRATION (Painful respiration) and PERICARDITIS (Pericarditis) in a 35-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 006C21) for COVID-19 vaccination. Concurrent medical conditions included High cholesterol and Migraine. Concomitant products included FEXOFENADINE HYDROCHLORIDE (ALLEGRA) and CAFFEINE, PARACETAMOL (EXCEDRIN [CAFFEINE;PARACETAMOL]) for an unknown indication. On 24-Apr-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 03-Aug-2021, the patient experienced BACK PAIN (Back pain) (seriousness criterion hospitalization). On 04-Aug-2021, the patient experienced ARTHRALGIA (Arthralgia) (seriousness criterion hospitalization), CHEST PAIN (Chest pain) (seriousness criterion hospitalization), HYPOPNOEA (Hypopnoea) (seriousness criterion hospitalization), MUSCULOSKELETAL PAIN (Musculoskeletal pain) (seriousness criterion hospitalization), PAIN (Pain) (seriousness criterion hospitalization), PAINFUL RESPIRATION (Painful respiration) (seriousness criterion hospitalization) and PERICARDITIS (Pericarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, ARTHRALGIA (Arthralgia), BACK PAIN (Back pain), CHEST PAIN	

Case ID	WW Identifier	Narrative	MAH Comment
		(Chest pain), HYPOPNOEA (Hypopnoea), MUSCULOSKELETAL PAIN (Musculoskeletal pain), PAIN (Pain), PAINFUL RESPIRATION (Painful respiration) and PERICARDITIS (Pericarditis) had resolved. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. No treatment medications were provided. Company Comment: This case concerns a 35-year-old, male patient with no relevant medical history, who experienced the expected serious adverse event of special interest of pericarditis and unexpected serious events of arthralgia, back pain, chest pain, hypopnea, musculoskeletal pain, pain, painful respiration. The events occurred approximately 3 months and 11 days after the second dose of Spikevax (Moderna COVID-19 vaccine). The rechallenge was assessed as not applicable as the AEs occurred after the second dose. The benefit-risk relationship of Spikevax (Moderna COVID-19 vaccine) is not affected by this report.	
4.1(b)	4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b) on 19-Oct-2021 and was forwarded to Moderna on 19-Oct-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of CHEST PAIN (Chest pain), DYSPNOEA (Dyspnoea) and MYOCARDITIS (Myocarditis) in a 23-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 048F21A) for COVID-19 vaccination. No Medical History information was reported.	23 years old male with unknown medical history who 2 days after the 2nd dose experienced chest pain and dyspnoea and was found to have elevated troponin, and normal EGC, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin; a causal relationship cannot be excluded due to the lack of other information.

Case ID	WW Identifier	Narrative	MAH Comment
		On 03-Oct-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 05-Oct-2021, the patient experienced CHEST PAIN (Chest pain) (seriousness criteria hospitalization and medically significant), DYSPNOEA (Dyspnoea) (seriousness criteria hospitalization and medically significant) and MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, CHEST PAIN (Chest pain), DYSPNOEA (Dyspnoea) and MYOCARDITIS (Myocarditis) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 05-Oct-2021, Electrocardiogram: normal (normal) normal. On 05-Oct-2021, Laboratory test: normal (normal) normal. On 05-Oct-2021, Troponin (8000-10.3000): increased (High) Increased, high sensitivity troponins with value of 10,337. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. No concomitant medications were reported No treatment medications were reported. The patient had Myocarditis - developed chest pain, shortness of breath quite suddenly the morning of 10/5/2021. This case concerns a 23-year-old, male patient with no relevant medical history, who experienced the unexpected events of chest pain and dyspnea and expected event of myocarditis. The events chest pain, dyspnea and myocarditis occurred 2 days after the second dose of mRNA-	

Case ID	WW Identifier	Narrative	MAH Comment
		1273 vaccine administration. The rechallenge was unknown as there's no information available about the first dose. The patient's age and gender remain confounders. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.	
4.1(b)	4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b) on 19-Oct-2021 and was forwarded to Moderna on 19-Oct-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of PERICARDITIS (Pericarditis) and PERICARDITIS (pericarditis) in a 21-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 031A21A) for COVID-19 vaccination. Concurrent medical conditions included Cerebral palsy (Minor bilateral cerebral palsy). On 16-Mar-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 16-Mar-2021, the patient experienced PERICARDITIS (Pericarditis) (seriousness criteria hospitalization and medically significant). In October 2021, after starting mRNA-1273 (Moderna COVID-19 Vaccine), the patient experienced PERICARDITIS (pericarditis) (seriousness criterion medically significant). The patient was hospitalized on 18-Mar-2021 due to PERICARDITIS. The patient was treated with COLCHICINE ongoing since an unknown date for Pericarditis, at a dose of .6 mg twice a day. At the time of the report, PERICARDITIS (Pericarditis) had not resolved and PERICARDITIS (pericarditis) outcome was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter	

Case ID	WW Identifier	Narrative	MAH Comment
		did not provide any causality assessments. Concomitant product use was not provided by the reporter. On 16-MAR-2021, the patient had an additional Echocardiogram test performed that included a test, however, the result was not provided. Company comment: This case concerns a 21-year-old, male patient with no relevant medical history, who experienced the expected event of pericarditis. The event pericarditis occurred 1 day after the second dose of mRNA-1273 vaccine administration and re-occurred approximately 7 months after the second dose of mRNA-1273 vaccine administration. The rechallenge was not applicable, as the event occurred after the second dose and no additional dose is expected at this moment. The patient's age and gender remain confounders. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. The RA SD structured field captured the onset latency of the event pericarditis as the same day with the second dose of mRNA-1273 vaccine administration, but the RA SD narrative stated that the event pericarditis occurred a day after the second dose of mRNA-1273 vaccine administration. The RA SD narrative event onset latency was captured and coded.	
4.1(b)	4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b) on 19-Oct-2021 and was forwarded to Moderna on 19-Oct-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of PERICARDITIS (Pericarditis) in a 35-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination.	

Case ID	WW Identifier	Narrative	MAH Comment
		The patient's past medical history included High cholesterol and Swollen lymph nodes (tender swollen lymph nodes following flu vaccine (but not every time)). Concomitant products included COLECALCIFEROL (VITAMIN D [COLECALCIFEROL]) for an unknown indication. On 30-Apr-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 03-May-2021, after starting mRNA-1273 (Moderna COVID-19 Vaccine), the patient experienced PERICARDITIS (Pericarditis) (seriousness criterion medically significant). At the time of the report, PERICARDITIS (Pericarditis) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 03-May-2021, Blood cholesterol increased: increased (High) Blood cholesterol increased. On 03-May-2021, Blood magnesium: decreased (Low) decreased Blood magnesium. On 03-May-2021, Blood test: abnormal (abnormal) abnormal. On 03-May-2021, Electrocardiogram: normal (normal) Normal. On 03-May-2021, Ultrasound scan: normal (normal) Normal. On 03-May-2021, Vitamin D: decreased (Low) decreased. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. The patient experienced pericarditis heart racing/pounding heavily especially when laying down at night. The patient had sonogram that he believed came back normal. blood panels showing low vit D high cholesterol, low magnesium he believed. since, He had a long term	

Case ID	WW Identifier	Narrative	MAH Comment
		(1 week) heart monitor ecg, another blood panel pending results. Stress test scheduled. The patient had Cardiac monitoring with unknown result. No treatment medication reported. Company Comment - This case concerns a 35-year-old, male patient with no relevant medical history, who experienced the unexpected event of palpitations and the expected event of pericarditis. The events palpitations and pericarditis occurred 3 days after the second dose of mRNA-1273 vaccine administration. The rechallenge was not applicable, as the event occurred after the second dose and no additional dose is expected at this moment. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.	
4.1(b)	4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b) on 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 FATIGUE (Fatigue), CHEST PAIN (Chest Pain), PALPITATIONS (Palpitations), TACHYCARDIA (Tachycardia) and PERICARDITIS (Pericarditis) in a 23-year-old female patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. On 08-Sep-2021, the patient received second dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 04-Oct-2021, after starting mRNA-1273 (Moderna CoviD-19 Vaccine), the patient experienced PERICARDITIS (Pericarditis) (seriousness criterion medically significant). On an unknown date, the	

Case ID	WW Identifier	Narrative	MAH Comment
		patient experienced FATIGUE (Fatigue) (seriousness criterion medically significant), CHEST PAIN (Chest Pain) (seriousness criterion medically significant), PALPITATIONS (Palpitations) (seriousness criterion medically significant) and TACHYCARDIA (Tachycardia) (seriousness criterion medically significant). At the time of the report, FATIGUE (Fatigue), CHEST PAIN (Chest Pain), PALPITATIONS (Palpitations) and TACHYCARDIA (Tachycardia) outcome was unknown and PERICARDITIS (Pericarditis) was resolving. The action taken with mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown) was unknown. For mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown), the reporter considered PERICARDITIS (Pericarditis) to be possibly related. No further causality assessments were provided for FATIGUE (Fatigue), CHEST PAIN (Chest Pain), PALPITATIONS (Palpitations) and TACHYCARDIA (Tachycardia). Concomitant product use was not provided by the reporter. No treatment information was provided. The patient had chest pain for one day after the first vaccine. Followed by two weeks of chest pain after the second dose. Confirmed as pericarditis as a result of the vaccine. Patient had not tested positive for COVID-19 since having the vaccine. Patient was not enrolled in clinical trial. Company Comment : This case concerns a 23-year-old, female patient with no reported medical history, who experienced the unexpected, serious events of palpitations, tachycardia, chest pain, fatigue and expected, serious and	

Case ID	WW Identifier	Narrative	MAH Comment
		AESI event of Pericarditis. The event pericarditis occurred 26 days after the second dose of Spikevax. The events palpitations, chest pain and fatigue occurred after second dose of Spikevax, time to onset from vaccination was not reported. Regulatory authority captured the rechallenge as unknown, as it should for Pericarditis, as outcome is recovering and no information disclosed about other doses, however, for events palpitations, tachycardia, chest pain, fatigue, the outcome is not recovered, hence rechallenge should be not applicable. The benefit-risk relationship of Spikevax vaccine is not affected by this report.	
4.1(b)	4.1(b)	This case was received via 4.1(b) Pharmaceuticals (Reference number: 4.1(b)) on 13-Oct-2021 and was forwarded to Moderna on 20-Oct-2021. This case, reported by a physician, was received by 4.1(b) via Moderna's adverse reaction reporting site (4.1(b)) . On 03-Sep-2021, at 15:00, the patient received the 1st dose of this vaccine. On an unknown date, body temperature before the vaccination: 36.4 degrees Celsius. On 01-Oct-2021, at 15:00, the patient received the 2nd dose of this vaccine. Pyrexia developed at night. On 02-Oct-2021, pyrexia went down. On 03-Oct-2021, at 21:00, chest pain developed. On 04-Oct-2021, the symptoms were exacerbated, and the patient was urgently transported to a medical institution. Troponin T was positive (1.300 ng/mL), CK: 762 U/L, CKMB: 72 U/L, and cardiac enzymes were elevated. Echocardiography showed diffuse wall hypokinesis (left ventricular ejection fraction: 46%).	18 years old male with unknown medical history who developed fever the same day after the 2nd dose of Spikevax and 2 days later experienced chest pain and was found to have elevated troponin, Ck, abnormal Echo, and myocardial biopsy showed mild lymphocytis infiltration and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and ECG results as well as the myocardial biopsy; a causal relationship cannot be excluded due to the lack of other information.

Case ID	WW Identifier	Narrative	MAH Comment
		The patient was diagnosed with perimyocarditis and was urgently hospitalized. Steroid pulse therapy was started. On 05-Oct-2021, myocardial biopsy showed mild lymphocytic infiltration, leading to a definitive diagnosis of myocarditis. On 07-Oct-2021, steroid treatment was effective, CK/CKMB were normalized, and troponin T decreased to 0.551 ng/mL. On 12-Oct-2021, colchicine was additionally administered. The patient's general condition was stabilized thereafter. On 13-Oct-2021, the symptoms were resolving. The outcome of pyrexia was reported as recovered. The outcome of perimyocarditis and diffuse wall hypokinesis was reported as resolving. Follow-up investigation will be made. Company Comment: The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	
4.1(b)	4.1(b)	This case was received via 4.1(b) Pharmaceuticals (Reference number: 4.1(b)) on 16-Oct-2021 and was forwarded to Moderna on 20-Oct-2021. This case, initially reported to the 4.1(b)) by a (pharmacist), was received via the 4.1(b) (Ref, 4.1(b) The patient had a history of epilepsy and was taking levetiracetam. On an unknown date, the patient received the 1st dose of this vaccine. On 12-Oct-2021, the patient received the 2nd dose of this vaccine. On 13-Oct-2021, chest pain and queasy developed. On 15-Oct-2021, in the morning, the patient was raced to a hospital with a pain scale of 10/10. No pericardial effusion was confirmed by ultrasound. Electrocardiogram and blood test showed increased cardiac enzymes, and acute pericarditis was suspected. The patient was hospitalized.	

Case ID	WW Identifier	Narrative	MAH Comment
		The outcome of chest pain, queasy, and suspected myocarditis was unknown. Follow-up investigation will be made. Company Comment: The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	
4.1(b)	4.1(b)	This case was received via 4.1(b) Pharmaceuticals (Reference number: 4.1(b) on 13-Oct-2021 and was forwarded to Moderna on 20-Oct-2021. This case, reported by a pharmacist via a medical representative, and reported to the 4.1(b) by a pharmacist, was received via the 4.1(b) (Ref, 4.1(b) On 02-Sep-2021, at 14:00, the patient received the 1st dose of this vaccine. On 30-Sep-2021, at 14:00, the patient received the 2nd dose of this vaccine. On 01-Oct-2021, chest pain developed. On 03-Oct-2021, in the early hours, an emergency call was made, and the patient visited a hospital. Increased cardiac enzymes, increased inflammatory reaction, and abnormality in the electrocardiogram were noted, and the patient was hospitalized for suspected myocarditis. Oral administration of 6 tablets of aspirin in 3 divided doses was started. On an unknown date, myocardial enzymes improved over time, and test values returned to normal. On 13-Oct-2021, the patient recovered but remained hospitalized for examinations. The outcome of chest pain and suspected myocarditis was reported as resolved.	

Case ID	WW Identifier	Narrative	MAH Comment
		Follow-up investigation will be made. Company Comment: The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	
4.1(b)	4.1(b)	This case was received via 4.1(b) Pharmaceuticals (Reference number: 4.1(b) on 16-Oct-2021 and was forwarded to Moderna on 20-Oct-2021. This case, initially reported to the 4.1(b) by a (physician), was received via the 4.1(b) (Ref, 4.1(b) On an unknown date, the patient received the 1st dose of this vaccine. On an unknown date, body temperature before the vaccination: 36.5 degrees Celsius. On 07-Oct-2021, at 15:00, the patient received the 2nd dose of this vaccine. At 19:00, it was thought that acute myocarditis devloped. During the night, pyrexia and chest pain developed. On an unknown date, the symptoms did not improve, and the patient visited the reporting hospital emergently. On 10-Oct-2021, the patient was hospitalized for treatment. Acute myocarditis was diagnosed based on abnormal electrocardiogram and increased CK. On an unknown date, the symptoms improved with oral treatment with anti-inflammatory agent. On 14-Oct-2021, the symptoms improved, and the patient was discharged from the hospital. The outcome of acute myocarditis was reported as resolved. Follow-up investigation will be made. Company Comment: The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	
4.1(b)	4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b) on 19-Oct-2021 and was forwarded to Moderna on 19-Oct-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCARDITIS (Myocarditis/Pericarditis) in a 22-	

Case ID	WW Identifier	Narrative	MAH Comment
		year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No relevant medical history was provided by the reporter. Concomitant products included IBUPROFEN for an unknown indication. On 30-Sep-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 02-Oct-2021, after starting mRNA-1273 (Moderna COVID-19 Vaccine), the patient experienced MYOCARDITIS (Myocarditis/Pericarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Myocarditis/Pericarditis) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 02-Oct-2021, Chest X-ray: normal (normal) chest x-ray normal. On 02-Oct-2021, Echocardiogram: normal (normal) echocardiogram normal. On 02-Oct-2021, Electrocardiogram: abnormal (abnormal) consistent with pericarditis. On 02-Oct-2021, Troponin: increased (High) Elevated. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Patient had myopericarditis. symptoms included chest pain, shortness of breath, dyspnea on exertion starting 2 days after the second dose of Moderna COVID-19 vaccine. No treatment medications were reported.	

Case ID	WW Identifier	Narrative	MAH Comment
		Company Comment: This case concerns a 22-year-old, male patient with no relevant medical history, who experienced the unexpected event of myocarditis. The events occurred approximately 2 days after the second dose of Moderna Covid-19 vaccine when patient was hospitalized. At the time of report outcome is still unknown. The rechallenge was unknown since no information about the first dose was disclosed. The benefit-risk relationship of the vaccine is not affected by this report.	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 20-Oct-2021 and was forwarded to Moderna on 20-Oct-2021. This regulatory authority case was reported by a physician and describes the occurrence of CHEST PAIN (Chest pain/Pericarditis) and PERICARDITIS (Chest pain/Pericarditis) in a 30-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3003604) for Vaccination. The occurrence of additional non-serious events is detailed below. Previously administered products included for Vaccination: Comirnaty. Past adverse reactions to the above products included No adverse reaction with Comirnaty. On 04-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 27-Sep-2021, the patient experienced CHEST PAIN (Chest pain/Pericarditis) (seriousness criterion hospitalization) and PERICARDITIS (Chest pain/Pericarditis) (seriousness criteria hospitalization and medically significant). On an unknown date, the patient experienced COVID-19 IMMUNISATION (Chest pain/Pericarditis). At the time of the	

Case ID	WW Identifier	Narrative	MAH Comment
		report, CHEST PAIN (Chest pain/Pericarditis), PERICARDITIS (Chest pain/Pericarditis) and COVID-19 IMMUNISATION (Chest pain/Pericarditis) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 27-Sep-2021, Electrocardiogram: abnormal (abnormal) Findings consistent with pericarditis. On 27-Sep-2021, Investigation: abnormal (abnormal) No myocardial affection. For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered CHEST PAIN (Chest pain/Pericarditis) and PERICARDITIS (Chest pain/Pericarditis) to be possibly related. No further causality assessment was provided for COVID-19 IMMUNISATION (Chest pain/Pericarditis). No concomitant medications were reported. No treatment medications were reported. This is a regulatory case concerning a 30 year-old, male patient with clinical history of previously administered Comirnaty products for Vaccination without adverse reaction, who experienced the unexpected serious event of CHEST PAIN, the expected (AESI) serious event of PERICARDITIS and other non-serious adverse event. The events occurred 24 days after the first dose of Spikevax vaccine, second doses of COVID-19 vaccine. 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. Most recent FOLLOW-UP information incorporated above includes:	

Case ID	WW Identifier	Narrative	MAH Comment
		On 20-Oct-2021: Translation received on 21-Oct-2021: Event verbatim was updated.	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b) on 20-Oct-2021 and was forwarded to Moderna on 20-Oct-2021. This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (PERIMYOCARDITIS) in an 18-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3006273) for COVID-19 vaccination. No medical history was provided by the reporter. On 05-Oct-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 08-Oct-2021, after starting mRNA-1273 (Spikevax), the patient experienced MYOCARDITIS (PERIMYOCARDITIS) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (PERIMYOCARDITIS) was resolving. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. No concomitant medication listed. No treatment information provided. Company comment -This is a regulatory case concerning a 18 year-old, male patient with no clinical history who experienced the expected (AESI) serious event of PERICARDITIS. The event occurred 4 days after the second dose of Spikevax vaccine The rechallenge is not applicable" as the events occurred after the second dose and no details were provided about the first dose	

Case ID	WW Identifier	Narrative	MAH Comment
		The benefit-risk relationship of Spikevax is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 20-Oct-2021: Translation Received on 21-Oct-2021 includes event verbatim updated.	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 20-Oct-2021 and was forwarded to Moderna on 20-Oct-2021. This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (MYOCARDITIS) in a 19-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3005835) for COVID-19 vaccination. No Medical History information was reported. On 22-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 25-Sep-2021, after starting mRNA-1273 (Spikevax), the patient experienced MYOCARDITIS (MYOCARDITIS) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (MYOCARDITIS) was resolving. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. No concomitant medication was reported. No treatment history was reported. Company Comment : This case concerns a 19-year-old, male patient with no relevant medical history, who experienced the expected serious event of Myocarditis. The event occurred approximately 04 days after the second dose of Spikevax. The	

Case ID	WW Identifier	Narrative	MAH Comment
		rechallenge was not applicable. The event is consistent with the current understanding of the mechanism of action of the vaccine. The benefit-risk relationship of Spikevax is not affected by this report. Event term, onset date, outcome and seriousness captured per SD from Regulatory Authority reporting. Most recent FOLLOW-UP information incorporated above includes: On 20-Oct-2021: Translation received on 21 Oct 2021 included event verbatim and dosage text updated.	
4.1(b)	4.1(b)	This case was received via an unknown source (no reference has been entered for a health authority or license partner) on 20-Oct-2021 and was forwarded to Moderna on 20-Oct-2021. This regulatory authority case was reported by a physician and describes the occurrence of INFLUENZA LIKE ILLNESS (flu-like symptoms), ABDOMINAL PAIN UPPER (Epigastric pain) and MYOCARDITIS (Peri-/Myocarditis) in a 38-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 immunisation. The patient's past medical history included Nephrolithiasis (History of nephrolithiasis, spontaneous resolution Aug 26, 2020; calcium oxalate concrement) on 26-Aug-2020, Hidradenitis suppurativa (Acne inversa) and Ex-smoker. Concurrent medical conditions included Allergy (Dyshidrotic finger/hand eczema without spread; idiopathic, possible atopic diathesis). In July 2021, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 100 microgram. On 02-Aug-2021, received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) dosage was changed to 100 microgram. On 02-Aug-2021, the patient experienced INFLUENZA	38 years old male with no relevant medical history who same day after the 2nd dose experienced influenza like illness, abdominal pain, and was was found to have elevated troponin, Ck, abnormal EGC and Echo, and was diagnosed with myopericarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and ECG results; a causal relationship cannot be excluded due to the lack of other information.

Case ID	WW Identifier	Narrative	MAH Comment
		LIKE ILLNESS (flu-like symptoms) (seriousness criterion hospitalization), ABDOMINAL PAIN UPPER (Epigastric pain) (seriousness criterion hospitalization) and MYOCARDITIS (Peri-/Myocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, INFLUENZA LIKE ILLNESS (flu-like symptoms), ABDOMINAL PAIN UPPER (Epigastric pain) and MYOCARDITIS (Peri-/Myocarditis) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 05-Aug-2021, Angiocardiogram: abnormal (abnormal) Stenosis-free coronary vessels, LVEF 55%; mid-ventricular hypokinesis. On 05-Aug-2021, Echocardiogram: abnormal (abnormal) mildly impaired systolic LV function EF visual 45% with diffuse hypokinesis, diastolic dysfunction, LA dilatation, no relevant valve defects, normal RV function and dimension, the pulmonary pressure cannot be captured, no indirect signs of a pulmonary hypertension, no pericardial effusion.. On 05-Aug-2021, Electrocardiogram: abnormal (abnormal) normal cardiac sinus rhythm, HR 60/min, PQinterval 191ms, QRS 86ms, R/S transition V4, STelevations I, II, aVL, V4-V6, ST-depressions aVR, V1, Negative T waves III, QTc 368ms. On 07-Aug-2021, Electrocardiogram: normal (normal) normal cardiac SR, 63/min, indifferent type, preterminal anterolateral negative T waves, PQ 196ms, QRS 90ms, QTc 401ms.. On 07-Aug-2021, Laboratory test: abnormal (abnormal) CK peak of 489 U/L and Troponin-T peak of 1003 ng/L then regressive cardiac enzymes and regressive CRP.. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered INFLUENZA LIKE ILLNESS (flu-like symptoms), ABDOMINAL PAIN UPPER	

Case ID	WW Identifier	Narrative	MAH Comment
		(Epigastric pain) and MYOCARDITIS (Peri-/Myocarditis) to be possibly related. No concomitant medications reported Patient was treated with Ibuprofen 600 mg 3x/day as well as a heart failure therapy with candesartan and metoprolol ,Pantoprazole and Metamizole for epigastric pain . Company Comment : This case concerns a 38-year-old, male patient with medical history of smoking (ex-smoker), who experienced the unexpected events of abdominal pain upper, influence like illness and expected event of myocarditis. The events occurred on the same day after the second dose of Moderna COVID-19 Vaccine. The patient developed fever of 37.5°C and limb pain and epigastric pain. Also patient had palpitation, rapid breathing. To alleviate the pain, the patient independently took pantoprazole and metamizole, which did not relieve the symptoms. At that point the patient presented to the primary care doctor, who detected elevated cardiac enzymes and D-dimers and referred the patient to the emergency department for a suspected myocarditis. The ECG showed a sinus rhythm with diffuse ST-elevations. Coronary angiography showed no stenoses in the coronary arteries. The TTE showed a mildly impaired systolic LVEF of 45% with diffuse hypokinesis, without pericardial effusion. The treating physicians diagnosed a perimyocarditis most likely in the context of the COVID vaccination. Lab data included CK of 386 U/L, Troponin-T of 782 ng/L, CRP of 42mg/L.with leukocytes in normal ranges. The patient was successfully treated with ibuprofen, candesartan and metoprolol and discharged two days later. The rechallenge was not applicable as events occurred after second dose and no further dosing was reported or planned, based on information provided. The reporter assessed the events as related to the	

Case ID	WW Identifier	Narrative	MAH Comment
		product. The medical history of smoking remains a confounder. The benefit-risk relationship of Moderna COVID-19 Vaccine is not affected by this report. It was reported that Patient was hospitalized on 05AUG2021 and discharged on 07AUG2021 . Lab data included CK of 386 U/L, Troponin Most recent FOLLOW-UP information incorporated above includes: On 20-Oct-2021: Translation received on 24OCT2021 Contains Medical history, Lab data, Treatment drugs, Translated narrative and Sender comments	
4.1(b)	4.1(b)	This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCARDITIS (4.1(b) in a 19-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) (batch nos. 3004219 and 3003606) for COVID-19 vaccination. No medical history was reported. Concurrent medical conditions included Non-smoker, Alcohol use (Occasional), Renal disease and Liver disorder (Liver Disease). On 29-Jun-2021, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 200 microgram. On 27-Jul-2021, received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) dosage was changed to 200 microgram. On 29-Jul-2021, after starting mRNA-1273 (COVID-19 Vaccine Moderna), the patient experienced MYOCARDITIS (4.1(b) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (4.1(b) was resolving.	19 years old male with unknown medical history who 2 days after the 2nd dose experienced chest pain and was found to have elevated troponin, abnormal EGC, and cMRI with evidence of moderate multifocal lateral myocarditis with no evidence of dysfunction and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and ECG and cMRI results; a causal relationship cannot be excluded due to the lack of other information.

Case ID	WW Identifier	Narrative	MAH Comment
		DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Electrocardiogram: high (High) ECG inferior and latest ST segment elevation without mirror. On an unknown date, Magnetic resonance imaging: abnormal (abnormal) evidence of moderate multifocal lateral myopericardtitis. On an unknown date, Troponin: high (High) 11779 ng/L. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered MYOCARDITIS (4.1(b) [redacted] to be possibly related. Concomitant product use was not provided by the reporter. No treatment information was provided. Approximately 2.5 days after second vaccination from 29-Jul-2021, the patient developed the first symptoms of Perimyocarditis in the form of mild chest pain. Initially the pain was almost completely gone following rest. However the same evening (about 4 hours later), he again experienced very severe chest symptoms and presented as an emergency. A diagnosis of Perimyocarditis was made. Clinically he presented very groggy and pale in the face. He was hospitalized where analgesic as well as antiphlogistic therapy was initiated and continuous monitoring performed. The ECG showed ST elevation inferiorly and laterally without mirror changes(ST depressions) in the anterior leads. Lab tests revealed a ma imum troponin I (hs) of 11,779 ng/L, which regressed over the course. MRI revealed evidence of moderate multifocal lateral myocarditis, with no evidence of dysfunction (LVEF 56%, no focal wall motility disturbance) or pericardial effusion. Differential diagnosis: a viral genesis was discussed. There were no known	

Case ID	WW Identifier	Narrative	MAH Comment
		cardiovascular risk factors. In addition to NSAIDs and colchicine, low-dose cardioprotective therapy was installed with an ACE inhibitor and a cardio-selective beta blocker. The further course was without complications and after 5 days the patient could be discharged in improved condition. At discharge, the following medications were prescribed: Pantoprazole, Ramipril, Bisoprolol, Acetylsalicylic acid and Colchicine. No known allergies. Company Comment: This case refers to a 19yearold male patient with no relevant medical history who experienced the unexpected event of Myocarditis approximately 2 days after the second dose of Moderna COVID-19 Vaccine. Rechallenge was assessed as not applicable. The event was considered related to the vaccine per the reporter's assessment. The benefit-risk relationship of Moderna COVID-19 Vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 20-Oct-2021: Translation received on 21-Oct-2021. Concurrent conditions, Lab tests added. Case narrative and Sender comments updated and added in inarrative supplement.	
4.1(b) [redacted]	4.1(b) [redacted]	This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 20-Oct-2021 and was forwarded to Moderna on 20-Oct-2021. This regulatory authority case was reported by a consumer and describes the occurrence of HYPERTENSION (An ECG was taken and I had high blood pressure and a high pulse, plus severe pain NRS 7-9.), PAIN (An ECG was taken and I had high blood pressure and a high pulse, plus severe pain NRS 7-9.), HYPERHIDROSIS (That same evening I felt extremely nauseous and sweated, and that lasted about 3-5 hours.), CHEST PAIN (I was awake for about 1.5 hours before I had acute stabbing chest pains on my left side.), NAUSEA (Nausea), LYMPHADENOPATHY (Swollen lymph nodes under arm) and PERICARDITIS (Pericarditis) in a 26-year-old female patient who received mRNA-1273 (Spikevax) for Vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 04-May-2021 at 11:30 AM, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to 1 dosage form.	

Case ID	WW Identifier	Narrative	MAH Comment
		On an unknown date, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 04-May-2021, the patient experienced HYPERHIDROSIS (That same evening I felt extremely nauseous and sweated, and that lasted about 3-5 hours.) (seriousness criterion hospitalization), NAUSEA (Nausea) (seriousness criterion hospitalization) and LYMPHADENOPATHY (Swollen lymph nodes under arm) (seriousness criterion hospitalization). On 05-May-2021, the patient experienced HYPERTENSION (An ECG was taken and I had high blood pressure and a high pulse, plus severe pain NRS 7-9.) (seriousness criterion hospitalization), PAIN (An ECG was taken and I had high blood pressure and a high pulse, plus severe pain NRS 7-9.) (seriousness criterion hospitalization), CHEST PAIN (I was awake for about 1.5 hours before I had acute stabbing chest pains on my left side.) (seriousness criterion hospitalization), PERICARDITIS (Pericarditis) (seriousness criteria hospitalization and medically significant) and HEART RATE INCREASED (An ECG was taken and I had high blood pressure and a high pulse, plus severe pain NRS 7-9.). On 05-May-2021, HYPERHIDROSIS (That same evening I felt extremely nauseous and sweated, and that lasted about 3-5 hours.) and NAUSEA (Nausea) had resolved. On 07-May-2021, LYMPHADENOPATHY (Swollen lymph nodes under arm) had resolved. At the time of the report, HYPERTENSION (An ECG was taken and I had high blood pressure and a high pulse, plus severe pain NRS 7-9.), PAIN (An ECG was taken and I had high blood pressure and a high pulse, plus severe pain NRS 7-9.), CHEST PAIN (I was awake for about 1.5 hours before I had acute stabbing chest pains on my left side.), PERICARDITIS (Pericarditis) and HEART RATE INCREASED (An ECG was taken and I had high blood pressure and a high pulse, plus severe pain NRS 7-9.) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Electrocardiogram: abnormal (abnormal) Patient reports had high pulse.. No concomitant medications were reported No treatment medications were reported. Patient experienced strong pain in arm (dose no. 1), and axillary lymph nodes enlarged (dose no.1) after receiving the 1st covid-19 vaccination dose from Moderna. Patient reported nausea and sweating on the evening after receiving the vaccine on 04/May/2021, this lasted for approximately 3-5 hours. The patient developed axillary lymph nodes enlarged on 04/MAY/2021. The morning after, 05/May/2021, the patient felt ok. 1.5 hours later the patient experienced stabbing acute chest pain left side. it became worse in intensity and patient went to a general practitioner. ECG was performed and patient had hypertension, increased pulse, and also had severe pain with NRS 7-9. Patient was taken to the emergency room. There it was evaluated as most likely to be pericarditis. patient developed pericarditis on 05/MAY/2021.. Company Comment: This case concerns a 26-year-old, female with no relevant medical history reported, who experienced the serious expected AESI event of Pericarditis, serious unexpected events of Hypertension, Pain, Hyperhidrosis, Chest pain and serious unexpected per reported severity events of Nausea, Lymphadenopathy coincided with the non-serious event of Heart rate increased. The events occurred within 1-2 days after the second dose of Spikevax administration. The rechallenge was not applicable since no	

Case ID	WW Identifier	Narrative	MAH Comment
		events were reported after the first dose and no additional dosing was expected. The benefit-risk relationship of mRNA-1273 Moderna vaccine in not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 20-Oct-2021: Translated document received on 22-Oct-2021 - Event verbatim and narrative updated.	
4.1(b)	4.1(b)	This regulatory authority case was reported by a pharmacist and describes the occurrence of MYOCARDITIS (Acute perimyocarditis) in a 25-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) (batch nos. 30036 and 3004215) for COVID-19 immunisation. No Medical History information was reported. On 03-Aug-2021, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) .5 milliliter. On 10-Sep-2021, received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) dosage was changed to .5 milliliter. On 12-Sep-2021, after starting mRNA-1273 (COVID-19 Vaccine Moderna), the patient experienced MYOCARDITIS (Acute perimyocarditis) (seriousness criteria hospitalization and medically significant). On 16-Sep-2021, MYOCARDITIS (Acute perimyocarditis) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 14-Sep-2021, Echocardiogram: normal (normal) Normal echocardiographic findings with an EF of 61% were found in the TTE.. In addition there was no evidence of constrictive physiology or pericardial effusion.. On 15-Sep-2021, Angiogram: abnormal (abnormal) Magnetic resonance imaging revealed subepicardial, midventricular inferior and apical anterior late gadolinium enhancement of the lateral wall with myocardial edema. In addition,	25 years old male with unknown medical history who 3 days after the 2nd dose experiencedfever, headache arthralgias and dyspnea and was found to have elevated troponin, abnormal EGC, Echo and cMRI, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and ECG results; a causal relationship cannot be excluded due to the lack of other information.

Case ID	WW Identifier	Narrative	MAH Comment
		minimal pericardial effusion and discrete late enhancement of the pericardium were found.. On an unknown date, Blood test: abnormal (abnormal) Significantly elevated cardiac enzymes/structural proteins were found by laboratory analysis (troponin T 866 ng/L, reference range < 49 ng/L).. On an unknown date, Electrocardiogram: normal (normal) Accentuated ST segments above V2-V5 were seen electrocardiographically. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered MYOCARDITIS (Acute perimyocarditis) to be possibly related. Patient had no other previous known diagnoses or allergies and it was unknown if patient was consuming nicotine or alcohol. The patients eGFR (MDRD) lab test was 93.58 mL/min. Based on lab examinations of patient acute peri-myocarditis was diagnosed. Concomitant medication details was reported. The patient was not taking any medications on admission. Patient was treated with analgesic/anti-inflammatory therapy with ibuprofen 3x600 mg for 2 weeks, pantoprazole, and colchicine 0.5 mg/d for at least 3 months for peri-myocarditis. The patient had suffered from fever, headache arthralgias and dyspnea from 12-SEP-2021.On14-SEP-2021, hospitalization occurred due to chest pain (difficulty breathing, burning chest, stabbing heartbeat, difficulty inhaling even at rest).On admission, a 25 year old patient who was orientated in all respects, presented in stable general and normal nutritional status. Clinically, the patient was unremarkable and hemodynamically stable. A cardiac	

Case ID	WW Identifier	Narrative	MAH Comment
		checkup was scheduled for 3 months time. The patient was discharged to home on 16-SEP-2021 in good general condition at his own request. Company comment: This case concerns a 25 year old male with no reported history who experienced the serious, listed AESI of Myocarditis 3 days after dose 2 of Spikevax. Re-challenge is not applicable for dose 2. Benefit-risk relationship of Spikevax is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 20-Oct-2021: Translation received on 22-OCT-2021 contains: Updated medical history information in narrative, Added comments for lab tests, Dosage text, Event verbatim and Narrative updated.	
4.1(b)	4.1(b)	This case was initially received via 4.1(b) Pharmaceuticals (Reference number: 4.1(b)) on 15-Oct-2021. The most recent information was received on 19-Oct-2021 and was forwarded to Moderna on 28-Oct-2021. This case, initially reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref, 4.1(b) On 19-Oct-2021, follow-up information was reported by a physician via a medical representative. On 15-Sep-2021, the patient received the 1st dose of this vaccine. On 13-Oct-2021, the patient received the 2nd dose of this vaccine. On 14-Oct-2021, around 02:00, the patient was aware of precordial tightness. In the morning, chest pain and pyrexia of 37.7 degrees Celsius developed, and the patient visited a medical institution where the patient was vaccinated. At 16:30, the patient was recommended to go to another hospital and visited. CPK increased to 2,400. The patient was hospitalized for myocarditis. On 19-Oct-2021, the symptoms were resolving. The outcome of myocarditis was reported as resolving. No follow-up investigation will be made. Follow-up received on 19-OCT-2021 Updated: Reporter Information, Lab Data, Event Information, Narrative, Reporter Comments	

Case ID	WW Identifier	Narrative	MAH Comment
		Company Comment: The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	
4.1(b)	4.1(b)	This case was received via 4.1(b) Pharmaceuticals (Reference number: 4.1(b) on 19-Oct-2021 and was forwarded to Moderna on 21-Oct-2021. This case, initially reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref, 4.1(b) On an unknown date, the patient received the 1st dose of this vaccine. On an unknown date, body temperature before the vaccination: 36.5 degrees Celsius. On 05-Oct-2021, at 10:51, the patient received the 2nd dose of this vaccine. On 06-Oct-2021, at night, pyrexia of 39 degrees Celsius developed. Antipyretics were taken. On 07-Oct-2021, in the early evening, pyrexia went down. On 08-Oct-2021, at around 00:00, myocarditis developed, and the patient was aware of chest pain. The patient was raced to a hospital. Electrocardiogram showed no abnormalities, but blood test showed high troponin T (867.7 pg/mL) and CRP (3.57 mg/dL) levels, and the patient was admitted to the hospital for follow-up. At night, the symptoms improved. On 09-Oct-2021, the symptoms resolved, and the patient was discharged from the hospital. The outcome of pyrexia and myocarditis was reported as resolved. Follow-up investigation will be made. Company Comment: The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	
4.1(b)	4.1(b)	This regulatory authority case was reported by a physician and describes the occurrence of INFLUENZA LIKE ILLNESS (Influenza like illness) and MYOCARDITIS (Myocarditis) in a 26-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) (batch nos. 3002918 and 3004215) for SARS-CoV-2 immunisation. No Medical History information was reported.	This is not a case of myocarditis. Noth the ECG and rhe Echo showed normal results. Only the troponin was elevated. No other information is available that may explained the high levels of troponin and the event of retrosternal pain

Case ID	WW Identifier	Narrative	MAH Comment
		On 16-Jun-2021, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form. On 28-Jul-2021, received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) dosage was changed to 1 dosage form. On 29-Jul-2021, after starting mRNA-1273 (COVID-19 Vaccine Moderna), the patient experienced INFLUENZA LIKE ILLNESS (Influenza like illness) (seriousness criterion hospitalization). On 30-Jul-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). On 03-Aug-2021, MYOCARDITIS (Myocarditis) was resolving. In August 2021, INFLUENZA LIKE ILLNESS (Influenza like illness) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 31-Jul-2021, Electrocardiogram: normal (normal) Regular and normal sinus rhythm at 81/min, no atrioventricular block with PR interval at 120 msec, narrow QRS at 89 msec, QRS axis at 27°, negative T waves in V1 and V2 and normal (normal) ECG (H1): generally applicable to the first, negative T waves in V1, but normalization of T waves in V2. On 31-Jul-2021, Troponin T: 246 ng/ml (High) 246 ng/ml and 327 ng/ml (High) 327 ng/ml. On 02-Aug-2021, Echocardiogram: normal (normal) Non-dilated, non-hypertrophic left ventricle with good systolic function (left ventricular ejection fraction calculated at 60%), despite very slight basal and mid inferior hypokinesia. Filling pressure considered normal. Left atrium of normal volume. Tricuspid aortic valve, normal opening and no [regurgitation]. Mitral valve normal in appearance, without leakage. Right ventricle not dilated, with overall function intact. No pericardial	

Case ID	WW Identifier	Narrative	MAH Comment
		effusion. Aortic root normal in size. Inferior vena cava not dilated with good respiratory fluctuation. Tricuspid valve normal in appearance, with no detectable [regurgitation].. On 02-Aug-2021, Troponin T: 1458 ng/ml (High) 1458 ng/ml. On 05-Aug-2021, Troponin T: 99 ng/l (High) 99 ng/L. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter did not provide any causality assessments. Concomitant product was not provided by the reporter. Patient reported that After receiving 2nd dose he experienced fever like symptoms, asthenia, myalgia, lack of appetite associated with profuse sweating, On 30-jul-2021 he experienced onset of retrosternal pain with progressive worsening, not alleviated by taking Paracetamol and Ibuprofen, it is adiation to the shoulder. Patient done with laboratory test On 31-Jul-2021 heart rate 71/min, blood pressure measured at 120/74 mmHg, temperature of 36.4 Celcius, and saturation at 98% in ambient air. Leukocytes at 10 g/L, Hb at 150 g/L, platelets at 160 g/L, CRP at 56.3 mg/L, D-dimers at 346 mcg/L. Patient received Ibuprofen, level II analgesia and Paracetamol as a treatment. Most recent FOLLOW-UP information incorporated above includes: On 20-Oct-2021: Translation received On 25-Oct-2021: Updated dosage text, lab data and case narrative.	
4.1(b)	4.1(b)	This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myopericarditis) in a 39-year-old male patient who received mRNA-1273 (COVID-19	39 years old male with unknown medical history who 2 days after the 2nd dose experienced chest pain that increased with inspiration, and dyspnoea on exertion. Patient was hospitalized next day and was found to have elevated troponin, CRP and

Case ID	WW Identifier	Narrative	MAH Comment
		Vaccine Moderna) for COVID-19 vaccination. Concurrent medical conditions included Hashimoto's thyroiditis. Concomitant products included LEVOTHYROXINE SODIUM (EUTHYROX) for an unknown indication. On 20-Aug-2021, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 100 microgram. On 17-Sep-2021, received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) dosage was changed to 100 microgram. On 19-Sep-2021, after starting mRNA-1273 (COVID-19 Vaccine Moderna), the patient experienced MYOCARDITIS (Myopericarditis) (seriousness criteria hospitalization and medically significant). On 22-Sep-2021, MYOCARDITIS (Myopericarditis) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 20-Sep-2021, Blood creatine phosphokinase: 281 (High) 281 U/L high. On 20-Sep-2021, C-reactive protein increased: 132 (High) 132 mg/L increased. On 20-Sep-2021, Echocardiogram: normal (normal) Echocardiography revealed normal LVEF (60%) and no structural changes.. On 20-Sep-2021, Electrocardiogram: normal (normal) An ECG showed ST depressions in lead III and T-negativity in AVL and AVR;. On 20-Sep-2021, Troponin increased: 442 (High) 442 ng/L elevation. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered MYOCARDITIS (Myopericarditis) to be possibly related.	abnormal EGC, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and ECG results; a causal relationship cannot be excluded due to the lack of other information.

Case ID	WW Identifier	Narrative	MAH Comment
		On 19-Sep-2021 at 03:00 a.m., the patient developed stabbing chest pain on both sides. Over the course, the pain increased to VAS 8/10. Pain increased with deep inspiration. In addition, the patient suffered from dyspnea on exertion (NYHA III according to the information provided by the reporter). On 20-Sep-2021, the patient presented clinically and was hospitalized. On 22-Sep-2021, due to significant regression of symptoms, inflammation and biomarkers, the patient could be discharged to his home with as-needed pain medication. No treatment medication reported. Company comment: This case concerns a 39-year-old, male patient with medical history of Hashimoto's thyroiditis, who experienced the expected event of myocarditis, which required hospitalization. The event occurred approximately 2 days after the second dose of Moderna COVID-19 Vaccine. The patient developed stabbing chest pain on both sides. Pain increased with deep inspiration. In addition, the patient suffered from dyspnea on exertion, presented clinically and was hospitalized. An ECG showed ST depressions in lead III and T-negativity in AVL and AVR, blood creatine phosphokinase was 281 U/L high and troponin was increased: 442 ng/L elevation. The event resolved 3 days later. The rechallenge was not applicable as events occurred after second dose and no further dosing was reported or planned, based on information provided. The reporter assessed the events as related to the product. The benefit-risk relationship of Moderna COVID-19 Vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 20-Oct-2021: Translated document received on 26-Oct-2021	

Case ID	WW Identifier	Narrative	MAH Comment
		contains updated lab data and narrative.	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 20-Oct-2021 and was forwarded to Moderna on 20-Oct-2021. This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myocarditis) in a 29-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The patient's past medical history included Adenoidectomy. Concurrent medical conditions included Obesity and Penicillin allergy. On 01-Oct-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 02-Oct-2021, after starting mRNA-1273 (Spikevax), the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Myocarditis) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 03-Oct-2021, C-reactive protein (0-6): 22 (High) High-sensitivity C-reactive protein- 22 milligram per litre. On 03-Oct-2021, N-terminal prohormone brain natriuretic peptide (0-100): 62 (normal) 62 picogram per millilitre. On 03-Oct-2021, Troponin I (0-17.5): 2424 (High) High Sensitive troponin I- 2424 nanogram per litre. On 04-Oct-2021, C-reactive protein (0-6): 18 (High) High-sensitivity C-reactive protein- 18 milligram per litre. On 04-Oct-2021, Troponin I (0-17.5): 1451 nanogram per litre (High) High Sensitive troponin I- 1451 nanogram per litre.	29 years old male with medical history of adenoidectomy and obesity who next day after the 2nd dose was found to have elevated troponin, NT-proBNP, CRP, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin; a causal relationship cannot be excluded due to the lack of other information.

Case ID	WW Identifier	Narrative	MAH Comment
		For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medication information provided by the reporter. No treatment medication information was provided. Company Comment : This case concerns a 29 year old male patient with medical history of obesity who experienced the expected event of myocarditis. The event occurred approximately 1 day after the second dose of the Moderna COVID-19 vaccine. The rechallenge was unknown. Patient's history of obesity remains a confounder. The benefit-risk relationship of the Moderna COVID-19 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 20-Oct-2021: Translated document received on 22 Oct 2021 includes medial history.	
4.1(b)	4.1(b)	This case was received via 4.1(b) Pharmaceuticals (Reference number: 4.1(b) on 11-Oct-2021 and was forwarded to Moderna on 21-Oct-2021. This case, reported by a physician via the Drug Information Center, and reported by a physician, was received by 4.1(b) Pharmaceutical Company Limited via Moderna's adverse reaction reporting site (4.1(b) and reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref, 4.1(b) The patient had a history of allergy to inhalation drug which was taken for common cold in childhood. The patient had a drinking habit, and hepatic function disorder was indicated in a medical checkup. The patient had a history of surgery.	

Case ID	WW Identifier	Narrative	MAH Comment
		On 03-Sep-2021, the patient received the 1st dose of the vaccine. On an unknown date, acute enteritis developed. On 13-Sep-2021, the patient started taking an over-the-counter cold medicine for the treatment of acute enteritis. On 15-Sep-2021, the patient stopped taking the over-the-counter cold medicine. On 01-Oct-2021, at 11:30, the patient received the 2nd dose of the vaccine. Pyrexia developed. On 03-Oct-2021, at 21:00, chest pain and queasy developed at night. The patient saw how the condition would be. The patient had not caught a cold in recent days. On 04-Oct-2021, on awakening, the symptoms had improved, but the patient had a recurrence and thus visited a hospital. The patient was transferred to the reporting hospital. As wide range of ST elevation was shown in electrocardiogram with increased CPK (CPK = 1,794), the patient was admitted to the hospital with a diagnosis of acute myocarditis. Oedema and enlargement of cardiac muscles were shown by MRI and UCG. Cardiac catheterization of both sides of heart and myocardial biopsy were performed on the day of admission. The findings of nonspecific inflammation were only mild fibrosis and lymphocytic infiltration. No significant stenosis was found in the coronary artery with cardiac function retained, and there were no signs of heart failure. Administration of 2 tablets of 1.25 mg of carvedilol distributed in 2 divided doses (after breakfast and after dinner) was started. Use of ethanol for disinfection was started for skin symptoms. PR: 101/min, BP: 154/91 mmHg, BT: 37.9 degrees Celsius,	

Case ID	WW Identifier	Narrative	MAH Comment
		and SpO2: 97% (RA). No anemia or yellowing of palpebral conjunctiva, no swelling in the cervical lymph nodes, no enlargement of the thyroid, and no distention of the neck veins were found. Respiratory sounds were clear without bilateral differences, and no cardiac murmur was heard. No appreciable problems were found in the abdomen, and no oedema was seen in the lower limbs. On 05-Oct-2021, transthoracic echocardiography was performed and showed no problems in the cardiac function. On 06-Oct-2021, fever subsided. PR: 56/min, BP: 118/66 mmHg, and SpO2: 95%-98% (RA). Respiratory sounds were clear without bilateral differences, and no cardiac murmur was heard. No oedema was seen in the lower limbs. Cardiac function was retained without pericardial effusions. Although troponin level showed no significant change, CK and CRP showed improving tendencies. The sheath was removed. Biopsy showed no eosinophilic infiltration or giant cells. The result of MRI was consistent with perimyocarditis. On 08-Oct-2021, PR: 98/min, BP: 134/92 mmHg, BT: 37.5 degrees Celsius, and SpO2: 97% (RA). Respiratory sounds were clear without bilateral differences, and no cardiac murmur was heard. The patient had low-grade fever. Although slight increases in WBC and CRP were noted, other cardiac enzymes showed improving tendencies. On 09-Oct-2021, the symptoms were resolving. On 11-Oct-2021, PR: 89/min, BP: 139/92 mmHg, BT: 36.7 degrees Celsius, and SpO2: 97% (RA). In rehabilitation, increased heart rate during exertion was prominent. The	

Case ID	WW Identifier	Narrative	MAH Comment
		result of blood test was smoothly improving. The outcome of acute enteritis was unknown. The outcome of acute myocarditis was reported as resolving. Follow-up investigation will be made. Company Comment: The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 21-Oct-2021 and was forwarded to Moderna on 21-Oct-2021. This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Perimyocarditis) in an 18-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The patient's past medical history included Depressive episode. Concomitant products included MELATONIN (MELATONIN AGB) from 28-May-2021 to an unknown date for an unknown indication. On 05-Oct-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 08-Oct-2021, after starting mRNA-1273 (Spikevax), the patient experienced MYOCARDITIS (Perimyocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Perimyocarditis) was resolving. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.	

Case ID	WW Identifier	Narrative	MAH Comment
		Treatment information was not provided. Company comment: This case concerns an 18-year-old male with no relevant medical history who experienced the listed, serious AESI event of myocarditis 3 days after receiving the second dose of Spikevax (batch not provided). The patient required hospitalization. The event was resolving at the time of the report. Treatment was not provided. No data for the first dose was provided, so rechallenge is not applicable. The benefit-risk relationship of Spikevax is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 21-Oct-2021: Translation received on 25 Oct 2021,with translated event verbatim.	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number:4.1(b) on 21-Oct-2021 and was forwarded to Moderna on 21-Oct-2021. This regulatory authority case was reported by a pharmacist and describes the occurrence of MYOCARDITIS (Myocarditis) and INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (late second dose) in a 26-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 21025 and 3004234) for COVID-19 vaccination. The patient's past medical history included Myocarditis. Concurrent medical conditions included Hypertension. On 06-Aug-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 20-Sep-2021, received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to 1 dosage form. On 24-Sep-2021, after starting mRNA-1273 (Spikevax), the patient experienced	

Case ID	WW Identifier	Narrative	MAH Comment
		MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). On an unknown date, the patient experienced INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (late second dose) (seriousness criterion medically significant). At the time of the report, MYOCARDITIS (Myocarditis) was resolving and INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (late second dose) had resolved. 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 26-year-old male patient with relevant medical history of Myocarditis and Hypertension who experienced serious expected event of Myocarditis. The event occurred four days following the vaccination with the second dose of the Spikevax. As per SD no rechallenge was done, and therefore, recurrence is not applicable. Very limited information regarding clinical course of the event has been provided at this time. The medical history of Myocarditis and Hypertension remains a confounder. The benefit-risk relationship of Spikevax is not affected by this report. Causality for the event Inappropriate schedule of product administration is assessed as not applicable.	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 21-Oct-2021 and was forwarded to Moderna on 21-Oct-2021. This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (4.1(b) in a 26-year-old female patient who	

Case ID	WW Identifier	Narrative	MAH Comment
		received mRNA-1273 (Spikevax) for COVID-19 vaccination. No Medical History information was reported. On 13-Jun-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 12-Jul-2021, received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. On 05-Sep-2021, the patient experienced MYOCARDITIS (4.1(b) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (4.1(b) was resolving. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medications were provided by the reporter. No treatment information was provided by the reporter. Company comment: This case concerns a 26 year-old female patient with no medical history provided, who experienced the expected event of Myocarditis(hospitalization not expected) (seriousness criteria hospitalization and medically significant). This event occurred approximately 2 months after the second dose of Spikevax. The reporter did not provide any causality assessments. The benefit-risk relationship of Spikevax is not affected by this report.	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 21-Oct-2021 and was forwarded to Moderna on 21-Oct-2021. This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (MYOCARDITIS) in a 20-year-old female patient who received mRNA-1273 (Spikevax)	

Case ID	WW Identifier	Narrative	MAH Comment
		(batch no. 3005697) for COVID-19 vaccination. No Medical History information was reported. On 22-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 25-Sep-2021, the patient experienced MYOCARDITIS (MYOCARDITIS) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (MYOCARDITIS) had not resolved. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. No relevant concomitant medications were reported. Treatment information was not provided. Company's comment: This case concerns a 20-year old, female subject with no relevant medical history, who experienced the serious expected event of Myocarditis(AESI). The event, which resulted in hospitalization, occurred 3 days after the second dose of Spikevax. Rechallenge is not applicable as no information about the first dose is available. The benefit-risk relationship of Spikevax is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 21-Oct-2021: Translation Document received on 22-OCT-2021 contains translated event verbatim.	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 21-Oct-2021 and was forwarded to Moderna on 21-Oct-2021. This regulatory authority case was reported by a consumer and	

Case ID	WW Identifier	Narrative	MAH Comment
		describes the occurrence of PERICARDITIS (Pericarditis) in a 39-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3003659) for COVID-19 vaccination. No Medical History information was reported. On 21-Jul-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 11-Aug-2021, after starting mRNA-1273 (Spikevax), the patient experienced PERICARDITIS (Pericarditis) (seriousness criterion medically significant). On 25-Aug-2021, PERICARDITIS (Pericarditis) had resolved. Concomitant medications were not reported. Treatment information was not provided. Company comment: This case concerns a 39-year-old, male patient with no relevant medical history, who experienced the expected AESI of pericarditis. The event occurred 3 weeks after administration of the second dose of Spikevax. The rechallenge was not applicable as no additional dosing will be given. The patient's gender remains a confounder. The benefit-risk relationship of Spikevax is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 21-Oct-2021: Translation document received on 25-Oct-2021, dosage text and event verbatim translated.	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 22-Oct-2021 and was forwarded to Moderna on 22-Oct-2021. This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (Rapid heart rate, increased pulse, fever: diagnosis of heart) in a 30-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 3004233) for Prophylactic vaccination. No Medical History information was reported.	

Case ID	WW Identifier	Narrative	MAH Comment
		On 14-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 07-Oct-2021, after starting mRNA-1273 (Spikevax), the patient experienced MYOCARDITIS (Rapid heart rate, increased pulse, fever: diagnosis of heart) (seriousness criterion medically significant). At the time of the report, MYOCARDITIS (Rapid heart rate, increased pulse, fever: diagnosis of heart) was resolving. No concomitant medications reported by reporter. No treatment medications provided by the reporter. Fever was lowered, tachycardia was lessened. Continued mild chest pain, fatigue, loss of appetite. Treatment with 4.1(b) 600, moxifloxacin for 7 days. Additionally, Colchicine [Ysat] and ivabradine for a total of 4 weeks/at least until the follow-up visit. Company Comment This case concerns a 30-year-old, female patient with no relevant medical history, who experienced the expected event of myocarditis. The event myocarditis occurred 23 days after the second dose of mRNA-1273 vaccine administration. The rechallenge was 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 22-Oct-2021: Translation document received on 25-Oct-2021 included: event verbatim and sender's comments translated.	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b) on 22-Oct-2021 and was forwarded to Moderna on 22-Oct-2021. This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (Myocarditis) in a 22-year-old male patient who received mRNA-1273 (Spikevax) for Prophylactic vaccination. No Medical History information was reported. On 08-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 01-Oct-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization, medically significant and life threatening). At the time of the report, MYOCARDITIS (Myocarditis) outcome was unknown. Concomitant medications were not reported. Treatment medications were not reported. Additional information included since 01-Oct-2021, patient had general [KH] feeling, fever, chills, chest pain at night. Myocarditis confirmed by cardiac MRI on 07-Oct. Completed Company: This case concerns a 22-year-old, male patient with no relevant medical history, who experienced the expected serious (Life-threatening and hospitalization) event of Myocarditis. The event of Myocarditis was also	

Case ID	WW Identifier	Narrative	MAH Comment
		upgraded to serious (Medically Significant) as per Important medical event terms list (MedDRA version 24.0). The event occurred approximately 24 days after the second dose of Spikevax. The rechallenge was not applicable as the AE occurred after the second dose. Since 01-Oct-2021, patient had general feeling, fever, chills, chest pain at night. Myocarditis confirmed by cardiac MRI on 07-Oct. The event is consistent with the current understanding of the mechanism of action of the vaccine. The benefit-risk relationship of Spikevax is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 22-Oct-2021: Translation received on 25-Oct-2021 and sender's comment translated.	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b) on 25-Oct-2021 and was forwarded to Moderna on 25-Oct-2021. This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myocarditis) in a 34-year-old male patient who received mRNA-1273 (Spikevax) for Prophylactic vaccination. No Medical History information was reported. On 26-Aug-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 31-Aug-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Myocarditis) had not resolved. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medications reported. No treatment information was provided. Course of adverse events and measures: On 31 Aug 2021, sudden chest pain, troponin elevation, monitoring in ICU, cardiac catheterization initially rejected,	

Case ID	WW Identifier	Narrative	MAH Comment
		performed on a supplementary basis during course. Course uncomplicated without cardiac arrhythmia, troponin but clearly increasing during the course, protracted monitoring in ICU. LV function always unremarkable. Company comment: This case concerns a 34 year-old, male with no relevant history reported, who experienced the serious expected event of Myocarditis (AESI). The event of Myocarditis was also upgraded to serious (Medically Significant) as per Important medical event terms list. The event occurred approximately 5 days after the second dose of Spikevax. The rechallenge is not applicable since the event occurred after the second dose and another dose will not be administered. The benefit-risk relationship of the vaccine in not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 25-Oct-2021: Translated document received. Reporter's comments provided.	
4.1(b)	4.1(b)	This case was received via 4.1(b) Pharmaceuticals (Reference number: 4.1(b) on 20-Oct-2021 and was forwarded to Moderna on 25-Oct-2021. This case, initially reported to the 4.1(b) by a (physician), was received via the 4.1(b) (Ref, 4.1(b) Suspected myocarditis was assessed as serious by the MAH. On 15-Sep-2021, the patient received the 1st dose of the vaccine. After the vaccination, decreased blood pressure developed. The patient lay in a bed for about 30 minutes and returned home. On 13-Oct-2021, the patient received the 2nd dose of the vaccine. The patient received the vaccine lying on a bed. No poorly feeling had developed throughout the course. On unknown date-Oct-2021, the patient experienced pyrexia. On 15-Oct-2021, at night, the patient had no particular symptoms. On 16-Oct-2021, in the morning, the patient had a pain around the heart. The patient had a tingling pain, queasy feeling, and chest pain. The chest pain appeared and disappeared repeatedly. Although the patient did not vomit, queasy persisted. Myocarditis was suspected.	

Case ID	WW Identifier	Narrative	MAH Comment
		On an unknown date, as of reporting, the patient did not have pyrexia. The outcome of decreased blood pressure was unknown. The outcome of pyrexia was reported as recovered. The outcome of suspected myocarditis, chest pain, and queasy was reported as ongoing and unchanged. Follow-up investigation will be made. Company Comment: The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b) on 25-Oct-2021 and was forwarded to Moderna on 25-Oct-2021. This regulatory authority case was reported by a physician and describes the occurrence of CHEST PAIN (Thorax pain), DYSPNOEA EXERTIONAL (Exertional dyspnoea), FATIGUE (Fatigue), INFLUENZA LIKE ILLNESS (Flu like symptoms) and PERICARDITIS (Pericarditis) in a 32-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The patient's past medical history included Gluten intolerance. Concurrent medical conditions included Alcohol use (Reported the use of alcohol rarely in a little amount). On 20-Jun-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 100 microgram. On 01-Jul-2021, the patient experienced CHEST PAIN (Thorax pain) (seriousness criterion medically significant), DYSPNOEA EXERTIONAL (Exertional dyspnoea) (seriousness criterion medically significant), FATIGUE (Fatigue) (seriousness criterion medically significant), INFLUENZA LIKE ILLNESS (Flu like symptoms) (seriousness criterion medically significant) and PERICARDITIS (Pericarditis) (seriousness criterion medically significant). At the time of	

Case ID	WW Identifier	Narrative	MAH Comment
		the report, CHEST PAIN (Thorax pain), DYSPNOEA EXERTIONAL (Exertional dyspnoea), FATIGUE (Fatigue), INFLUENZA LIKE ILLNESS (Flu like symptoms) and PERICARDITIS (Pericarditis) had not resolved. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Concomitant product use included pantoprazole 20 mg as 1-0-0. From 07 Jul 2021 to 20 Jul 2021 the patient had consumed Ibuprofen 600mg as 3x1. No further treatment information was provided. Following transient flu-like infection symptoms for a few days, sharp chest pain, fatigue, and exertional dyspnea NYHA II-III had occurred later. The patient had excellent resilience during competitive sports like rowing. She experienced pericarditis after SARS-CoV-2 immunization which was a mild peri myocarditis that cannot be identified by echocardiography but may be possible by paraclinical investigation. Cardiac MRI was not performed due to a lack of therapeutic consequence. Company comment: This is a regulatory case concerning a 32-year-old, female patient with medical history of gluten intolerance , who experienced the serious unexpected events of CHEST PAIN, DYSPNOEA EXERTIONAL, FATIGUE, INFLUENZA LIKE ILLNESS and the serious expected and AESI event of PERICARDITIS 12 days after receiving the second dose of spikevax. Time to onset for the first dose is unknown. The benefit-risk relationship of Spikevax is not affected by this report. Most recent FOLLOW-UP information incorporated above includes:	

Case ID	WW Identifier	Narrative	MAH Comment
		On 25-Oct-2021: Translation received on 26 Oct 2021. Added patients medical history and dose number. Narrative was also updated.	
4.1(b)	4.1(b)	This case was received via 4.1(b) Pharmaceuticals (Reference number: 4.1(b)) on 20-Oct-2021 and was forwarded to Moderna on 26-Oct-2021. This case, initially reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref, 4.1(b) On an unknown date, the patient received the 1st dose of this vaccine. On 26-Jul-2021, the patient received the 2nd dose of this vaccination. Pyrexia developed. On 28-Jul-2021, the patient visited another hospital with chest pain. On 29-Jul-2021, at 04:00, myocarditis developed. The patient visited an emergency department of the reporting hospital and was admitted. ECG showed ST elevation in 2, 3, aVF, and V2-6. Elevated CK and troponin were noted. There was no stenosis in the emergency catheterization, and autoimmune myocarditis or the like was negative in the myocadiac biopsy. On an unknown date, after that, the patient rested, and no cardiac failure or fatal arrhythmia occurred with NSAIDs, and chest pain also improved. On 02-Aug-2021, the patient was discharged from the hospital. On 10-AUg-2021, the symptoms were resolving. The outcome of pyrexia and myocarditis was reported as resolving. Follow-up investigation will be made.	22 years old male with unknown medical history who 3 days after the 2nd dose experienced chest pain and was found to have elevated troponin, and abnormal EGC, myocardial biopsy was normal, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and ECG results; a causal relationship cannot be excluded due to the lack of other information.

Case ID	WW Identifier	Narrative	MAH Comment
		Company Comment: The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	
4.1(b)	4.1(b)	This regulatory authority case was reported by a physician and describes the occurrence of CHEST PAIN (sudden, respiro-dependent, diffuse chest pain between the scapulae radiating to the right arm), HYPERHIDROSIS (episodes of sweating after injection) and MYOCARDITIS (Myocarditis) in a 20-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 immunisation. No Medical History information was reported. On 11-Oct-2021, the patient received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form. On 11-Oct-2021, after starting mRNA-1273 (COVID-19 Vaccine Moderna), the patient experienced HYPERHIDROSIS (episodes of sweating after injection) (seriousness criteria hospitalization and medically significant). On 13-Oct-2021, the patient experienced CHEST PAIN (sudden, respiro-dependent, diffuse chest pain between the scapulae radiating to the right arm) (seriousness criteria hospitalization and medically significant). On 14-Oct-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, CHEST PAIN (sudden, respiro-dependent, diffuse chest pain between the scapulae radiating to the right arm) and MYOCARDITIS (Myocarditis) had not resolved and HYPERHIDROSIS (episodes of	20 years old male with unknown medical history who 2 days after the 2nd dose experienced chest pain and wthe next day as found to have elevated troponin, Ck, CRP, abnormal EGC, SARS-CoV-2 negative, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and ECG results; a causal relationship cannot be excluded due to the lack of other information.

Case ID	WW Identifier	Narrative	MAH Comment
		sweating after injection) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 14-Oct-2021, Blood creatine phosphokinase (47-222 international unit per litre): 514 international unit per litre (High) 514 iU/L and 909 international unit per litre (High) 909 iU/L. On 14-Oct-2021, C-reactive protein (0-10 milligram per litre): 55 milligram per litre (High) high. On 14-Oct-2021, Chest X-ray: normal (normal) Normal. On 14-Oct-2021, Electrocardiogram: abnormal (abnormal) Elevation in DII-III-aVF, V4-6 with descending PR interval DII-III-avF. On 14-Oct-2021, SARS-CoV-2 test: negative (Negative) Negative. On 14-Oct-2021, Troponin (Unknown-14 ng/L): 838 ng/L (High) 838 ng/L and 1096 ng/L (High) 1096 ng/L. On 14-Oct-2021, White blood cell count (4-11): 13 (High) high. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered CHEST PAIN (sudden, respiro-dependent, diffuse chest pain between the scapulae radiating to the right arm), HYPERHIDROSIS (episodes of sweating after injection) and MYOCARDITIS (Myocarditis) to be possibly related. No concomitant medications were reported. Patient was presented to Emergency during the night of 13-Oct to 14-Oct for respirodependent, diffuse chest pain, especially between the scapulae and radiating to the right arm, and whose sudden onset awakened him. Patient had family history of history of myocarditis following a viral disease.	

Case ID	WW Identifier	Narrative	MAH Comment
		Lab data also included of, LDH 285 U/L, AST 101 U/L, remainder of liver and kidney function panel aligned. Analgesic therapy with Paracetamol was started, and a cardiac MRI was planned. Most recent FOLLOW-UP information incorporated above includes: On 25-Oct-2021: Translation document received on 27-Oct-2021: Lab data, event verbatim, narrative and senders comment updated.	
4.1(b)	4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b)) on 24-Oct-2021 and was forwarded to Moderna on 24-Oct-2021. This regulatory authority case was reported by a consumer and describes the occurrence of PERICARDITIS (Pericarditis) and MEDICATION ERROR (Medication error) in a 40-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for Ill-defined disorder. No Medical History information was reported. On 30-Jun-2021, the patient received first dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (Parenteral) 1 dosage form. On 06-Sep-2021, received second dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (Parenteral) dosage was changed to 1 dosage form. On 14-Sep-2021, after starting mRNA-1273 (Moderna CoviD-19 Vaccine), the patient experienced PERICARDITIS (Pericarditis) (seriousness criterion medically significant). On an unknown date, the patient experienced MEDICATION ERROR (Medication error) (seriousness criterion medically significant). On 30-Sep-2021, PERICARDITIS (Pericarditis) had resolved with sequelae. At the time of the report, MEDICATION ERROR (Medication error) outcome was unknown.	COnsumer report on a 40 years old male with unknown medical history who 8 days after the 2nd dose experienced chest pain and palpitations, and was found to have elevated troponin, and abnormal cMRI, and was diagnosed with pericarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and cMRI results; a causal relationship cannot be excluded due to the lack of other information.

Case ID	WW Identifier	Narrative	MAH Comment
		mRNA-1273 (Moderna CoviD-19 Vaccine) (Parenteral) dosing remained unchanged. No concomitant medications were reported. Treatment information was not provided. The patients past medical history included 4.1(b) syndrome and was reported that it was recently confirmed. Patient lab data included Troponin high" , MRI result: confirmed pericarditis. The details reported included strong chest pain, palpitations, high troponin, and pericarditis that got confirmed from MRI. The patient was administered with Moderna vaccine for COVID 19. Based on the guidelines action was there to avoid aspiration due to increased pain in new born and toddlers but the one reported was related to adult. patient got every reason to believe that the vaccine itself is safe however the intramuscular administration must be performed with aspiration to avoid inadvertent intravenous administration." Company comment: This case concerns a 40-year-old, male patient with medical history of 4.1(b) syndrome, who experienced the expected, serious and AESI event of pericarditis. Medication error is also reported. The event occurred approximately 8 days after second dose of Spikevax. The rechallenge is unknown, as the outcome of the event is recovered and no additional dosing information was disclosed. The medical history of 4.1(b) syndrome, remains as a confounder. The benefit-risk relationship of Spikevax vaccine is not affected by this report.	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on	37 years old male with medical history of ADHD, obesity, gout, asthma, hypertension, and concomitant medications of

Case ID	WW Identifier	Narrative	MAH Comment
		25-Oct-2021 and was forwarded to Moderna on 25-Oct-2021. This regulatory authority case was reported by a physician and describes the occurrence of WHITE BLOOD CELL COUNT INCREASED (Leukocyte count increased), EJECTION FRACTION DECREASED (mildly impaired EF), TROPONIN INCREASED (Troponin increased), C-REACTIVE PROTEIN INCREASED (C-reactive protein increased), PYREXIA (Fever) and MYOCARDITIS (Myocarditis) in a 37-year-old male patient who received mRNA-1273 (Spikevax) for Prophylactic vaccination. The patient's past medical history included Attention deficit/hyperactivity disorder and Obesity. Concurrent medical conditions included Gout and Asthma bronchial. Concomitant products included BECLOMETASONE DIPROPIONATE, FORMOTEROL FUMARATE (FOSTER [BECLOMETASONE DIPROPIONATE;FORMOTEROL FUMARATE]) for Asthma bronchial, METHYLPHENIDATE HYDROCHLORIDE (MEDIKINET) for Attention deficit/hyperactivity disorder, REPEVAX from 23-Jul-2021 to an unknown date for Booster, ALLOPURINOL for Gout, PNEUMOCOCCAL VACCINE POLYSACCH 23V (PNEUMOVAX 23) for an unknown indication. On 24-Jun-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 23-Jul-2021, the patient experienced WHITE BLOOD CELL COUNT INCREASED (Leukocyte count increased) (seriousness criteria hospitalization and medically significant), EJECTION FRACTION DECREASED (mildly impaired EF) (seriousness criteria hospitalization and medically significant), TROPONIN INCREASED (Troponin increased) (seriousness criteria	methylphenidate HCL (labelled for cardiomyopathies), and who received a booster shot of Tdap-IPV, and Pneumovax 23 the same day he developed pyrexia, was hospitalized and found to have increased WBC, increased CRP, increased troponin, decreased ejection fraction, and was diagnosed with myocarditis. The diagnosis of myocarditis was 29 days after the 2nd dose of Spikevax. No other information was provided. Important information is missing in the report including why the patient was hospitalized, any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and the report of decreased ejection fraction, but it heavily confounded by the concurrent administration of the other two vaccines. A causal relationship cannot be excluded due to the lack of other information.

Case ID	WW Identifier	Narrative	MAH Comment
		hospitalization and medically significant), C-REACTIVE PROTEIN INCREASED (C-reactive protein increased) (seriousness criteria hospitalization and medically significant), PYREXIA (Fever) (seriousness criteria hospitalization and medically significant) and MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, WHITE BLOOD CELL COUNT INCREASED (Leukocyte count increased), EJECTION FRACTION DECREASED (mildly impaired EF), TROPONIN INCREASED (Troponin increased), C-REACTIVE PROTEIN INCREASED (C-reactive protein increased), PYREXIA (Fever) and MYOCARDITIS (Myocarditis) outcome was unknown. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Patient was treated with ASA 100 mg (temporarily limited according to myocardial biopsy) and Ramipril 2 x 2.5 mg. Company comment This case concerns a 37-year-old male patient with concurrent medical history of Obesity, Gout and bronchial asthma who experienced the expected event of myocarditis and unexpected events of pyrexia, white blood cell count increased, ejection fraction decreased, troponin increased and c-reactive protein increased. The events occurred approximately 1 month after second dose of mRNA-1273 (Spikevax). The rechallenge was not applicable as event occurred after second dose and no information provided about first dose. Though Myocarditis is consistent with the current understanding of the mechanism of action of the vaccine; however, this patient history of Obesity remains a confounder . The benefit-risk	

Case ID	WW Identifier	Narrative	MAH Comment
		relationship of mRNA-1273 Vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 25-Oct-2021: Translation Received on 28-OCT-2021. Updated medical history, event verbatim, dose details, action taken, inarrative and reporter's comments.	
4.1(b)	4.1(b)	This case was received via 4.1(b) Pharmaceuticals (Reference number: 4.1(b) on 14-Oct-2021 and was forwarded to Moderna on 27-Oct-2021. This case, reported by a pharmacist, was received by 4.1(b) via Moderna's adverse reaction reporting site (4.1(b) and reported to the 4.1(b) by a pharmacist, was received via the 4.1(b) (Ref, 4.1(b) The patient had coronary risk factors such as smoking and abnormal lipids. On 07-Sep-2021, the patient received the 1st dose of the vaccine. On 05-Oct-2021, at 12:40, the patient received the 2nd dose of the vaccine. At night, the patient experienced pyrexia, which persisted thereafter. On 06-Oct-2021, around 03:00, acute myocarditis developed. The patient had chest pain. The degree of pain fluctuated and persisted. On 07-Oct-2021, at 23:30, the patient was aware of taste disorder. Chest pain persisted. An emergency call was made, and the patient was transported and admitted to the reporting hospital. On 08-Oct-2021, before dawn, elevated cardiac enzymes were noted. As the patient had coronary risk factors, coronary angiography (CAG) was performed, showing no abnormalities. Echocardiography showed no abnormal left ventricular contraction. Inpatient conservative treatments were continued. On 14-Oct-2021, the patient was discharged from the hospital as the symptoms were resolving. The outcome of pyrexia, acute myocarditis, and taste disorder was reported as resolving. Follow-up was not possible due to lack of cooperation from the reporter. Company Comment: The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	
4.1(b)	4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b) on 26-Oct-2021	32 years old male with unknown medical history who 4 days after the 2nd dose experienced chest pain and was found to have elevated troponin,

Case ID	WW Identifier	Narrative	MAH Comment
		and was forwarded to Moderna on 26-Oct-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCARDITIS (Myocarditis), PERICARDITIS (Pericarditis) and CHEST PAIN (Chest pain) in a 32-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. On 03-Oct-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 07-Oct-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant), PERICARDITIS (Pericarditis) (seriousness criteria hospitalization and medically significant) and CHEST PAIN (Chest pain) (seriousness criterion hospitalization). The patient was hospitalized from 07-Oct-2021 to 09-Oct-2021 due to CHEST PAIN, MYOCARDITIS and PERICARDITIS. The patient was treated with IBUPROFEN (MOTRIN [IBUPROFEN]) for Myopericarditis, at an unspecified dose and frequency and COLCHICINE for Pericarditis, at an unspecified dose and frequency. At the time of the report, MYOCARDITIS (Myocarditis), PERICARDITIS (Pericarditis) and CHEST PAIN (Chest pain) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 07-Oct-2021, Cardiac imaging procedure: abnormal (abnormal) Cardiac MRI showed LGE indicative of myocarditis. On 07-Oct-2021, Catheterisation cardiac: normal (normal) normal.	abnormal EGC, Echo and cMRI, and was diagnosed with myopericarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and ECG, Echo and cMRI results; a causal relationship cannot be excluded due to the lack of other information.

Case ID	WW Identifier	Narrative	MAH Comment
		On 07-Oct-2021, Echocardiogram: abnormal (abnormal) focal WMA. On 07-Oct-2021, Electrocardiogram: abnormal (abnormal) abnormal. On 07-Oct-2021, Troponin: 1.31 (High) increased. On 07-Oct-2021, Wall motion score index: abnormal (abnormal) abnormal. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Concomitant medications was not reported.	
4.1(b)	4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b) on 26-Oct-2021 and was forwarded to Moderna on 26-Oct-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of CHEST PAIN (Chest pain) and MYOCARDITIS (Myocarditis) in a 25-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 076C21A) for COVID-19 vaccination. No Medical History information was reported. On 10-Oct-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 13-Oct-2021, the patient experienced CHEST PAIN (Chest pain) (seriousness criterion hospitalization) and MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, CHEST PAIN (Chest pain) and MYOCARDITIS (Myocarditis) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):	25 years old male with unknown medical history who 2 days after the 2nd dose experienced chest pain and was found to have elevated troponin, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin; a causal relationship cannot be excluded due to the lack of other information.

Case ID	WW Identifier	Narrative	MAH Comment
		On 13-Oct-2021, Troponin: increased (High) High. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. No concomitant medications were reported No treatment information was provided	
4.1(b)	4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b) on 26-Oct-2021 and was forwarded to Moderna on 26-Oct-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCARDITIS (Myocarditis) in a 36-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 047c21a) for COVID-19 vaccination. No medical history was provided by the reporter. Concomitant products included FUROSEMIDE, METOPROLOL TARTRATE and CALCITRIOL for an unknown indication. On 26-Sep-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 30-Sep-2021, after starting mRNA-1273 (Moderna COVID-19 Vaccine), the patient experienced MYOCARDITIS (Myocarditis) (seriousness criterion medically significant). At the time of the report, MYOCARDITIS (Myocarditis) outcome was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments.	

Case ID	WW Identifier	Narrative	MAH Comment
		Treatment medications were not provided.	
4.1(b)	4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b) on 26-Oct-2021 and was forwarded to Moderna on 26-Oct-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of CHEST PAIN (Chest pain), SENSORY DISTURBANCE (Sensory disturbance) and MYOCARDITIS (Myocarditis) in a 23-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 027A21A) for COVID-19 vaccination. No Medical History information was reported. On 04-Mar-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 06-Mar-2021, the patient experienced CHEST PAIN (Chest pain) (seriousness criterion hospitalization), SENSORY DISTURBANCE (Sensory disturbance) (seriousness criterion hospitalization) and MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). The patient was hospitalized for 2 days due to CHEST PAIN, MYOCARDITIS and SENSORY DISTURBANCE. The patient was treated with ASPIRIN [ACETYLSALICYLIC ACID] for Adverse event, at an unspecified dose and frequency. At the time of the report, CHEST PAIN (Chest pain), SENSORY DISTURBANCE (Sensory disturbance) and MYOCARDITIS (Myocarditis) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 07-Mar-2021, Blood test: abnormal (abnormal) Abnormal.	23 years old male with unknown medical history who 2 days after the 2nd dose experienced chest pain and sensory disturbances, and was found to have elevated troponin, abnormal EGC,abnormal Echo and normal chest x-ray, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and ECG and Echo results; a causal relationship cannot be excluded due to the lack of other information.

Case ID	WW Identifier	Narrative	MAH Comment
		On 07-Mar-2021, Catheterisation cardiac: diagnosed as myocarditis (abnormal) Officially diagnosed as myocarditis. On 07-Mar-2021, Chest X-ray: normal (normal) The chest x-ray came back fine.. On 07-Mar-2021, Echocardiogram: diagnosed as myocarditis (abnormal) Officially diagnosed as myocarditis. On 07-Mar-2021, Electrocardiogram: abnormal (abnormal) Slight abnormality. On 07-Mar-2021, Troponin: elevated (High) Elevated. In April 2021, Echocardiogram: 100 percent good to go (normal) 100 percent good to go. In April 2021, Electrocardiogram: 100 percent good to go (normal) 100 percent good to go. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. On 06-Mar-2021, at around 12:30, patient felt slight pain in sternum (middle of chest), that lasted less than a second and it felt similar to heartburn and patient felt it again and at approx. 07:30 pm that day patient had the same symptoms and also at 11:30 pm that night patient again had the same symptoms. On 07-Mar-2021, at the same location patient had the same feeling except time increased to a second and a half, a pinching sensation in the middle of the sternum. Patient reported to a clinic and was sent to hospital and had performed tests. The patient had EKG, chest x-ray and blood tests. They noted very slight abnormality on the EKG and the chest x-ray came back fine and patient had elevated Troponin. At that point, the patient was admitted to a local larger hospital. The patient had another EKG, echocardiogram and a cath exam with a camera and was	

Case ID	WW Identifier	Narrative	MAH Comment
		officially diagnosed as myocarditis. It was in the apex of heart-the very bottom tip. The patient was admitted for an overnight evaluation (two nights). Treatment included Ace inhibitor, beta blocker and normal aspirin for 30 days. After 30 days, patient went to Heart hospital doctor and patient had a follow up EKG and echo-cardiogram and was said it was 100 percent good to go, like nothing ever happened.	
4.1(b)	4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b) on 26-Oct-2021 and was forwarded to Moderna on 26-Oct-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCARDITIS (Myocarditis) in a 34-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 001C21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 26-Apr-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 26-Apr-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criterion medically significant). 26-Apr-2021, the patient experienced CHEST PAIN (Excessive chest pain for 2 days and then chest pain off). On an unknown date, the patient experienced CHEST PAIN (Chest pain on for the next 4 months). On 28-Apr-2021, CHEST PAIN (Excessive chest pain for 2 days and then chest pain off) had resolved. At the time of the report, MYOCARDITIS (Myocarditis) and	34 years old female with unknown medical history who same day after the 2nd dose experienced chest pain and was found to have abnormal Echo and cMRI, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the Echo results; a causal relationship cannot be excluded due to the lack of other information.

Case ID	WW Identifier	Narrative	MAH Comment
		CHEST PAIN (Chest pain on for the next 4 months) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 26-Apr-2021, Chest X-ray: normal (normal) Normal. On 26-Apr-2021, Echocardiogram: normal (normal) Normal. On 26-Apr-2021, Magnetic resonance imaging: abnormal (abnormal) Cardiac MRI showing myocarditis. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Concomitant product use was not provided by the reporter. No treatment information was provided.	
4.1(b)	4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b) on 26-Oct-2021 and was forwarded to Moderna on 26-Oct-2021. This regulatory authority retrospective pregnancy case was reported by an other health care professional and describes the occurrence of DYSPNOEA (Dyspnoea), INDUCED LABOUR (Induced labour), PREMATURE DELIVERY (Premature delivery), PERICARDITIS (Acute pericarditis) and MATERNAL EXPOSURE DURING PREGNANCY (Maternal exposure during pregnancy) in a 28-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 011D21A) for COVID-19 vaccination. Concurrent medical conditions included Allergy to antibiotic (Moxifloxacin). On 24-Sep-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine)	28 years old pregnant female with unknown medical history who next day after the 2nd dose of Spikevax experienced dyspnoea, was hospitalized and was found to have elevated inflammatory markers (not specified), elevated liver enzymes and abnormal Echo, and was diagnosed with pericarditis. Five days later labour was induced and she had a premature live baby 34 weeks and 5 days old. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. The reason for inducing labor, etc. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated inflammatory markers and Echo results; a causal relationship cannot be excluded due to the lack of other information.

Case ID	WW Identifier	Narrative	MAH Comment
		(Intramuscular) 1 dosage form. Last menstrual period and estimated date of delivery were not provided. On 24-Sep-2021, the patient experienced MATERNAL EXPOSURE DURING PREGNANCY (Maternal exposure during pregnancy) (seriousness criterion hospitalization prolonged). On 25-Sep-2021, the patient experienced DYSPNOEA (Dyspnoea) (seriousness criterion hospitalization) and PERICARDITIS (Acute pericarditis) (seriousness criteria hospitalization prolonged and medically significant). On 4.1(b)-2021, the patient experienced INDUCED LABOUR (Induced labour) (seriousness criterion hospitalization prolonged) and PREMATURE DELIVERY (Premature delivery) (seriousness criterion hospitalization prolonged). The delivery occurred on 4.1(b)-2021, which was reported as Premature. For neonate 1, The outcome was reported as Pre-Term Birth w Complications. On 24-Sep-2021, MATERNAL EXPOSURE DURING PREGNANCY (Maternal exposure during pregnancy) had resolved. At the time of the report, DYSPNOEA (Dyspnoea), INDUCED LABOUR (Induced labour), PREMATURE DELIVERY (Premature delivery) and PERICARDITIS (Acute pericarditis) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 25-Sep-2021, Blood test: abnormal (abnormal) abnormal confirmed acute pericarditis. On 25-Sep-2021, Echocardiogram: abnormal (abnormal) abnormal confirmed acute pericarditis. On 25-Sep-2021, Hepatic enzyme: high (High) High, Liver enzymes with 100+ (AST/ALT). On 25-Sep-2021, Inflammatory marker test: high (High) High. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter	

Case ID	WW Identifier	Narrative	MAH Comment
		did not provide any causality assessments. Was induced and gave birth on 4.1(b) to a baby 34 weeks and 5 days old.	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 27-Oct-2021 and was forwarded to Moderna on 27-Oct-2021. This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (4.1(b) in a 20-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3005835) for COVID-19 vaccination. No Medical History information was reported. On 23-Sep-2021, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 03-Oct-2021, after starting , the patient experienced MYOCARDITIS (4.1(b) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (4.1(b) outcome was unknown. The action taken with mRNA-1273 (Spikevax) (Unknown) was unknown. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. Concomitant medication was not reported. Treatment information was not reported.	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 27-Oct-2021 and was forwarded to Moderna on 27-Oct-2021. This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Acute myocarditis) in a 22-year-old male patient who received mRNA-1273 (Spikevax)	22 years old male with unknown medical history who 2 days after the 2nd dose was found to have elevated troponin, CRP, fibrin D-dimer, and abnormal Echo, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2.

Case ID	WW Identifier	Narrative	MAH Comment
		(batch nos. 3005790 and 3005695) for COVID-19 vaccination. No Medical History information was reported. On 06-Sep-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 04-Oct-2021, received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. On 06-Oct-2021, the patient experienced MYOCARDITIS (Acute myocarditis) (seriousness criteria hospitalization and medically significant). On 14-Oct-2021, MYOCARDITIS (Acute myocarditis) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 07-Oct-2021, C-reactive protein (0-10): 123.7 (High) CRP - 123.7 mg/l. On 07-Oct-2021, Echocardiogram: abnormal (abnormal) Conclusions - Non dilated left ventricle with slightly depressed subjective systolic function (LVEF 45 percent) and BSA to lateral level.. On 07-Oct-2021, Fibrin D dimer: 815 (High) D DIMER - 815 ng/ml. On 07-Oct-2021, Magnetic resonance imaging heart: normal (normal) CONCLUSION - Normal left and right ventricle. There is no edema, or areas of delayed enhancement.. On 07-Oct-2021, Troponin I (0.01-0.02): 2.3 (High) 2.3 ng/mL. On 09-Oct-2021, SARS-CoV-2 test: negative (Negative) Negative. mRNA-1273 (Spikevax) (Unknown) was withdrawn on 06-Sep-2021. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. No concomitant medications reported by reporter.	According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and Echo results; a causal relationship cannot be excluded due to the lack of other information.

Case ID	WW Identifier	Narrative	MAH Comment
		No treatment medications provided by the reporter. Most recent FOLLOW-UP information incorporated above includes: On 27-Oct-2021: Translated received on 29-Oct-2021 and patient laboratory data notes and event verbatim updated.	
4.1(b)	4.1(b)	This case was received via 4.1(b) Pharmaceuticals (Reference number: 4.1(b) on 16-Oct-2021 and was forwarded to Moderna on 28-Oct-2021. This case, initially reported to the 4.1(b) by a (pharmacist), was received via the 4.1(b) (Ref, 4.1(b) On an unknown date, the patient received the 1st dose of this vaccine. On an unknown date, body temperature before the vaccination: 36.3 degrees Celsius. On 08-Oct-2021, the patient received the 2nd dose of this vaccine. On 10-Oct-2021, at 02:00, myocarditis developed, and chest pain developed. The patient took over-the-counter loxoprofen sodium hydrate and went to bed. However, at the time of awakening, the patient had chest pain and visited a hospital. There were no major changes on the electrocardiogram. No increase in cardiac enzymes was observed, and the patient was hospitalized with consideration of the possibility of developing into serious myocarditis. On 11-Oct-2021, the patient had chest pain and discomfort, and loxoprofen sodium hydrate as needed was prescribed On 12-Oct-2021, there were no major changes on the electrocardiogram and cardiac enzyme data. Chest pain improved, but the patient complained of a touch of discomfort.	No changes in ECG or cardiac enzymes

Case ID	WW Identifier	Narrative	MAH Comment
		On 13-Oct-2021, the patient did not complain of chest symptoms and did not have any problems in hospital life. On 14-Oct-2021, the patient was discharged from the hospital. On 15-Oct-2021, recovery of the symptoms was confirmed. The outcome of myocarditis was reported as resolved. Follow-up investigation will be made. Company Comment: The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	
4.1(b)	4.1(b)	This case was received via 4.1(b) Pharmaceuticals (Reference number: 4.1(b) on 20-Oct-2021 and was forwarded to Moderna on 28-Oct-2021. This case was received via an unknown source (no reference has been entered for a health authority or license partner) on 20-Oct-2021 and was forwarded to Moderna on 28-Oct-2021. This case, initially reported to the 4.1(b) by a pharmacist, was received via the 4.1(b) (Ref, 4.1(b) Myocarditis was assessed as serious by the MAH. On 26-Aug-2021, the patient received the 1st dose of this vaccine. On 30-Sep-2021, the patient received the 2nd dose of this vaccine. On 01-Oct-2021, pyrexia and chills developed. On 02-Oct-2021, around noon, feeling of tightness in the neck and upper arm from the left shoulder developed and was resolving in about	31 years old male with unknown medical history who next day after the 2nd dose experienced pyrexia and chills, and 2 days later experienced chest pain and was found to have elevated troponin, CRP, Ck, abnormal Echo, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and Echo results; a causal relationship cannot be excluded due to the lack of other information.

Case ID	WW Identifier	Narrative	MAH Comment
		1 hour. There was no queasy or cold feeling. On 03-Oct-2021, chest pain developed. The symptom was resolving in about 1 hour, but chest pain recurred. There was slight chest pain before going to bed. The patient visited a medical institution. Electrocardiogram showed normal sinus rhythm with no significant ST-T changes. Echocardiography showed good left ventricular ejection fraction (EF), but ejection fraction of the base of the heart was slightly weaker than that of the apex without wall motion abnormality. CRP: 1.42 mg/mL, troponin I: 2,428 pg/mL, CK-MB: 21 U/L, and CK: 309 U/L. The patient was diagnosed with myocarditis. On 04-Oct-2021, no chest pain was noted at rest. The patient walked for about 10 minutes to see a physician and became aware of chest discomfort. Echocardiography showed EF of 63% and slight mitral regurgitation (MR). CRP: 0.77 mg/mL, troponin I: 1,904.5 pg/mL, CK-MB: 14 U/L, and CK: 246 U/L. On 05-Oct-2021, chest pain subsided. Recovery of the symptoms was confirmed. On 08-Oct-2021, echocardiography showed EF of 69% and slight MR. CRP: less than 0.24 mg/mL, troponin I: 76.7 pg/mL, CK-MB :6 U/L, and CK: 74 U/L. The outcome of pyrexia, chills, myocarditis, feeling of tightness in the neck and upper arm from the left shoulder was reported as resolved. Follow-up investigation will be made. Company Comment: The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	

Case ID	WW Identifier	Narrative	MAH Comment
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 27-Oct-2021 and was forwarded to Moderna on 27-Oct-2021. This regulatory authority case was reported by a physician and describes the occurrence of HEART RATE INCREASED (4.1(b) MYOCARDITIS (4.1(b) CHEST PAIN (4.1(b) MYALGIA (4.1(b) SWELLING (4.1(b)), VACCINATION SITE PAIN (4.1(b)), PYREXIA (4.1(b) and HEADACHE (4.1(b) in a 30-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 3005697) for COVID-19 vaccination. No Medical History information was reported. On 23-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 23-Sep-2021, the patient experienced HEART RATE INCREASED (4.1(b) (seriousness criterion medically significant), MYOCARDITIS (4.1(b)) (seriousness criterion medically significant), CHEST PAIN (4.1(b) (seriousness criterion medically significant), MYALGIA (4.1(b) (seriousness criterion medically significant), SWELLING (4.1(b)) (seriousness criterion medically significant), VACCINATION SITE PAIN (4.1(b) (seriousness criterion medically significant), PYREXIA (4.1(b) (seriousness criterion medically significant) and HEADACHE (4.1(b) (seriousness criterion medically significant). On 25-Sep-2021, PYREXIA (4.1(b) had resolved. At the time of the report, HEART RATE	

Case ID	WW Identifier	Narrative	MAH Comment
		INCREASED (4.1(b) MYOCARDITIS (4.1(b)) and CHEST PAIN (4.1(b) had not resolved and MYALGIA (4.1(b) SWELLING (4.1(b)), VACCINATION SITE PAIN 4.1(b)) and HEADACHE (4.1(b) was resolving. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. Concomitant medications were not provided. This case was linked to 4.1(b) (E2B Linked Report).	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 27-Oct-2021 and was forwarded to Moderna on 27-Oct-2021. This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (Myocarditis) in a 27-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3004235) for Prophylactic vaccination. No Medical History information was reported. On 29-Aug-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 01-Sep-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Myocarditis) was resolving. No concomitant medication were reported. No treatment information was provided by the reporter.	

Case ID	WW Identifier	Narrative	MAH Comment
		Most recent FOLLOW-UP information incorporated above includes: On 27-Oct-2021: Translated document received on 29 Oct 2021 contains translated event terms.	
4.1(b)	4.1(b)	This case was received via 4.1(b) Pharmaceuticals (Reference number: 4.1(b) on 15-Oct-2021 and was forwarded to Moderna on 28-Oct-2021. This case, initially reported to the 4.1(b) by a pharmacist, was received via the 4.1(b) (Ref, 4.1(b) The patient had a history of allergy to antibiotics and a history of urticaria due to faropenem sodium hydrate. On an unknown date, the patient received the 1st dose of the vaccine. On an unknown date, body temperature before the vaccination: 36.5 degrees Celsius. On 08-Oct-2021, at 11:00, the patient received the 2nd dose of the vaccine. On 09-Oct-2021, at 21:00, myocarditis developed. The patient visited a hospital for chest pain, queasy, and pyrexia. Changes on the electrocardiogram included early repolarization waveforms. Heart rate was 120/min. Blood test showed troponin of 0.011 with CK of 68 and no elevation in cardiac enzymes. Drip infusion of acetaminophen 1000 mg was given for chest pain. The patient was hospitalized because follow-up was needed for changes on the electrocardiogram and chest symptoms. On 10-Oct-2021, blood collection was performed to show elevated troponin of 0.055 with CK of 57. Electrocardiogram showed high T waves in the V2 lead to V6 lead. Heart rate was 90/min. There were no subjective symptoms.	22 years old male with unknown medical history who next day after the 2nd dose experienced chest pain and pyrexia and was hospitalized and found to have elevated troponin, Ck, and abnormal EGC, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and ECG results; a causal relationship cannot be excluded due to the lack of other information.

Case ID	WW Identifier	Narrative	MAH Comment
		On 11-Oct-2021, CK decreased to 35 and troponin to 0.011. There were no subjective symptoms. There were no changes on the electrocardiogram. The patient had no problems with a stay at the hospital. On 14-Oct-2021, the symptoms improved. Resolution was confirmed, and the patient was discharged from the hospital. The outcome of myocarditis was reported as resolved. Follow-up investigation will be made. Company Comment: The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 27-Oct-2021 and was forwarded to Moderna on 27-Oct-2021. This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (MYOCARDITIS) in a 28-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. No Medical History information was reported. On 23-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 26-Sep-2021, the patient experienced MYOCARDITIS (MYOCARDITIS) (seriousness criteria hospitalization, medically significant and life threatening). At the time of the report, MYOCARDITIS (MYOCARDITIS) was resolving. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments.	

Case ID	WW Identifier	Narrative	MAH Comment
		No concomitant medication was given. No treatment medication was given. Most recent FOLLOW-UP information incorporated above includes: On 27-Oct-2021: Translated document attached on 29-Oct-2021 contains verbatim of event updated to English.	
4.1(b)	4.1(b)	This case was initially received via European Medicines Agency (Reference number: 4.1(b)) on 27-Oct-2021. The most recent information was received on 29-Oct-2021 and was forwarded to Moderna on 29-Oct-2021. This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myocarditis approximately 20 days after administration of the first dose of COVID -19 moderna vaccine and 2 days after administration of second dose of the same vaccine.) in an 18-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3003601) for COVID-19 vaccination. The patient's past medical history included Bicuspid aortic valve (Congenita.) on 24-Jul-2003. Concomitant products included LOSARTAN for Blood pressure high. On 17-Sep-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 15-Oct-2021, received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to 1 dosage form in total. On 18-Oct-2021, the patient experienced MYOCARDITIS (Myocarditis approximately 20 days after administration of the first dose of COVID -19 moderna vaccine and 2 days after administration of second dose of the same vaccine.) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Myocarditis approximately 20 days after administration of the first dose of COVID -19 moderna vaccine and 2 days after administration of second dose of the same vaccine.) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 18-Oct-2021, Blood pressure measurement: high (High) High. On 18-Oct-2021, C-reactive protein: abnormal (abnormal) 6,7 INTERNATIONAL UNIT(S)-(UNDER 100). On 18-Oct-2021, Troponin: abnormal (abnormal) 12500 INTERNATIONAL UNIT(S)-(UNDER 100). For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No treatment information mentioned. Most recent FOLLOW-UP information incorporated above includes: On 27-Oct-2021: Translated document received on 27-OCT-2021, Event verbatim updated.	

Case ID	WW Identifier	Narrative	MAH Comment
		On 29-Oct-2021: Significant follow up received, Lab data, first and second dose details , Event outcome were updated.	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) 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 PERICARDITIS (Pericarditis) in a 24-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3003604) for Vaccination. No Medical History information was reported. On 06-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 16-Oct-2021, the patient experienced PERICARDITIS (Pericarditis) (seriousness criterion medically significant). At the time of the report, PERICARDITIS (Pericarditis) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 16-Oct-2021, C-reactive protein: elevated (High) Elevated. On 16-Oct-2021, Echocardiogram: normal (normal) Normal findings. On 16-Oct-2021, Electrocardiogram: abnormal (abnormal) Abnormal. For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered PERICARDITIS (Pericarditis) to be possibly related. No concomitant medications were provided. No treatment information was provided. Most recent FOLLOW-UP information incorporated above includes: On 28-Oct-2021: Translation received on 29-Oct-2021. Translated event verbatim and sender's comment updated.	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) 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 MYOCARDITIS (Perimyocarditis: 4.1(b) in a 27-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3004493) for COVID-19 immunisation. The occurrence of	

Case ID	WW Identifier	Narrative	MAH Comment
		additional non-serious events is detailed below. No Medical History information was reported. On 01-Jul-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 15-Sep-2021, received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. On 03-Oct-2021, the patient experienced MYOCARDITIS (Perimyocarditis: 4.1(b) .) (seriousness criteria hospitalization, disability and medically significant) and PYREXIA 4.1(b)). At the time of the report, MYOCARDITIS (Perimyocarditis: 4.1(b) and PYREXIA (4.1(b)) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 07-Oct-2021, Pyrexia: high (High) 4.1(b) For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. No Concomitant medication details were provided. No Treatment medication details were provided.	
4.1(b)	4.1(b)	This case was received via 4.1(b) Pharmaceuticals (Reference number: 4.1(b) on 23-Oct-2021 and was forwarded to Moderna on 29-Oct-2021.	

Case ID	WW Identifier	Narrative	MAH Comment
		This case, initially reported to the 4.1(b) by a physician, was received via the PMDA (Ref, 4.1(b) On 02-Sep-2021, the patient received the 1st dose of this vaccine. On 01-Oct-2021, the patient received the 2nd dose of this vaccine. On 04-Oct-2021, at 02:00, myocarditis developed. Precordial pain was noted. Blood test showed elevated cardiac enzymes, and electrocardiogram showed diffuse ST elevation. The patient was hospitalized. On 13-Oct-2021, the symptoms resolved, and the patient was discharged from the hospital. The outcome of myocarditis was reported as resolved. Follow-up investigation will be made. Company Comment: The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	
4.1(b)	4.1(b)	This case was received via 4.1(b) Pharmaceuticals (Reference number: 4.1(b) on 25-Oct-2021 and was forwarded to Moderna on 29-Oct-2021. This case was reported by a physician via the companys medical representative. On an unknown date, the patient received the 1st dose of this vaccination. On 24-Oct-2021, the patient received the 2nd dose of this vaccination. On 25-Oct-2021, the patient complained of pyrexia and tiredness. The patient visited a medical institution, and the symptoms turned out to be a myocarditis when electrocardiogram was taken, and the patient was urgently transported. The patient was hospitalized. The outcome of pyrexia and myocarditis was reported as unknown. Follow-up investigation will be made. Company Comment: The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	
4.1(b)	4.1(b)	This case was received via 4.1(b) Pharmaceuticals (Reference number: 4.1(b)) on 22-Oct-2021 and was forwarded to Moderna on 29-Oct-2021. This case, initially reported to the 4.1(b) by a	27 years old male with unknown medical history who 4 days after the 2nd dose experienced chest pain and was found to have abnormal EGC, abnormal Echo and abnormal cMRI and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical

Case ID	WW Identifier	Narrative	MAH Comment
		physician, was received via the 4.1(b) (Ref, 4.1(b) On an unknown date, the patient received the 1st dose of this vaccine. On 12-Oct-2021, the patient received the 2nd dose of this vaccine. On 16-Oct-2021, at 17:00, the patient was suddenly aware of chest pain and was raced to a hospital. After the visit, an electrocardiogram showed extensive ST elevation, and echocardiography showed hypokinesis of the apical wall. Emergency cardiac catheterization was performed. There was no stenosis in the coronary artery. Afterwards, LGE was noted predominantly in the epicardium by contrast-enhanced MRI, and it was considered as myocarditis. On 21-Oct-2021, the symptom was ongoing. The outcome of myocarditis was reported as ongoing and unchanged. Follow-up investigation will be made. Company Comment: The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the ECG, Echo and cMRI results; a causal relationship cannot be excluded due to the lack of other information.
4.1(b)	4.1(b)	This case was received via 4.1(b) Pharmaceuticals (Reference number: 4.1(b) on 23-Oct-2021 and was forwarded to Moderna on 29-Oct-2021. This case, initially reported to the 4.1(b) by a pharmacist, was received via the 4.1(b) (Ref, 4.1(b) On 19-Sep-2021, at 10:00, the patient received the 1st dose of this vaccine. On 17-Oct-2021, at 10:00, the patient received the 2nd dose of this vaccine.	27 years old male with unknown medical history who the next day after the the 2nd dose developed pyrexia and chest discomfort and 2 days later experienced severe chest pain and was found to have elevated troponin, and abnormal EGC, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events,

Case ID	WW Identifier	Narrative	MAH Comment
		On 18-Oct-2021, at 01:00, pyrexia of 38 degrees Celsius or higher developed. At 13:00, myocarditis developed. The patient had chest discomfort. On 20-Oct-2021, at 02:00, the patient visited a nearby hospital because of severe chest symptoms. The patient was referred to our hospital due to suspected myocarditis after vaccination with this vaccine because of ST elevation and troponin T positive. The patient was then hospitalized. After the patient was hospitalized, oral administration of A (330) containing aspirin, aluminum glycinate, and magnesium carbonate was started for 3 times of 6 tablets. The outcome of pyrexia, myocarditis was unknown. Follow-up investigation will be made. Company Comment: The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	as well as the elevated troponin and ECG results; a causal relationship cannot be excluded due to the lack of other information.
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 29-Oct-2021 and was forwarded to Moderna on 29-Oct-2021. This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (4.1(b) DYSPNOEA (4.1(b) and CHEST PAIN (4.1(b) in an 18-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3005835) for COVID-19 vaccination. No Medical History information was reported. On 23-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 16-Oct-2021, the patient	

Case ID	WW Identifier	Narrative	MAH Comment
		experienced MYOCARDITIS (4.1(b) (seriousness criteria hospitalization, disability, medically significant and life threatening), DYSPNOEA (4.1(b) (seriousness criteria hospitalization, disability and life threatening) and CHEST PAIN (4.1(b) (seriousness criteria hospitalization, disability and life threatening). At the time of the report, MYOCARDITIS (4.1(b) DYSPNOEA (4.1(b) and CHEST PAIN (4.1(b) had not resolved. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. No concomitant medication was reported by the reporter. No treatment was reported by the reporter.	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 29-Oct-2021 and was forwarded to Moderna on 29-Oct-2021. This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (4.1(b) in a 24-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3006273) for COVID-19 vaccination. No Medical History information was reported. On 05-Oct-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 05-Oct-2021, after starting mRNA-1273 (Spikevax), the patient experienced MYOCARDITIS (4.1(b) (seriousness criterion medically significant). At the time of the report, MYOCARDITIS (4.1(b) was resolving.	

Case ID	WW Identifier	Narrative	MAH Comment
		For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. Concomitant medication details were not reported by the reporter. Treatment details was not reported by the reporter.	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 29-Oct-2021 and was forwarded to Moderna on 29-Oct-2021. This regulatory authority case was reported by a physician and describes the occurrence of PERICARDITIS (Acute pericarditis) in a 31-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 3005834 and 214017) for COVID-19 vaccination. No Medical History information was reported. On 09-Sep-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 07-Oct-2021, received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to 1 dosage form. On 09-Oct-2021, the patient experienced PERICARDITIS (Acute pericarditis) (seriousness criterion medically significant). At the time of the report, PERICARDITIS (Acute pericarditis) was resolving. 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.	
4.1(b)	4.1(b)	This case was received via 4.1(b) Pharmaceuticals (Reference number: 4.1(b) on 23-Oct-2021 and was forwarded to Moderna on 29-Oct-2021. This case, initially reported to the 4.1(b) by a physician, was received via 4.1(b) (Ref 4.1(b) On an unknown date, the patient received the 1st dose of this vaccine.	

Case ID	WW Identifier	Narrative	MAH Comment
		On an unknown date, body temperature before the vaccination: 36.2 degrees Celsius. On 08-Oct-2021, at 16:30, the patient received the 2nd dose of this vaccine. Onn 09-Oct-2021, around 22:00, precordial pain developed. On 10-Oct-2021, around 05:00, chest pain was exacerbated. An emergency call was made, and the patient visited the reporting emergency outpatient department. The patient was hospitalized for epicarditis. On 15-Oct-2021, the symptoms were resolving, and the patient was discharged from the hospital. The outcome of chest pain and epicarditis was reported as resolving. Follow-up investigation will be made. Company Comment: The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	
4.1(b)	4.1(b)	This case was received via 4.1(b) Pharmaceuticals (Reference number: 4.1(b) on 23-Oct-2021 and was forwarded to Moderna on 29-Oct-2021. This case, initially reported to the 4.1(b) by a (nurse), was received via the 4.1(b) (Ref, 4.1(b) On an unknown date, the patient received the 1st dose of this vaccine. On 28-Sep-2021, the patient received the 2nd dose of this vaccine. On 29-Sep-2021, pyrexia of 39 degrees Celsius developed. On 30-Sep-2021, pyrexia went down, and the patient went to work and did exercise after returning home. Thereafter, chest pain, disordered breathing, and pyrexia of 39 degrees Celsius developed again. On 01-Oct-2021, the patient visited a hospital and was referred to the reporting hospital due to suspected myocarditis. At the visit, troponin I: 1,864.8, BPN: 25.5, CRP: 5.41, heart	25 years old male with unknown medical history who the next day after the 2nd dose experienced pyrexia, and the next day after exercising experienced chest pain and dyspnoea, and was found to have elevated troponin, BPN, CRP, abnormal EGC, normal cMRI, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and ECG results; a causal relationship cannot be excluded due to the lack of other information.

Case ID	WW Identifier	Narrative	MAH Comment
		rate: 56 times/min, and increased ST-T in 12-lead electrocardiogram. The patient was hospitalized. On 03-Oct-2021, CPK peaked out. On 04-Oct-2021, cardiac MRI showed no problem, and acute myocarditis was diagnosed. On 06-Oct-2021, the patient was discharged from the hospital. On 11-Oct-2021, recovery of the symptoms was confirmed. The outcome of pyrexia, chest pain, and acute myocarditis was reported as resolved. Follow-up investigation will be made. Company Comment: The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	
4.1(b)	4.1(b)	This case was initially received via an unknown source (no reference has been entered for a health authority or license partner) on 03-Sep-2021. The most recent information was received on 03-Sep-2021 and was forwarded to Moderna on 08-Sep-2021. This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (4.1(b) (Moderna), ED 27.07.2021) in a 37-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination. Family history included Family history of cardiovascular disorder (Father died at 51 years of age from myocardial infarction.). On 27-Jun-2021, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form. On 24-Jul-2021, received second dose of mRNA-1273 (COVID-19	37 years old male with familial medical history of CV disorder who 3 days after the 2nd dose of the vaccine was diagnosed with myocarditis. Laboratory results showed elevated CRP, elevated troponin, elevated, abnormal EKG, cMRI, and Echo. No other information was provided. Important information is missing in this report including patient's medical history, as well as clinical course of the events, laboratory tests conducted and any results, including SARS-CoV2 test.

Case ID	WW Identifier	Narrative	MAH Comment
		Vaccine Moderna) (Intramuscular) dosage was changed to 1 dosage form. On 27-Jul-2021, after starting mRNA-1273 (COVID-19 Vaccine Moderna), the patient experienced MYOCARDITIS (4.1(b) (Moderna), ED 27.07.2021) (seriousness criteria hospitalization and medically significant). The patient was hospitalized from 27-Jul-2021 to 30-Jul-2021 due to MYOCARDITIS. The patient was treated with ASA on 27-Jul-2021 for Adverse event, at an unspecified dose and frequency; BISOPROLOL FUMARATE (4.1(b) on 27-Jul-2021 for Adverse event, at an unspecified dose and frequency and RAMIPRIL on 27-Jul-2021 for Adverse event, at an unspecified dose and frequency. On 30-Jul-2021, MYOCARDITIS (4.1(b) (Moderna), ED 27.07.2021) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 27-Jul-2021, Catheterisation cardiac: normal (normal) Epicardial coronary arteries normal.. On 27-Jul-2021, Echocardiogram: slightly reduced systolic function (abnormal) Normal sized ventricle with slightly reduced systolic function (LVEF biplan 47% GLS with GE Vivid -14.1%) with mid inferolateral circumscribed hypokinesis.. On 27-Jul-2021, Electrocardiogram: abnormal (abnormal) nc SR, IT, no block image, discrete ST elevations in I, II, aVF, PQ depressions in I, II.. On 27-Jul-2021, Magnetic resonance imaging: abnormal (abnormal) Normal biventricular dimensions with slightly reduced left ventricular function (EF 51%). No evidence of myocardial infarction. Patchy subepicardial fibrosis at the midventricular and septal levels with evidence of related myocardial edema. Results compatible with myocarditis..	

Case ID	WW Identifier	Narrative	MAH Comment
		On 27-Jul-2021, N-terminal prohormone brain natriuretic peptide: 783 ng/l (Inconclusive) 783 ng/L Abnormal. On 27-Jul-2021, Troponin I: 1603 ng/l (Inconclusive) 1603 ng/L abnormal. On 27-Jul-2021, Troponin T: 195 ng/l (High) Troponin T hs 195 ng/l (Peak 484 ng/l). For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered MYOCARDITIS (4.1(b) (Moderna), ED 27.07.2021) to be probably related. No concomitant medications were provided. The patient presented with chest pain radiating to the neck and left shoulder. Company Comment: Based on the current available information and temporal association between the use of the product and the onset date of the events, a causal relationship cannot be excluded. Therefore, causality is assessed as possibly related. Translation is being requested. Most recent FOLLOW-UP information incorporated above includes: On 03-Sep-2021: Translation received on 08-Sep-2021, patient past medical history, labs, hospitalization end date, treatment medications and inarrative updated.	
4.1(b)	4.1(b)	This case was initially received via European Medicines Agency (Reference number: 4.1(b)) on 04-Sep-2021. The most recent information was received on 28-Sep-2021 and was forwarded to Moderna on 28-Sep-2021. This regulatory authority case was reported by a physician and describes the occurrence of HYPERHIDROSIS (4.1(b)	19 years old female with unknown medical history who same day after the 2nd dose of the vaccine experienced hyperhydrosis, cough, chest discomfort, dypsnea, pyrexia, and was diagnosed with myocarditis. Laboratory results showed mild thrombocytopenia, elevated CRP, elevated troponin, abnormal Echo. No other information was provided. Important information is missing in this report including patient's medical history, as well as clinical course of

Case ID	WW Identifier	Narrative	MAH Comment
		COUGH (4.1(b) CHEST DISCOMFORT (4.1(b) DYSPNOEA (4.1(b) HEADACHE (4.1(b) PYREXIA (4.1(b) and MYOCARDITIS (4.1(b) in a 19-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3002919) for COVID-19 vaccination. No Medical History information was reported. On 09-Aug-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 2 dosage form. On 09-Aug-2021, the patient experienced HYPERHIDROSIS (4.1(b) (seriousness criterion hospitalization), COUGH (4.1(b) (seriousness criterion hospitalization), CHEST DISCOMFORT (4.1(b) (seriousness criterion hospitalization), DYSPNOEA (4.1(b) (seriousness criterion hospitalization), HEADACHE (4.1(b) (seriousness criterion hospitalization), PYREXIA (4.1(b) (seriousness criterion hospitalization) and MYOCARDITIS (4.1(b) (seriousness criteria hospitalization and medically significant). At the time of the report, HYPERHIDROSIS (4.1(b) COUGH (4.1(b) CHEST DISCOMFORT (4.1(b) DYSPNOEA (4.1(b) HEADACHE (4.1(b) PYREXIA (4.1(b) and MYOCARDITIS (4.1(b) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In August 2021, Blood bilirubin: 31 (High) 31 umol/L (micromole per litre). In August 2021, Blood creatinine: 87 (normal) 87 umol/L (micromole per litre) and 78 (normal) 78 umol/L (micromole per litre).	the events, laboratory tests conducted and any results

Case ID	WW Identifier	Narrative	MAH Comment
		In August 2021, C-reactive protein: 103 (High) 103 mg/L (milligram per litre) and 118 (High) 118 mg/L (milligram per litre). In August 2021, Chest X-ray: normal (normal) No pathology. In August 2021, Echocardiogram: abnormal (abnormal) Smal area with pericardial fluid outside of the right ventricle. Otherwise normal findings.. In August 2021, Haematocrit: 0.4 (abnormal) Hematocrit 0.4. In August 2021, Haemoglobin: 13.8 (normal) 13.8 g/dL (gram per decilitre). In August 2021, Platelet count: 129 (abnormal) 129 g/dL (gram per decilitre), 142 (abnormal) 142 g/dL (gram per decilitre) and 111 (abnormal) 111 g/dL (gram per decilitre). In August 2021, SARS-CoV-2 test: negative (Negative) Negative. In August 2021, Troponin T: 37 (High) 37 ng/L (nanogram per litre), 79 (High) 79 ng/L (nanogram per litre), 65 (High) 65 ng/L (nanogram per litre) and 79 (High) 79 ng/L (nanogram per litre). For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered HYPERHIDROSIS (4.1(b) COUGH (4.1(b) CHEST DISCOMFORT (4.1(b) DYSPNOEA (4.1(b) HEADACHE (4.1(b) PYREXIA (4.1(b) and MYOCARDITIS (4.1(b) to be possibly related. No relevant concomitant and treatment medications were reported. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Most recent FOLLOW-UP information incorporated above includes:	

Case ID	WW Identifier	Narrative	MAH Comment
		On 04-Sep-2021: Non-significant follow up: Translation Document received on 08 Sep 2021 include translated Sender's comments which contain no new information.	
4.1(b)	4.1(b)	This regulatory authority case was reported by a physician and describes the occurrence of PERICARDITIS (4.1(b)) in a 35-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination. Concurrent medical conditions included Drug allergy (Aspirin), Drug allergy (Ibuprofen) and Alcoholism (Alcohol : rarely). In May 2021, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form. On 25-Jun-2021, received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) dosage was changed to 1 dosage form. On 26-Jun-2021, the patient experienced PERICARDITIS (4.1(b)) (seriousness criterion medically significant). At the time of the report, PERICARDITIS (4.1(b)) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In June 2021, C-reactive protein: 18 (High) C-reactive protein Elevated 18 mg/L. In June 2021, Electrocardiogram: abnormal (abnormal) ECG with pre-existing right bundle branch block and negative concordant T. In June 2021, Troponin: negative (Negative) Cardiac Troponin negative. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered PERICARDITIS (4.1(b)) to be possibly related. Patient experienced pericarditis which was diagnosed following	35 years old male with unknown medical history who same day after the 2nd dose of the vaccine pateint exoerience fever and chills. The following day there was an increased feeling of left side chest pressure without radiation. Laboratory results showed elevated CRP, and troponin. ECG with preexisting right bundle branch block and concordant negative. No other information was provided. Important information is missing in this report including patient's medical history, as well as clinical course of the events, laboratory tests conducted and any results, including SARS-CoV2 test.

Case ID	WW Identifier	Narrative	MAH Comment
		various laboratory and imaging investigations. The same evening of second vaccination patient also fever and chills. The following day there was an increased feeling of left side chest pressure without radiation. ECG with preexisting right bundle branch block and concordant negative. Patient was under physical rest and NSAID therapy with celecoxic (allergic to Ibuprofen and aspirin). There was a marked improvement and patient had only few infrequent symptoms. Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. Most recent FOLLOW-UP information incorporated above includes: On 03-Sep-2021: Translation received on 08-Sep-2021: Narrative was updated with significant information.	
4.1(b)	4.1(b)	This case was initially received via European Medicines Agency (Reference number: 4.1(b)) on 03-Sep-2021. The most recent information was received on 07-Sep-2021 and was forwarded to Moderna on 08-Sep-2021. This regulatory authority case was reported by a pharmacist and describes the occurrence of CHEST DISCOMFORT (4.1(b)), ABDOMINAL PAIN UPPER (4.1(b)) and MYOCARDITIS (4.1(b)) in a 21-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 3005695 and 214010) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Asthma. On 26-Jul-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form.	21 years old male with unknown medical history who 3 days after the 2nd dose of the vaccine experienced discomfort, malaise, musculoskeletal pain, pyrexia and was diagnosed with myocarditis. Laboratory results showed elevated CRP, elevated troponin. No other information was provided. Important information is missing in this report including patient's medical history, as well as clinical course of the events, laboratory tests conducted and any results, including SARS-CoV2 test.

Case ID	WW Identifier	Narrative	MAH Comment
		On 23-Aug-2021, received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. On 23-Aug-2021, the patient experienced DISCOMFORT (4.1(b) [redacted] MALAISE (4.1(b) [redacted]), MUSCULOSKELETAL PAIN (4.1(b) [redacted]) and PYREXIA (4.1(b) [redacted]. On 25-Aug-2021, the patient experienced CHEST DISCOMFORT (4.1(b) [redacted]) (seriousness criteria hospitalization and medically significant) and ABDOMINAL PAIN UPPER (4.1(b) [redacted]) (seriousness criteria hospitalization and medically significant). On 26-Aug-2021, the patient experienced MYOCARDITIS (4.1(b) [redacted] (seriousness criteria hospitalization and medically significant). The patient was treated with PARACETAMOL for Adverse event, at a dose of 1 dosage form. On 23-Aug-2021, MUSCULOSKELETAL PAIN (4.1(b) [redacted]) had resolved. On 24-Aug-2021, DISCOMFORT (4.1(b) [redacted], MALAISE 4.1(b) [redacted]) and PYREXIA (4.1(b)	

Case ID	WW Identifier	Narrative	MAH Comment
		4.1(b) had resolved. At the time of the report, CHEST DISCOMFORT (4.1(b)), ABDOMINAL PAIN UPPER(4.1(b)) and MYOCARDITIS(4.1(b)) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 26-Aug-2021, Blood creatine phosphokinase (20-200): 371 (abnormal) 371 enzyme unit per litre, 382 (abnormal) 382 enzyme unit per litre, 371 371 enzyme unit per litre and 382 382 enzyme unit per litre. On 26-Aug-2021, Troponin T: 313 (abnormal) 313 nanogram per litre, 233 (abnormal) 233 nanogram per litre, 313 313 nanogram per litre and 233 233 nanogram per litre. On 27-Aug-2021, Blood creatine phosphokinase (20-200): 281 (abnormal) 281 enzyme unit per litre and 281 281 enzyme unit per litre. On 27-Aug-2021, Troponin T: 264 (abnormal) 264 nanogram per litre and 264 264 nanogram per litre. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. Concomitant medications were not reported. Treatment medications were not reported. Company Comment: This case concerns a 21 year old male patient, who experienced unexpected serious events of CHEST DISCOMFORT, ABDOMINAL PAIN UPPER, MYOCARDITIS. The serious events occurred 2-3 days after the second dose of mRNA-1273 vaccine. The patient also experienced non-serious events of discomfort, malaise, musculoskeletal pain, pyrexia. The non-serious events	

Case ID	WW Identifier	Narrative	MAH Comment
		occurred on same day after the second dose of mRNA-1273 vaccine. Limited information regarding the events have been provided at this time. The benefit-risk relationship of the vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 07-Sep-2021: Follow-up document received and contain include patient height added. On 07-Sep-2021: Translation received on 08-SEP-2021 and description to be coded has change for event tightness in chest as tight Chest and general discomfort in place of initial general malaise.	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 03-Sep-2021 and was forwarded to Moderna on 03-Sep-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of CHEST PAIN (Chest pain) and MYOCARDITIS (Myopericarditis) in a 22-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. No Medical History information was reported. On 23-Jul-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 20-Aug-2021, received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. On 21-Aug-2021, the patient experienced CHEST PAIN (Chest pain) (seriousness criterion hospitalization). On 24-Aug-2021, the patient experienced MYOCARDITIS (Myopericarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, CHEST PAIN (Chest pain) and MYOCARDITIS (Myopericarditis) was resolving.	22 years old male with unknown medical history 4 days after the 2nd dose of the vaccine experienced chest pain, and was diagnosed with myocarditis. Laboratory results showed elevated troponin, and abnormal Echo. No other information was provided. Important information is missing in this report including patient's medical history, as well as clinical course of the events, laboratory tests conducted and any results, including SARS-CoV2 test.

Case ID	WW Identifier	Narrative	MAH Comment
		DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In August 2021, Echocardiogram: abnormal (abnormal) Echocardiograph: preserved LVEF without segmental contractility alterations. RV with normal function and morphology. Mitral valve with minimal insufficiency. Tricuspid aortic valve, good opening. Tricuspid valve without impairment. No pericardial effusion, but increased enhancement of the pericardium.. In August 2021, Troponin: abnormal (abnormal) serial troponins 3302 ---› 3747 ---›2215.. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. No concomitant medication information was provided No treatment product information was provided The action taken with mRNA-1273 (Spikevax) (unknown) was not applicable. Company comment: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Most recent FOLLOW-UP information incorporated above includes: On 03-Sep-2021: Translation document received on 07-Sep-2021, updated the lab investigation results	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 04-Sep-2021 and was forwarded to Moderna on 04-Sep-2021. This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myopericarditis) and PERICARDITIS (Chest pain	23 years old male with unknown medical history 2 days after the 2nd dose of the vaccine experienced chest pain, and was diagnosed with myopericarditis. Laboratory results showed elevated CRP, abnormal EKG. No other information was provided. Important information is missing in this report including patient's medical history, as well as

Case ID	WW Identifier	Narrative	MAH Comment
		worsened by lying flat consistent with pericarditis) in a 23-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 3004218 and 3002290) for COVID-19 immunisation. No Medical History information was reported. On 07-Jul-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 06-Aug-2021, received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. On 08-Aug-2021, the patient experienced MYOCARDITIS (Myopericarditis) (seriousness criteria hospitalization and medically significant). On an unknown date, the patient experienced PERICARDITIS (Chest pain worsened by lying flat consistent with pericarditis) (seriousness criteria disability and medically significant). At the time of the report, MYOCARDITIS (Myopericarditis) and PERICARDITIS (Chest pain worsened by lying flat consistent with pericarditis) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In August 2021, C-reactive protein: abnormal (abnormal) Raised inflammatory marker CRP = 115. In August 2021, Electrocardiogram: abnormal (abnormal) ECG changes - ST elevation and PR depression.. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. Concomitant product use was not provided by the reporter. Treatment information was not provided. Company Comment : Based on the current available information and temporal association between the	clinical course of the events, laboratory tests conducted and any results, including SARS-CoV2 test.

Case ID	WW Identifier	Narrative	MAH Comment
		use of the product and the start date of the events, a causal relationship cannot be excluded.	
4.1(b)	4.1(b)	This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (4.1(b)) in a 30-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) (batch nos. 3003188 and 3003188) for COVID-19 vaccination. No Medical History information was reported. On 06-Jul-2021, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 200 microgram. On 03-Aug-2021, received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) dosage was changed to 200 microgram. On 05-Aug-2021, after starting mRNA-1273 (COVID-19 Vaccine Moderna), the patient experienced MYOCARDITIS (4.1(b)) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (4.1(b)) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Blood creatine phosphokinase: 456 456. On an unknown date, Blood creatinine: 83 83 umol/L. On an unknown date, Blood potassium: 3.74 3.74 mmol/L. On an unknown date, Blood sodium: 138 138mmol/L. On an unknown date, Blood thyroid stimulating hormone: 2.44 2.44. On an unknown date, C-reactive protein increased: 2.2 2.2mg/L. On an unknown date, Haemoglobin: 15.2 15.2 g/dL. On an unknown date, International normalised ratio: 1.06 1.06. On an unknown date, Troponin: 552 552.	30 years old male with unkonw medical history who 2 days after the 2nd dose of the vaccine developed fever, retrosternal, extensive, oppressive chest pain, fatigue and mild exertional dyspnea on exertion. The patient was hospitalized and diagnosed with myopericarditis. Coronary angiography revealed stenosis-free coronary arteries with smooth walls. Echo revealed a normal systolic ejection fraction of 60% without regional kinetic disorders. Resting ECG revealed sinus rhythm with a heart rate of 61 bpm, a normal heart axis with normal PQ and QRS intervals, but ST elevations in leads I, aVL and V2-6, normal repolarization and a QTc interval of 380 ms. CRP elevated, elevated troponin, elevated CK. Important information is missing in the report including pateint's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2.

Case ID	WW Identifier	Narrative	MAH Comment
		On an unknown date, White blood cell disorder: 6.2 6.2 G/L. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medication, treatment medication were provided. It was reported that on 05-Aug- 2021, patient developed fever as well as retrosternal, extensive, oppressive chest pain. In addition, the patient reported rapid fatigue and mild exertional dyspnea on exertion. The patient was hospitalized and diagnosed with Peri-myocarditis. Etiologically, a connection with the COVID vaccination (Moderna) was most likely seen. Reportes showed that coronary angiography on 06-Aug-2021 revealed stenosis-free coronary arteries with smooth walls. TTE revealed a normal systolic ejection fraction of 60% without regional kinetic disorders. The resting ECG revealed sinus rhythm with a heart rate of 61 bpm, a normal heart axis with normal PQ and QRS intervals, but ST elevations in leads I, aVL and V2-6, normal repolarization and a QTc interval of 380 ms. Laboratory chemistry results on 06-Aug-2021 revealed the following values: Leukocytes 6.2 G/L, CRP 2.2 mg/L, Hb 15.2 g/dL, platelets 129 G/L, INR 1.06, creatinine 83 umol/L, Na 138 mmol/L, K 3.74 mmol/L, troponin 552 ng/L, CK 456 U/L, TSH 2.44 mU/L. The patient was monitored on an inpatient basis due to initially increasing troponin and increasing CK. Over the course, the patient's symptoms were regressive. Was a non-smoker and did not consume alcohol. There were no known allergies or liver disorders.	

Case ID	WW Identifier	Narrative	MAH Comment
		This case concerns a 30-year-old, male patient with no relevant medical history, who experienced the expected event of Myocarditis. The event occurred approximately 3 days after the second dose of Spikevax. The rechallenge was not applicable, as the event happened after the second dose. The reporter assessed the event as related to the product. The benefit-risk relationship of Spikevax is not affected by this report. Event seriousness assessed as per Regulatory Authority reporting, however there was no information in the source document supporting that the events resulted in a persistent or permanent incapacity. Most recent FOLLOW-UP information incorporated above includes: On 17-Sep-2021: Translation Document Received on 21 Sep 2021 contains significant information - updated inarrative.	
4.1(b)	4.1(b)	This regulatory authority case was reported by a consumer and describes the occurrence of PYREXIA (Fever) and MYOCARDITIS 4.1(b) 4.1(b) in a 37-year-old female patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination. Concurrent medical conditions included Palpitations (Arrhythmic pulse, partly tachycardic). On 07-Jul-2021, the patient received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form. On 07-Jul-2021, after starting mRNA-1273 (COVID-19 Vaccine Moderna), the patient experienced PYREXIA (Fever) (seriousness criterion medically significant). On 14-Jul-2021, the patient experienced MYOCARDITIS (4.1(b)) (seriousness criterion medically significant). On 09-Jul-2021, PYREXIA (Fever) had resolved. At the time of the report, MYOCARDITIS	37 years old female with history of palpitations who the same day after the 2nd dose of the vaccine experience pyrexia, and 7 days later experienced exertional dypsnea, retrosternal chest pain and aggravation of palpitations. Pateint was diagnised with myopericarditis. Laboratory results showed increased troponin and minor pericardial efusion during sonography. No other information was provided. Important information is missing in the report including pateint's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2.

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

Case ID	WW Identifier	Narrative	MAH Comment
		On 17-Sep-2021: Translation received on 26-Sep-2021 included event verbatim translated and significant information from case narrative added.	
4.1(b)	4.1(b)	This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (4.1(b)) in a 35-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) (batch no. 3002541) for COVID-19 vaccination. 4.1(b) Concurrent medical conditions included Tobacco user (known tobacco use), Alcohol use (rare alcohol consumption.), Pollen allergy and Allergy to animal dander (animal hair). Concomitant products included DOXYCYCLINE HYCLATE (DOXYCLIN [DOXYCYCLINE HYCLATE]) for an unknown indication. On 25-May-2021, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (unknown route) 1 dosage form. On 22-Jun-2021, received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (unknown route) dosage was changed to 1 dosage form. On 24-Jun-2021, after starting mRNA-1273 (COVID-19 Vaccine Moderna), the patient experienced MYOCARDITIS (4.1(b)) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (4.1(b)) was resolving. For mRNA-1273 (COVID-19 Vaccine Moderna) (Unknown), the reporter considered MYOCARDITIS (4.1(b)) to be possibly related.	35 years old male with concomitant use of doxycicline for an imflamatory process in the testicles (no other infomration provided) who 2 days after the 2nd dose of the vaccine experienced chest pain and was diagnosed with myopericarditis. Laboratory results showed abnormal EKG (St segment elevations) and abnormal Echo. No other information was provided. No other information was provided. Important information is missing in the report including pateint's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2.

Case ID	WW Identifier	Narrative	MAH Comment
		Patient received the vaccinations through intramuscular route immunization against COVID-19. From 24 Jun 2021, the patient developed increasing chest pain due to acute myopericarditis. Electrocardiogram (ECG) was initially unremarkable, over further course there were ST segment elevations in the inferior leads and in V2-5, without PQ depression, with “J wave”. Pericarditis or “early repolarization” was discussed as a differential diagnosis. Transthoracic echocardiogram (TTE) showed left ventricular ejection fraction of 50-55%, hypokinesia of the inferoinferoseptobasal region, and global longitudinal strain of 19%. Therapy with Irfen (ibuprofen) and colchicine was started. Over further course, the patient's condition improved. As concomitant medication, the patient was using doxycycline 200 mg/day due to testicular pain (19 Jun 2021 – 24 Jun 2021). Company comment: This case concerns a 35-year-old, male patient, known tobacco user with no relevant medical history, who experienced the expected event of Myocarditis. The event occurred approximately 2 days after the second dose of Moderna vaccine. The event was considered related to the product per the reporter’s assessment. The event is consistent with the current understanding of the mechanism of action of the study medication. The benefit-risk relationship of Spikevax is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 17-Sep-2021: Translation was received on 22-sep-2021, and the medical history was updated. The route of administration of vaccine, concomitant medicine information, event description, laboratory	

Case ID	WW Identifier	Narrative	MAH Comment
		information, treatment medications were updated in I narrative.	
4.1(b)	4.1(b)	This regulatory authority case was reported by a physician and describes the occurrence of INFLUENZA LIKE ILLNESS (4.1(b)) and MYOCARDITIS (Perimyocarditis) in an 18-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) (batch nos. 3002912 and 3003185) for SARS-CoV-2 immunization. No Medical History information was reported. On 11-Jun-2021, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) .5 milliliter. On 09-Jul-2021, received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) dosage was changed to .5 milliliter. On 09-Jul-2021, after starting mRNA-1273 (COVID-19 Vaccine Moderna), the patient experienced INFLUENZA LIKE ILLNESS (4.1(b)) (seriousness criterion hospitalization). On 11-Jul-2021, the patient experienced MYOCARDITIS (Perimyocarditis) (seriousness criteria hospitalization and medically significant). On 15-Jul-2021, INFLUENZA LIKE ILLNESS (4.1(b)) had resolved. At the time of the report, MYOCARDITIS (Perimyocarditis) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 15-Jul-2021, Echocardiogram: normal (normal) no pericardial effusion, LV systolic function normal. On 15-Jul-2021, Electrocardiogram: normal (normal) regular, normal rhythm, QRS narrow and regular with no signs of ischemia. In August 2021, Magnetic resonance imaging heart: normal (normal) Normal.	18 year old male patient who is a 4.1(b) and sporty who drinks alcohol occasionally. Patient's medical history included consultation for palpitations on unspecified date of 2020 and 2021. Same day after receiving 2nd dose of vaccine, patient experienced fever, chills, feeling hot, muscle pain, and abundant night sweats. 2 days later patien experienced lower oppressive chest pain and pain aggravated by deep inhalation, with the pain radiating towards the right flank. Patient was treated with analgesics but symptoms was not improved. Patient also experienced tachycardia, with no indication of malaise or loss of consciousness. Patient's lab data reported elevated troponins I and elevated CK. EKG, Echo and cMRI were all normal. No other information was provided. Important information is missing in the report including pateint's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. This case is heavily confounded by the negative imaging test results

Case ID	WW Identifier	Narrative	MAH Comment
		For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered INFLUENZA LIKE ILLNESS ([redacted]) and MYOCARDITIS (Perimyocarditis) to be probably related. This case concerns an 18 year old male patient who is a [redacted] and sporty who drinks alcohol occasionally. Patient's medical history reported included consultation for palpitations on unspecified date of 2020 and 2021. After receiving second dose of vaccine, on 09-Jul-2021 patient experienced fever with a temperature of 38.7°C, accompanied by chills, feeling hot, muscle pain, and abundant night sweats. Fever was recovered on 15-Jul-2021. Patient was hospitalized on 15-Jul-2021 due to lower chest pain with an intensity of 5/10 on the visual analogue scale. It was reported that pain was oppressive with progressive onset since 11-Jul-2021 and pain aggravated by deep inhalation, with the pain radiating towards the right flank. Patient was treated with analgesics but symptoms was not improved. Patient also experienced tachycardia, with no indication of malaise or loss of consciousness. Patient's lab data reported also included Ultra-sensitive troponins I (N <60 ng/L): 140 ng/L (15.07.2021); 124 ng/L (16.07.2021). CK: 61 U/L (15.07.2021); 38 U/L (16.07.2021) Patient was discharged from hospital on 16-Jul-2021 with nonsteroidal anti-inflammatory drugs (NSAID) prescribed for 10 days, combined with colchicine for 2 months. Vitals signs measurement at the time of discharge included blood pressure 133/65 mmHg, pulse 74 bpm, temperature 36.8°C, 98%saturation in ambient air. Patient also experienced short of breath when working and episodes of mild chest pain around 17-Aug-2021. It was reported that patient stopped taking colchicine based on the MRI result. This case concerns a 18-year-old, male patient with no relevant medical	

Case ID	WW Identifier	Narrative	MAH Comment
		history, who experienced the unexpected event of influenza like illness and the expected event of myocarditis. The event influenza like illness occurred the same day with the second dose of mRNA-1273 vaccine administration, and the event myocarditis occurred 2 days after second dose of mRNA-1273 vaccine administration. The rechallenge was unknow Most recent FOLLOW-UP information incorporated above includes: On 17-Sep-2021: Translation received on 21-Sep-2021 included patient's medical history (palpitations), lab data results and additional events (fever, chills, feeling hot, muscle pain, night sweats).	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 17-Sep-2021 and was forwarded to Moderna on 17-Sep-2021. This regulatory authority case was reported by a pharmacist and describes the occurrence of CHEST PAIN (Chest pain), ABDOMINAL PAIN UPPER (epigastrialgia), PYREXIA (Fever), MALAISE (Malaise), PALPITATIONS (Palpitation) and MYOCARDITIS (Perimyocarditis) in a 21-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 immunisation. Previously administered products included for an unreported indication: COVID-19 VACCINE JANSSEN (AD26.COV2.S) in 2021. On 17-Aug-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. In August 2021, the patient experienced CHEST PAIN (Chest pain) (seriousness criteria hospitalization and life threatening), ABDOMINAL PAIN UPPER (epigastrialgia) (seriousness criteria hospitalization and life threatening) and PALPITATIONS (Palpitation)	21-year-old, male patient with unknown medical history, and who received the Janssen vaccine at an undetermine time and the next day after the 3?? dose of the Moderna vaccine experienced chest pain, adominal pain upper, pyrexia, malaise, palpitation and was diagnosed with mocarditis 2 days later. Laboratory results showed elevated troponin, CRP, and BNP; decreased platelet levels, normal chest x-rays; ECG and EKG were abnormal. No other information was provided. It is not clear how many doses this patient actually received give n that the Janssen vaccine is a one-dose COVID-19 vaccine, and it is also not clear if this was then a second Moderna vaccine dose or just one dose. This report is confounded by the administration of the other COVID-19 vaccine

Case ID	WW Identifier	Narrative	MAH Comment
		(seriousness criteria hospitalization and life threatening). On 18-Aug-2021, the patient experienced PYREXIA (Fever) (seriousness criteria hospitalization and life threatening) and MALAISE (Malaise) (seriousness criteria hospitalization and life threatening). On 20-Aug-2021, the patient experienced MYOCARDITIS (Perimyocarditis) (seriousness criteria hospitalization, medically significant and life threatening). At the time of the report, CHEST PAIN (Chest pain) had not resolved and ABDOMINAL PAIN UPPER (epigastrialgia), PYREXIA (Fever), MALAISE (Malaise), PALPITATIONS (Palpitation) and MYOCARDITIS (Perimyocarditis) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In August 2021, Blood test: tnt 39 (abnormal) TNT 39 and was 13 when discharged. CRP: 53 and was 8 when discharged. BNP: 450 and is 10 when discharge. Platelets: 128 and was 152 when discharge.. In August 2021, Chest X-ray: no signs of air or fluid in the pleura. no infecti (normal) No signs of air or fluid in the pleura. No infection is demarcated. Heart size and blood vessel dimension within normal limits. Free air is not detected under the diaphragm. In August 2021, Echocardiogram: echocardiography. preserved left ventricular contr (abnormal) Insignificant echocardiography. Preserved left ventricular contraction, emission fraction 60%. Not to see motile lumps on the valves. There is mild calcification on the cordae on the tricuspid valve but no clear signs of vegetation. There is a mild leak in the tricuspid valve.. In August 2021, Electrocardiogram: sinus rhythm, hr 95. (abnormal) Sinus rhythm, HR 95. High take of ST-segment (V3-V6).. In August 2021, Urine analysis: negative (Negative) Negative.	

Case ID	WW Identifier	Narrative	MAH Comment
		The action taken with mRNA-1273 (Spikevax) (Unknown) was unknown. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. Company Comment: This case concerns a 21-year-old, male patient with no previous relevant medical history, who experienced the unexpected events of chest pain, adominal pain upper, pyrexia, malaise, palpitation and expected events of mocarditis. Pyrexia and malaise occurred 1 day after, and myocarditis occurred 3 days after the first dose of mRNA-1273 (Moderna COVID-19 Vaccine). The rechallenge was not applicable since only information about the first dose was disclosed. The reporter assessed the events as possible. The benefit-risk relationship of mRNA-1273 (Moderna COVID-19 Vaccine) is not affected by this report.	
4.1(b) [redacted]	4.1(b) [redacted]	This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 17-Sep-2021 and was forwarded to Moderna on 17-Sep-2021. This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (4.1(b) [redacted]) and troponin-T (4.1(b) [redacted] 378) in a 20-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3003604) for Vaccination. Co-suspect product included non-company product TOZINAMERAN (COMIRNATY) for COVID-19 vaccination. No Medical History information was reported. On 01-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form.	20 years old male with history of receiving the other mRNA vaccine as the 1st dose, and who 3 days after the 2nd dose was diagnosed with myopericarditis. Lab results showed elevated troponin and CRP. Echo normal and EKG abnormal. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. This report is confounded by the adminstration of the other mRNA vaccine

Case ID	WW Identifier	Narrative	MAH Comment
		On an unknown date, the patient started TOZINAMERAN (COMIRNATY) (unknown route) at an unspecified dose. On 04-Sep-2021, the patient experienced MYOCARDITIS (4.1(b) troponin-T 4.1(b) 378) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (4.1(b) troponin-T 4.1(b) 378) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 04-Sep-2021, C-reactive protein: high (High) Slightly increased. On 04-Sep-2021, Echocardiogram: normal (normal) Normal. On 04-Sep-2021, Electrocardiogram: perimyocarditis (abnormal) Findings consistent with perimyocarditis. On 04-Sep-2021, Troponin T: 378 (abnormal) 378. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No relevant concomitant medications were reported. The patient had Perimyocarditis, troponin-t increase to 378. No treatment information was provided. Company Comment: This case concerns a 20-year-old, male patient with no relevant medical history, who experienced the unexpected event of Myocarditis. The event occurred approximately 3 days after the second dose of Moderna Covid-19 vaccine. The rechallenge was not applicable, as limited information was provided about the first dose. The event was considered related to the product per the reporter's assessment. The event is consistent with the current understanding of the mechanism of action of the study medication The benefit-risk relationship of Moderna	

Case ID	WW Identifier	Narrative	MAH Comment
		Covid-19 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 17-Sep-2021: Translation Received on 22-Sep-2021, Narration was updated.	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 17-Sep-2021 and was forwarded to Moderna on 17-Sep-2021. This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (4.1(b)) and COVID-19 IMMUNISATION (REVACCINATION WITH DIFFERENT COVID-19 VACCINE) in a 25-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3004959) for Vaccination. Previously administered products included for Vaccination: Comirnaty. On 27-Aug-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 30-Aug-2021, the patient experienced MYOCARDITIS 4.1(b)) (seriousness criteria hospitalization and medically significant). On an unknown date, the patient experienced COVID-19 IMMUNISATION (REVACCINATION WITH DIFFERENT COVID-19 VACCINE) (seriousness criterion hospitalization). At the time of the report, MYOCARDITIS 4.1(b)) and COVID-19 IMMUNISATION (REVACCINATION WITH DIFFERENT COVID-19 VACCINE) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 30-Aug-2021, Cardiac telemetry: normal (normal) Normal. On 30-Aug-2021, Magnetic resonance imaging heart: abnormal	25 years old male with history of receiving the other mRNA vaccine as the 1st dose, and who 3 days after the 2nd dose was diagnosed with myopericarditis. Lab results showed elevated troponin. cMRI abnormal. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. This report is confounded by the adminstration of the other mRNA vaccine

Case ID	WW Identifier	Narrative	MAH Comment
		(abnormal) Findings compatible with acute PERI MYOCARDITIS. On 30-Aug-2021, Troponin: 500 (abnormal) Troponines max around 500. For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered MYOCARDITIS (4.1(b) [redacted]) and COVID-19 IMMUNISATION (REVACCINATION WITH DIFFERENT COVID-19 VACCINE) to be possibly related. No concomitant medication was reported. Treatment information was not provided by reporter. Company comment This is a case of revaccination with different COVID-19 vaccine concerning a 24-year-old female patient, with no reported medical history who experienced the unexpected event of myocarditis. The event occurred 3 days after the second dose of Spikevax. The rechallenge was unknown as no details about the first dose was provided. Causality assessment for the event was not provided by the reporter. The event is consistent with the current understanding of the mechanism of action of mRNA-1273. The benefit-risk relationship of mRNA-1273 is not affected by this report. Event seriousness assessed as per Regulatory Authority reporting and event is a medical important event. Most recent FOLLOW-UP information incorporated above includes: On 17-Sep-2021: Translation document received on 22-Sep-2021 include no newinformation.	
4.1(b) [redacted]	4.1(b) [redacted]	This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 17-Sep-2021 and was forwarded to Moderna on 17-Sep-2021.	33 years old male with history of receiving the other mRNA vaccine as the 1st dose, and who 1 days after the 2nd dose was diagnosed with myopericarditis. Abnormal EKG and normal Echo wihtout pericardial

Case ID	WW Identifier	Narrative	MAH Comment
		This regulatory authority case was reported by a physician and describes the occurrence of CHEST PAIN (4.1(b) COVID-19 IMMUNISATION (4.1(b) and PERICARDITIS (4.1(b) in a 33-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3004224) for COVID-19 vaccination. Previously administered products included for Vaccination: COMIRNATY. On 02-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 02-Sep-2021, the patient experienced CHEST PAIN (4.1(b) (seriousness criterion medically significant), COVID-19 IMMUNISATION (4.1(b) (seriousness criterion medically significant) and PERICARDITIS (4.1(b) (seriousness criterion medically significant). At the time of the report, CHEST PAIN (4.1(b) COVID-19 IMMUNISATION (4.1(b) and PERICARDITIS (4.1(b) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 03-Sep-2021, Electrocardiogram: abnormal (abnormal) ST elevations in most precordial leads and some extremity leads (do not have access to this). Suspected pericarditis.. In September 2021, Echocardiogram: normal (normal) Normal without pericardial effusion. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No relevant concomitant and treatment medications were reported. Company Comment: The case concerns a 33-year-old-male patient with previous relevant	effusion. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. This report is confounded by the adminstration of the other mRNA vaccine

Case ID	WW Identifier	Narrative	MAH Comment
		medical history of vaccination with COMIRNATY, who experienced the unexpected event of chest pain and the expected evet pericarditis. Revaccination with different COVID-19 vaccine was considered as an additional event. The event occurred the same day, after the first dose of Spikevax. The rechallenge was not applicable since only information about the first dose was disclosed. The medical history of vaccination with COMIRNATY remains a confounder for the events pericarditis and chest pain. The events are consistent with the current understanding of the mechanism of action of the vaccine. The benefit-risk relationship of Spikevax is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 17-Sep-2021: Translation Received on 22-SEP-2021, Narration & Event Verbatim is Translated	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 17-Sep-2021 and was forwarded to Moderna on 17-Sep-2021. This regulatory authority case was reported by a physician and describes the occurrence of COVID-19 IMMUNISATION (4.1(b) CHEST PAIN (4.1(b) and MYOCARDITIS (4.1(b) in a 19-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3003604) for COVID-19 vaccination. Previously administered products included for Vaccination: Comirnaty (5'capped mRNA encoding full length SARS-CoV-2 spike protein). On 03-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 05-Sep-2021, the patient experienced COVID-19	19 years old male with history of receiving the other mRNA vaccine as the 1st dose, and who 2 days after the 2nd dose experienced chest pain and was diagnosed with myocarditis. Lab results showed elevated troponin and abnormal EKG. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. This report is confounded by the administration of the other mRNA vaccine

Case ID	WW Identifier	Narrative	MAH Comment
		IMMUNISATION (4.1(b) (seriousness criterion hospitalization), CHEST PAIN (4.1(b) (seriousness criterion hospitalization) and MYOCARDITIS (4.1(b) (seriousness criteria hospitalization and medically significant). At the time of the report, COVID-19 IMMUNISATION (4.1(b) CHEST PAIN (4.1(b) and MYOCARDITIS (4.1(b) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 05-Sep-2021, Electrocardiogram: abnormal (abnormal) Electrocardiogram shows ST-depression.. On 05-Sep-2021, Troponin I: 400 (Inconclusive) inconclusive. In September 2021, Troponin I: 29633 (Inconclusive) inconclusive. For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered COVID-19 IMMUNISATION (4.1(b) CHEST PAIN (4.1(b) and MYOCARDITIS (4.1(b) to be possibly related. No concomitant medications were provided by the reporter No treatment information was provided by the reporter. This case concerns a 19-year-old, male patient with no relevant medical history, who experienced the unexpected events of chest pain and revaccination with different Covid vaccine and expected event of myocarditis. The events of chest pain and myocarditis occurred approximately 2 days after the dose of Moderna COVID-19 Vaccine. The patient received Comirnaty vaccine previously. The rechallenge was not applicable. The reporter assessed the events as related to the product. The benefit-risk relationship of Moderna	

Case ID	WW Identifier	Narrative	MAH Comment
		COVID-19 Vaccine is not affected by this report. Chest pain could be the symptom of myocarditis. Most recent FOLLOW-UP information incorporated above includes: On 17-Sep-2021: Translated document received on 22-SEP-2021 included suspect drug related additional information and dosage form updated.	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 17-Sep-2021 and was forwarded to Moderna on 17-Sep-2021. This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (4.1(b) in a 20-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3004224) for COVID-19 vaccination. No Medical History information was reported. On 27-Aug-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 28-Aug-2021, the patient experienced MYOCARDITIS (4.1(b) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (4.1(b) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 28-Aug-2021, Echocardiogram: abnormal (abnormal) Thickened pericardium.. On 28-Aug-2021, Electrocardiogram: abnormal (abnormal) Globalized ST elevations and abnormal (abnormal) PQ depressions.. On 28-Aug-2021, Troponin T: 757 nanogram per liter (High) 757 nanogram per liter.	20 years old male with unknown medical history who next day after the 2nd dose was diagnosed with myocarditis. Lab results showed elevated troponin, abnormal Echo and EKG. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2.

Case ID	WW Identifier	Narrative	MAH Comment
		For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered MYOCARDITIS (4.1(b) to be possibly related. No concomitant medications were provided. No treatment information was provided. Company Comment : This case concerns a 20-year-old male subject with no reported relevant medical history, who experienced the expected event of Myocarditis (AESI). The event occurred 2 days after the second dose of Spikevax. The rechallenge was not applicable since only information about one dose was disclosed. The events were considered possibly related to Spikevax Vaccine per the reporter's assessment. The event is consistent with the current understanding of the mechanism of action of the study medication. The benefit-risk relationship of Spikevax Vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 17-Sep-2021: Translation Received on 22-SEP-2021, No new information	
4.1(b)	4.1(b)	This case was received via 4.1(b) Pharmaceuticals (Reference number: 4.1(b)) on 11-Sep-2021 and was forwarded to Moderna on 11-Sep-2021. This case, initially reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref, 4.1(b) On an unknown date, the patient received the 1st dose of this vaccine. on 18-Aug-2021, the patient received the 2nd dose of this vaccine. At night, pyrexia of 38.0 degrees Celsius developed and persisted up until 20-Aug-2021.	22 years old male with unknown medical history who 2 days after the 2nd dose was diagnosed with myocarditis. Lab results showed elevated troponin, abnormal EKG and cMRI. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2.

Case ID	WW Identifier	Narrative	MAH Comment
		On 21-Aug-2021, at the time of awakening, chest pain developed. The patient visited the reporting hospital. Electrocardiogram showed ST elevation in a wide range of lead, and Trop 1 was also positive (0.985 ng/mL). The patient was hospitalized with suspected pericarditis and myocarditis. Subsequent cardiac MRI showed LGE in the side of the epicardium. Myocarditis was diagnosed because there was also a high signal at 92 W. On 26-Aug-2021, the patient was discharged from the hospital. On 08-Sep-2021, it was confirmed the symptoms were resolving. The outcome of myocarditis was reported as resolving. Follow-up investigation will be made. Company Comment: The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 17-Sep-2021 and was forwarded to Moderna on 17-Sep-2021. This regulatory authority case was reported by a physician and describes the occurrence of the first episode of CHEST DISCOMFORT (4.1(b) the second episode of CHEST DISCOMFORT (4.1(b) and PERICARDITIS (4.1(b) in a 22-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 1601800) for Vaccination. The occurrence of additional non-serious events is detailed below. Co-suspect product included non-company product TOZINAMERAN (COMIRNATY) for Vaccination.	22 years old male with history of receiving the other mRNA vaccine as the 1st dose, and who 4 days after the 2nd dose was diagnosed with pericarditis. Lab results showed elevated troponin and CRP but normal Echo amd EKG. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. This report is confounded by the administration of the other mRNA vaccine

Case ID	WW Identifier	Narrative	MAH Comment
		No Medical History information was reported. On 08-Jul-2021 at 12:00 PM, the patient received first dose of TOZINAMERAN (COMIRNATY) (Intramuscular) 1 dosage form. On 25-Aug-2021 at 12:00 PM, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 29-Aug-2021, the patient experienced the first episode of CHEST DISCOMFORT (4.1(b) (seriousness criterion medically significant), the second episode of CHEST DISCOMFORT (4.1(b) (seriousness criterion medically significant) and PERICARDITIS (4.1(b) (seriousness criterion medically significant). On an unknown date, the patient experienced COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine). At the time of the report, last episode of CHEST DISCOMFORT (4.1(b) and PERICARDITIS (4.1(b) outcome was unknown and COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In August 2021, C-reactive protein: 19 (High) 19 mg/L. In August 2021, Echocardiogram: normal (normal) No finding of pathological amounts of pericardial fluid, only subnormal systolic function at rest.. In August 2021, Electrocardiogram: normal (normal) Normal. In August 2021, Troponin: 20 (High) 20 ng/L. In August 2021, White blood cell count: normal (normal) Normal. For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered CHEST DISCOMFORT (4.1(b) CHEST DISCOMFORT	

Case ID	WW Identifier	Narrative	MAH Comment
		(4.1(b) and PERICARDITIS (4.1(b) to be possibly related. No further causality assessment was provided for COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine). Concomitant medications were not provided by the reporter. Treatment information was not provided. Company Comment: This case concerns a 22-year-old, male patient with no known medical history, who experienced the unexpected events of chest discomfort, chest pressure and revaccination with different covid 19 vaccine and and expected event of pericarditis. The events occurred approximately 5 days after the dose of Spikevax and had an unknown outcome. The patient received one dose of Cominarty prior to Spikevax. The rechallenge is not applicable, as another dose of spikevax is not expected. The event was considered related to the product per the reporter's assessment. The event pericarditis is consistent with the current understanding of the mechanism of action of the study medication. The product Cominarty vaccine remains as a confounding factor to the events. The benefit-risk relationship of Spikevax is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 17-Sep-2021: Translation document received on 23-SEP-2021, contains no new information.	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 16-Sep-2021 and was forwarded to Moderna on 16-Sep-2021. This regulatory authority case was reported by a physician and describes the occurrence of CHEST PAIN 4.1(b)), TACHYCARDIA (4.1(b) and MYOCARDITIS (4.1(b) in	22 years old male with medical history of asthma who 4 days after the 2nd dose experienced chest pain and tachycardia and was diagnosed with myocarditis. Lab results showed elevated troponin, abnormal Echo and cMRI. No other information was provided. Important information is missing in the report including patient's medical history as well as

Case ID	WW Identifier	Narrative	MAH Comment
		a 22-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 3002916 and 3002916) for COVID-19 vaccination. The patient's past medical history included Bronchial asthma since an unknown date. Concomitant products included CICLESONIDE (ALVESCO) and CETIRIZINE HYDROCHLORIDE (ZODAC) for Bronchial asthma. On 25-Jun-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 06-Aug-2021, received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to 1 dosage form. On 10-Aug-2021, the patient experienced CHEST PAIN (4.1(b)) (seriousness criteria hospitalization, medically significant and life threatening), TACHYCARDIA (4.1(b) (seriousness criteria hospitalization, medically significant and life threatening) and MYOCARDITIS (4.1(b) (seriousness criteria hospitalization, disability, medically significant and life threatening). At the time of the report, CHEST PAIN (4.1(b)), TACHYCARDIA (4.1(b) and MYOCARDITIS (4.1(b) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 10-Aug-2021, Angiogram: abnormal (abnormal) Coronary arteries without any pathology. On 10-Aug-2021, Echocardiogram: abnormal (abnormal) borderline dilatation of the left ventricle and borderline ejection fraction, no kinetic disturbance, minimal pericardial effusion. On 10-Aug-2021, Ejection fraction: borderline (Borderline) Borderline. On 10-Aug-2021, Magnetic resonance imaging heart: abnormal (abnormal) acute myocarditis with oedema and late saturation, mildly	any other laboratory test conducted, including testing for SARS-CoV-2.

Case ID	WW Identifier	Narrative	MAH Comment
		reduced systolic function of the borderline large left ventricle, mildly reduced systolic function of the slightly enlarged right ventricle. In August 2021, Troponin T: 1147 ng/l; 1744 ng/l (abnormal) highly sensitive Troponin T. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Lab tests were conducted on an unknown date in Aug,2021 to rule out an autoimmune or infectious cause of peri myocarditis (results not provided). Treatment information was not provided. Company Comment : This case concerns a 22-year-old, male patient with no relevant medical history, who experienced the unexpected events of Chest pain, Tachycardia, and the expected event of Myocarditis. The events occurred around 5 days after second dose of Spikevax. The rechallenge was not applicable since no events were reported after the first dose. The event Myocarditis is consistent with the current understanding of the mechanism of action of the vaccine. The benefit-risk relationship of Spikevax is not affected by this report.	
4.1(b)	4.1(b)	This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS 4.1(b) in a 22-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination. No Medical History information was reported. On 14-Jul-2021, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 100 microgram. On 11-Aug-2021, received second dose of mRNA-1273 (COVID-19	22 years old male with unknown medical history who 2 days after the 2nd dose experienced fatigue and chest pain and discomfort and was diagnosed with myocarditis. Lab results showed elevated troponin, CPK, and abnormal EKG. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2.

Case ID	WW Identifier	Narrative	MAH Comment
		Vaccine Moderna) (Intramuscular) dosage was changed to 100 microgram. On 13-Aug-2021, after starting mRNA-1273 (COVID-19 Vaccine Moderna), the patient experienced MYOCARDITIS (4.1(b) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (4.1(b) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 14-Aug-2021, Blood creatine phosphokinase: 1100 1100 IU/L, taken at 10:00 am, 1333 1333 IU/l MB 103 IU/L and 1690 1690 IU/L, CK MB 150 IU/L taken at 11:00pm. On 14-Aug-2021, Electrocardiogram: normal (normal) Normal rate sinus rhythm. PQ depressions I, V5, V5 [sic], ST segment elevation II, V4-V6. Ejection fraction was visually 65%.. On 14-Aug-2021, Heart rate: 70 70 BPM. On 14-Aug-2021, Troponin: 1176 1176 ng/L, Taken at 10:00 am, 1245 hs T 1245 ng/L, Taken at 5:00 pm and 1346 1346 ng/L, Taken at 11:00pm. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered MYOCARDITIS (4.1(b) to be possibly related. No concomitant medication was reported. No treatment medication was reported. After the second vaccination, patient developed sever fatigue and chest pain and discomfort when bending on the left side. Was hospitalized for possible acute coronary syndrome or myocarditis. Cardiac ultrasound showed normal results and no pericardial effusions.	

Case ID	WW Identifier	Narrative	MAH Comment
		company comment: This case concerns a 22-year-old, male patient with no relevant medical history, who experienced the expected events of Myocarditis. The events occurred approximately 3 days after the second dose of Spikevax. The rechallenge was unknown since no event about the first dose was disclosed. The benefit-risk relationship of Spikevax is not affected by this report. Event seriousness assessed as per Regulatory Authority reporting, however there was no information in the source document supporting that the events resulted in a persistent or permanent incapacity Most recent FOLLOW-UP information incorporated above includes: On 21-Sep-2021: Translation document received on 23-Sep-2021, laboratory tests and findings updated.	
4.1(b)	4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b) on 21-Sep-2021 and was forwarded to Moderna on 21-Sep-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCARDITIS (Myocarditis), CHEST DISCOMFORT (Chest discomfort) and PAIN IN JAW (Pain in jaw) in a 26-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 051C21A) for COVID-19 vaccination. Concomitant products included MULTIVITAMIN [VITAMINS NOS] for an unknown indication. On 29-Jul-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 01-Aug-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant), CHEST DISCOMFORT (Chest discomfort)	26 years old female with unknown medical history and taking contraceptives for an unknown time who 2 days after the 2nd dose experienced chest discomfort and pain in the jaw and was diagnosed with myocarditis. Lab results showed elevated troponin and CRP, and abnormal MRI. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2.

Case ID	WW Identifier	Narrative	MAH Comment
		(seriousness criterion hospitalization) and PAIN IN JAW (Pain in jaw) (seriousness criterion hospitalization). The patient was hospitalized on 02-Aug-2021 due to CHEST DISCOMFORT, MYOCARDITIS and PAIN IN JAW. At the time of the report, MYOCARDITIS (Myocarditis), CHEST DISCOMFORT (Chest discomfort) and PAIN IN JAW (Pain in jaw) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 01-Aug-2021, C-reactive protein: increased (High) increased. On 01-Aug-2021, Magnetic resonance imaging thoracic: abnormal (abnormal) abnormal. On 01-Aug-2021, Red blood cell sedimentation rate: increased (High) increased. On 01-Aug-2021, Troponin: 3.2 (High) 3.2. On 02-Aug-2021, Magnetic resonance imaging: abnormal (abnormal) revealed inflammation in the myocardium.. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter considered MYOCARDITIS (Myocarditis) to be related. No further causality assessments were provided for CHEST DISCOMFORT (Chest discomfort) and PAIN IN JAW (Pain in jaw). Patient received an echo, EKG, and was attached to a holter monitor,Electrocardiogram ambulatory. concomitant medications :birth control pill. No treatment medication details was reported. Company Comment: This case concerns a 26-year old, female subject with no relevant medical history, who experienced the expected event of Myocarditis and the unexpected events of Chest	

Case ID	WW Identifier	Narrative	MAH Comment
		discomfort and Pain in jaw. The events occurred approximately 3 days after the second dose of MODERNA COVID-19 VACCINE. The reporter assessed the event Myocarditis as likely related to the product. The benefit-risk relationship of MODERNA COVID-19 VACCINE is not affected by this report.	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 21-Sep-2021 and was forwarded to Moderna on 21-Sep-2021. This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (4.1(b) in a 22-year-old male patient who received mRNA-1273 (Spikevax) (batch no. FE9174) for Vaccination. The occurrence of additional non-serious events is detailed below. Previously administered products included for Vaccination: Comirnaty. On 08-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 10-Sep-2021, the patient experienced MYOCARDITIS (4.1(b) (seriousness criteria hospitalization and medically significant), ABDOMINAL PAIN UPPER (EPIGASTRIC PAIN), COLD SWEAT (COLD SWEAT), INFLUENZA LIKE ILLNESS (INFLUENZA-LIKE SYMPTOMS), NAUSEA (NAUSEA) and VOMITING (VOMITING). On an unknown date, the patient experienced COVID-19 IMMUNISATION (REVACCINATION WITH DIFFERENT COVID-19 VACCINE). At the time of the report, MYOCARDITIS (4.1(b) ABDOMINAL PAIN UPPER (EPIGASTRIC PAIN), COLD SWEAT (COLD SWEAT), INFLUENZA LIKE ILLNESS (INFLUENZA-LIKE SYMPTOMS), NAUSEA (NAUSEA) and VOMITING (VOMITING) was resolving and COVID-19	22 years old male with history of receiving the other mRNA vaccine as the 1st dose, and who 2 days after the 2nd dose experienced abdominal pain upper, cold sweat, nausea and vomiting and was diagnosed with myocarditis. Lab results showed elevated troponin and CRP and abnormal EKG. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. This report is confounded by the administration of the other mRNA vaccine

Case ID	WW Identifier	Narrative	MAH Comment
		IMMUNISATION (REVACCINATION WITH DIFFERENT COVID-19 VACCINE) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 10-Sep-2021, C-reactive protein: slightly elevated (High) Slightly elevated (not specified). On 10-Sep-2021, Cardiac telemetry: abnormal (abnormal) VT-complexes. On 10-Sep-2021, Electrocardiogram: abnormal (abnormal) Global ST-elevations and PR-depressions.. On 10-Sep-2021, Troponin I: abnormal (abnormal) 25000 Fluctuating troponins on day 2 in hospital. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Patient was hospitalized 2 days after vaccination with Spikevax. First dose was Comirnaty. No concomitant medications were reported. Patient exhibited clinical improvement on the 2nd day of hospitalization. No treatment medications were reported. Company comment: This case concerns a 22-year-old male patient with no relevant medical history, who experienced serious, listed event of myocarditis. The serious event occurred after 3 days of 2nd dose of Moderna COVID-19 Vaccine. The rechallenge was not applicable as the event occurred after 2nd dose of Moderna COVID-19 Vaccine. The benefit-risk relationship of Moderna COVID-19 Vaccine is not affected by this report. Previously well Hospitalized 2 days after COVID-19 vaccination with Spikevax, 1st dose Comirnaty Severe epigastric pain, nausea, vomiting, cold sweats and prodromal influenza-like symptoms Clinically and biochemically diagnosed with perimyocarditis, considered	

Case ID	WW Identifier	Narrative	MAH Comment
		vaccination related. Clinical improvement on the 2nd day of hospitalization. Most recent FOLLOW-UP information incorporated above includes: On 21-Sep-2021: Translation received on 24-Sep-21 contains no significant information. Sender's comments were updated.	
4.1(b) [redacted]	4.1(b) [redacted]	This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 21-Sep-2021 and was forwarded to Moderna on 21-Sep-2021. This regulatory authority case was reported by a physician and describes the occurrence of PERICARDITIS (PERICARDITIS) in a 35-year-old male patient who received mRNA-1273 (Spikevax) (batch no. FE9174) for Vaccination. The occurrence of additional non-serious events is detailed below. Previously administered products included for Vaccination: Comirnaty. On 01-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 04-Sep-2021, the patient experienced PERICARDITIS (PERICARDITIS) (seriousness criteria hospitalization and medically significant). On an unknown date, the patient experienced COVID-19 IMMUNISATION (REVACCINATION WITH DIFFERENT COVID-19 VACCINE). At the time of the report, PERICARDITIS (PERICARDITIS) and COVID-19 IMMUNISATION (REVACCINATION WITH DIFFERENT COVID-19 VACCINE) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 04-Sep-2021, C-reactive protein: 79 (abnormal) 79/milligram per litre. On 04-Sep-2021, N-terminal prohormone brain natriuretic peptide:	35 years old male with history of receiving the other mRNA vaccine as the 1st dose, and who 3 days after the 2nd dose experienced burning chest pain and was diagnosed with pericarditis. Lab results showed elevated troponin, CRP and NTp-BNP, and abnormal cMRI. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. This report is confounded by the administration of the other mRNA vaccine

Case ID	WW Identifier	Narrative	MAH Comment
		954 nanogram per litre (abnormal) Maximum of 954 ng/L. On 04-Sep-2021, Troponin I: 770 (abnormal) Maximum of 770. On 07-Sep-2021, Ejection fraction: 49 (abnormal) 49%. On 07-Sep-2021, Magnetic resonance imaging heart: abnormal (abnormal) Weak intermediary contrast uptake epicardially in parts of left ventricle. Slightly reduced systolic function of left ventricle.. For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered PERICARDITIS (PERICARDITIS) to be possibly related. No further causality assessment was provided for COVID-19 IMMUNISATION (REVACCINATION WITH DIFFERENT COVID-19 VACCINE). Concomitant product use was not provided by the reporter. Treatment medications included were Colchicine, Ibuprofen and Paracetamol for the pain. Patient was hospitalized with central burning chest pain, worsening when standing upright and deep inspiration. Patient was diagnosed with pericarditis, which has been uncomplicated up to point of reporting. Company comment: This case concerns a 35 year-old male patient with no reported medical history, who experienced the unexpected serious event of Pericarditis and the non-serious event of Revaccination with different COVID-19 vaccine. The event of Pericarditis occurred 4 days after the second dose of mRNA-1273 vaccine. The event of Revaccination with different COVID-19 vaccine occurred when patient was initially dosed with Comirnaty followed by the second dose with Spikevax. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.	

Case ID	WW Identifier	Narrative	MAH Comment
		Most recent FOLLOW-UP information incorporated above includes: On 21-Sep-2021: Translation received on 24-Sep-2021 and contains no new information.	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 22-Sep-2021 and was forwarded to Moderna on 22-Sep-2021. This regulatory authority case was reported by a physician and describes the occurrence of CHEST PAIN (4.1(b) and MYOCARDITIS (4.1(b) in an 18-year-old male patient who received mRNA-1273 (Spikevax) for Vaccination. Previously administered products included for Vaccination: COMIRNATY. On 28-Aug-2021 at 12:41 PM, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 31-Aug-2021, the patient experienced CHEST PAIN (4.1(b) (seriousness criterion hospitalization) and MYOCARDITIS (4.1(b) (seriousness criteria hospitalization and medically significant). At the time of the report, CHEST PAIN (4.1(b) and MYOCARDITIS (4.1(b) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 31-Aug-2021, Echocardiogram: normal (normal) Normal. On 31-Aug-2021, Troponin: 250 (High) 250 ng/L (nanogram per litre). For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered CHEST PAIN (4.1(b) and MYOCARDITIS (4.1(b) to be possibly related.	18 years old male with history of receiving the other mRNA vaccine as the 1st dose, and who 3 days after the 2nd dose experienced chest pain was diagnosed with myocarditis. Lab results showed elevated troponin and normal Echo. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. This report is confounded by the administration of the other mRNA vaccine

Case ID	WW Identifier	Narrative	MAH Comment
		No concomitant medication was reported. No treatment was reported. Company comment: This case concerns a 18 year old male patient with no relevant medical history ,who experienced the serious unexpected event of Chest pain and expected event of Myocarditis . The events occurred 2 days after second dose of Spikevax . The rechallenge was unknown since no information about the first dose was disclosed.The reporter assessed the events as related to the product.The benefit-risk relationship of Spikevax is not affected by this report. Case awaiting translation.	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number:4.1(b)) on 23-Sep-2021 and was forwarded to Moderna on 23-Sep-2021. This regulatory authority case was reported by a physician and describes the occurrence of CHEST PAIN (CHEST PAIN) and MYOCARDITIS (myocarditis) in a 33-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3004224) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Co-suspect product included non-company product TOZINAMERAN (COMIRNATY) for Vaccination. No Medical History information was reported. On 19-Jul-2021, the patient started TOZINAMERAN (COMIRNATY) (Intramuscular) 1 dosage form. On 31-Aug-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 03-Sep-2021, the patient experienced CHEST PAIN (CHEST PAIN) (seriousness criterion hospitalization). On 04-Sep-2021, the patient experienced MYOCARDITIS (myocarditis) (seriousness criterion	33 years old male with history of receiving the other mRNA vaccine as the 1st dose, and who 3 days after the 2nd dose expereinced chest pain and was diagnosed with myocarditis. Lab results showed elevated troponin and CRP. Echo was normal, but EKG and cMRI were abnormal. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. This report is confounded by the administration of the other mRNA vaccine

Case ID	WW Identifier	Narrative	MAH Comment
		hospitalization). On an unknown date, the patient experienced COVID-19 IMMUNISATION (REVACCINATION WITH DIFFERENT COVID-19 VACCINE). At the time of the report, CHEST PAIN (CHEST PAIN) and MYOCARDITIS (myocarditis) had not resolved and COVID-19 IMMUNISATION (REVACCINATION WITH DIFFERENT COVID-19 VACCINE) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 03-Sep-2021, C-reactive protein: 40 (abnormal) 40 and 40 milligram per litre. On 03-Sep-2021, Echocardiogram: normal No pathological findings and no pathological findings (normal) No pathological findings. On 03-Sep-2021, Electrocardiogram: abnormal (abnormal) Global ST-elvations and global st-elvations (abnormal) Global ST-elvations. On 03-Sep-2021, Magnetic resonance imaging heart: abnormal (abnormal) Findings compatible with myocarditis. On 03-Sep-2021, Troponin I: 2000 - 3000 - 2000 ng/l (abnormal) 2000 - 3000 - 2000 ng/L. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medication listed No treatment medications provided It was originally reported perimyocarditis, but the after receiving results from cardiac MRI, the diagnosis was changed to myocarditis Most recent FOLLOW-UP information incorporated above includes: On 23-Sep-2021: Translated document received on 29-sep-2021 contain no new information On 29-Sep-2021: Significant follow up received on 29-sep-	

Case ID	WW Identifier	Narrative	MAH Comment
		2021,comirnanty updated from historical vaccine to suspect vaccineand event perimyocarditis updated to myocarditis.	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 23-Sep-2021 and was forwarded to Moderna on 23-Sep-2021. This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (PERIMYOCARDITIS) in a 24-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3004498) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Previously administered products included for Vaccination: Comirnaty. Concurrent medical conditions included Childhood asthma. On 09-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 11-Sep-2021, the patient experienced MYOCARDITIS (PERIMYOCARDITIS) (seriousness criteria hospitalization and medically significant). On an unknown date, the patient experienced the first episode of COVID-19 IMMUNISATION (REVACCINATION WITH DIFFERENT COVID-19 VACCINE), INCORRECT DOSE ADMINISTERED (Inappropriate dose of vaccine administered), the second episode of COVID-19 IMMUNISATION (REVACCINATION WITH DIFFERENT COVID-19 VACCINE) and CHEST PAIN (chest pain). At the time of the report, MYOCARDITIS (PERIMYOCARDITIS) was resolving, INCORRECT DOSE ADMINISTERED (Inappropriate dose of vaccine administered) had	24 years old male with history of receiving the other mRNA vaccine as the 1st dose, and who 2 days after the 2nd dose exoerienced chest pain was diagnosed with myocarditis. Lab results showed elevated troponin, CRP, and abnormal Echo, but normal EKG. A cMRI performed 4 days later showed sparse perimyocarditis changes basal inferolateral. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. This report is confounded by the administration of the other mRNA vaccine

Case ID	WW Identifier	Narrative	MAH Comment
		resolved and last episode of COVID-19 IMMUNISATION (REVACCINATION WITH DIFFERENT COVID-19 VACCINE) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 11-Sep-2021, C-reactive protein: 100 (High) 100. On 11-Sep-2021, Echocardiogram: abnormal (abnormal) Small amount of pericardial fluid. On 11-Sep-2021, Electrocardiogram: normal (normal) No distinct abnormality. On 11-Sep-2021, Pain assessment: nrs3 (High) NRS 3. On 11-Sep-2021, Troponin T: high (High) 620. On 12-Sep-2021, Echocardiogram: normal (normal) Done by cardiologist. No pericardial fluid. Fine contractility.. On 12-Sep-2021, White blood cell count: abnormal (abnormal) Slight leucopenia, monocytopenia and neutropenia.. On 14-Sep-2021, Troponin T: 709 (High) high. On 15-Sep-2021, C-reactive protein: 18 (abnormal) 18. In September 2021, Electrocardiogram: abnormal (abnormal) 11.9 No distinct abnormality 16.9 ECG was normal at first, but development of global ST-elevations during one of the episodes with chest pain.(New reporter, duplicate report). In September 2021, Magnetic resonance imaging heart: abnormal (abnormal) 15.9 Sparse perimyocarditis changes basal inferolateral. 16.9 Perimyocarditis changes detected as well as reduced contractility in affected myocardium (New reporter, duplicate reportab and. On 15-Sep-2021, Magnetic resonance imaging heart abnormal (abnormal) Sparse perimyocarditis changes basal inferolateral.. On an unknown date, Troponin T: low (Low) 498 (lowest value).	

Case ID	WW Identifier	Narrative	MAH Comment
		For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. No concomitant medications were provided by the reporter. No treatment information was provided by the reporter. Most recent FOLLOW-UP information incorporated above includes: On 24-Sep-2021: follow-up received on 24-SEP-2021, significant follow-up lab data information updated.	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 23-Sep-2021 and was forwarded to Moderna on 23-Sep-2021. This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (MYO-PERICARDITIS - CHEST DISCOMFORT), LOSS OF PERSONAL INDEPENDENCE IN DAILY ACTIVITIES (COULD NOT TAKE PART IN CONTACT SPORTS. HE CAN RETURN TO HIS USUAL ACTIVITIES IN ABOUT 2 WEEKS / AVOIDING EXTREMES OF EXERTION) and IMPAIRED WORK ABILITY (SHOULD STAY OFF WORK UNTIL MONDAY WEEK) in a 22-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 3004218 and 3003604) for COVID-19 vaccination. None. On 28-Jul-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 26-Aug-2021, received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. On 27-Aug-2021, the patient experienced MYOCARDITIS (MYO-PERICARDITIS - CHEST DISCOMFORT) (seriousness criteria hospitalization and medically	22 years old male with unknown medical history who next day after the 2nd dose experienced chest discomfort and was diagnosed with myopericarditis. Lab results showed elevated troponin and CRP, abnormal EKG and normal Echo. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2.

Case ID	WW Identifier	Narrative	MAH Comment
		significant). On an unknown date, the patient experienced LOSS OF PERSONAL INDEPENDENCE IN DAILY ACTIVITIES (COULD NOT TAKE PART IN CONTACT SPORTS. HE CAN RETURN TO HIS USUAL ACTIVITIES IN ABOUT 2 WEEKS / AVOIDING EXTREMES OF EXERTION) (seriousness criteria hospitalization and medically significant) and IMPAIRED WORK ABILITY (SHOULD STAY OFF WORK UNTIL MONDAY WEEK) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (MYO-PERICARDITIS - CHEST DISCOMFORT) was resolving and LOSS OF PERSONAL INDEPENDENCE IN DAILY ACTIVITIES (COULD NOT TAKE PART IN CONTACT SPORTS. HE CAN RETURN TO HIS USUAL ACTIVITIES IN ABOUT 2 WEEKS / AVOIDING EXTREMES OF EXERTION) and IMPAIRED WORK ABILITY (SHOULD STAY OFF WORK UNTIL MONDAY WEEK) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In August 2021, Electrocardiogram: inconclusive (Inconclusive) ECG wide spread concave upwards ST elevation. On 27-Aug-2021, C-reactive protein: 66 (abnormal) Admission CRP 66. On 27-Aug-2021, Echocardiogram: normal (normal) No pericardial effusion. Normal LV function. On 27-Aug-2021, Troponin: 893 (abnormal) Admission Troponin 893. On 30-Aug-2021, C-reactive protein: 10 (normal) normal. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. No treatment information was provided.	

Case ID	WW Identifier	Narrative	MAH Comment
		No relevant concomitant medications were reported. Company comment: This case concerns a 22-year-old, male patient with no relevant medical history, who experienced the unexpected events of impaired work ability, loss of personal independence in daily activities, and the expected event of Myocarditis. The event Myocarditis occurred 1 day after the second dose of Spikevax. The rechallenge was not applicable, as no additional dosing will be given. The event myocarditis is consistent with the current understanding of the mechanism of action of the vaccine. The benefit-risk relationship of Spikevax is not affected by this report. Events term, onset date, outcome and seriousness captured per SD from Regulatory Authority reporting.	
4.1(b)	4.1(b)	This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (4.1(b)) in a 33-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination. Concurrent medical conditions included Alcohol use and Tobacco user. On 10-Jun-2021, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 200 microgram. On 08-Jul-2021, received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) dosage was changed to 200 microgram. On 19-Aug-2021, after starting mRNA-1273 (COVID-19 Vaccine Moderna), the patient experienced MYOCARDITIS (4.1(b)) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (4.1(b)) had not resolved.	33 years old male with unknown medical history who 42 days after the 2nd dose experienced left thoracic pain and was diagnosed with myocarditis. Lab results showed elevated troponin and CPK, abnormal Echo and EKG. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2.

Case ID	WW Identifier	Narrative	MAH Comment
		DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 20-Aug-2021, Echocardiogram: abnormal (abnormal) abnormal. On an unknown date, Angiogram: normal (normal) normal. On an unknown date, Blood creatine phosphokinase: 1506 peak: 1707 (High) 1506 peak: 1707. On an unknown date, Electrocardiogram: abnormal (abnormal) abnormal. On an unknown date, Troponin T: 2251 peak: 4441 (High) 2251 peak: 4441. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered MYOCARDITIS (4.1(b) to be possibly related. patient took moderna covid-19 vaccine on 08-JUL-2021 and on 19-AUG-2021 patient had complained of left thoracic pain without any previous symptoms of infection. Concomitant product use was not provided by the reporter. No treatment information was provided. Most recent FOLLOW-UP information incorporated above includes: On 23-Sep-2021: Translation Received on 28-SEP-2021 contains significant information ECG, transthoracic echocardiogram, coronary angiography added in lab data.in history alcohol use, tobacco use added narrative updated.	
4.1(b)	4.1(b)	This regulatory authority case was reported by a physician and describes the occurrence of CHEST PAIN (4.1(b) PYREXIA (4.1(b)), HEADACHE (4.1(b) LIMB DISCOMFORT (4.1(b) ABDOMINAL PAIN (4.1(b) and MYOCARDITIS (4.1(b) in a 37-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) (batch nos.	37 years old male with unknown medical history who 4 days after the 2nd dose experienced chest pain was diagnosed with myocarditis. Lab results showed abnormal angiogram and abnormal EKG. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2.

Case ID	WW Identifier	Narrative	MAH Comment
		30380777700688 and 3002541) for COVID-19 vaccination. No Medical History information was reported. On 03-May-2021, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form. On 31-May-2021, received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) dosage was changed to 1 dosage form. On 31-May-2021, the patient experienced PYREXIA ([redacted]) (seriousness criteria hospitalization and medically significant), HEADACHE ([redacted]) (seriousness criteria hospitalization and medically significant), LIMB DISCOMFORT ([redacted]) (seriousness criteria hospitalization and medically significant) and ABDOMINAL PAIN ([redacted]) (seriousness criteria hospitalization and medically significant). On 02-Jun-2021, the patient experienced CHEST PAIN ([redacted]) (seriousness criteria hospitalization and medically significant). On 04-Jun-2021, the patient experienced MYOCARDITIS ([redacted]) (seriousness criteria hospitalization and medically significant). On 02-Jun-2021, PYREXIA ([redacted]), HEADACHE ([redacted]) LIMB DISCOMFORT ([redacted]) and ABDOMINAL PAIN ([redacted]) had resolved. At the time of the report, CHEST PAIN ([redacted]) and MYOCARDITIS ([redacted]) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 04-Apr-2021, Angiocardiogram: abnormal (abnormal) Bland coronary arteries with smooth walls,Apical hypokinesia, LVEF 45-50%. On 04-Jun-2021, Electrocardiogram: abnormal (abnormal) Sinus rhythm	

Case ID	WW Identifier	Narrative	MAH Comment
		with normal heart rate (68bpm)heart axis between +30degrees and +60 degrees PQ interval (146 ms) narrow QRS, R/S transition V3/V4,Diffuse ST segment elevation , no other repolarization abnormalities. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered PYREXIA (4.1(b)) and HEADACHE (4.1(b) to be probably related and CHEST PAIN (4.1(b) LIMB DISCOMFORT (4.1(b) ABDOMINAL PAIN (4.1(b) and MYOCARDITIS (4.1(b) to be possibly related. Concomitant products were not provided. Treatment medication were not reported. Post second dose patient developed body ache, headache, abdominal cramps, fever. On 02-JUN-2021 patient developed chest pain in the middle , with radiation into left upper arm and also in the right arm. The event got recovered and reoccurred on 03-JUN- 2021 and 04-JUN-2021.Later the patient was taken to emergency room and upon admission the vitals were observed as blood pressure 124/93 mmHg, pulse 77 bpm, O2 100% and body temperature of 36.3 degree Celsius. The patient was hospitalized on 04-JUN-2021. At the time of reporting the condition of the patient was reported as improving. The patient had a family history of myocarditis for his uncle at age of 60. Company Comment: This case concerns a 37 year old male patient with no medical history reported, who experienced the unexpected serious events of PYREXIA, HEADACHE, LIMB DISCOMFORT and ABDOMINAL PAIN within the same day after the second dose of mRNA-	

Case ID	WW Identifier	Narrative	MAH Comment
		1273 vaccine and experienced the unexpected serious event of CHEST PAIN, within 2 days after the second dose of mRNA-1273 vaccine and experienced the expected serious event of MYOCARDITIS, within 4 days after the second dose of mRNA-1273 vaccine. The HCP reporter considered PYREXIA and HEADACHE to be probably related and CHEST PAIN, LIMB DISCOMFORT, ABDOMINAL PAIN and MYOCARDITIS to be possibly related. Rechallenge is not applicable. The benefit-risk relationship of the vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 22-Sep-2021: Translation received on 28-Sep-2021 and had significant information. Updated lab data investigation and narrative.	
4.1(b)	4.1(b)	This regulatory authority case was reported by a physician and describes the occurrence of PERICARDITIS (4.1(b)) in a 28-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for SARS-CoV-2 immunisation. No Medical History information was reported. On 12-Jul-2021, the patient received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) .5 milliliter. On 13-Jul-2021, after starting mRNA-1273 (COVID-19 Vaccine Moderna), the patient experienced PERICARDITIS (4.1(b)) (seriousness criterion medically significant). At the time of the report, PERICARDITIS 4.1(b)) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 14-Jul-2021, Chest X-ray: normal (normal) no infected site.	28 years old male with unknown medical history who next day after the 2nd dose experienced respire-dependent retrosternal pain, radiating to the jaw and was diagnosed with pericarditis. Lab results showed ultrasensitive troponin assay negative, elevated CRP with normal EKG and chest x-ray. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. Report confounded by the normal tests including the chest x-raym the EKG and the ultrasensitive troponin assay.

Case ID	WW Identifier	Narrative	MAH Comment
		On 14-Jul-2021, Electrocardiogram: normal (normal) Regular sinus rhythm. On 14-Jul-2021, Electrocardiogram ST segment: normal (normal) normal. On 14-Jul-2021, Sinus rhythm: 70 (normal) 70 bpm. On 14-Jul-2021, Troponin: high High sensitive. On 15-Jul-2021, Troponin: high High sensitive. On an unknown date, Blood pressure measurement: 122/71 mmHg 122/71. On an unknown date, C-reactive protein: 38.6 mg/l 38.6 mg/L. On an unknown date, Heart rate: 75 75 bpm. On an unknown date, Oxygen saturation: 98 percent 98%. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered PERICARDITIS (4.1(b)) to be probably related. Concomitant medications were not provided. Treatment medications included were NSAIDs for one week Patient had received second dose after that 13-JUL-2021 with respire-dependent retrosternal pain, of sudden onset, radiating to the jaw, evaluated at 5/10, increased with exertion, not relieved in anteversion. Patient was received second dose after few hr later chills without a measured fever. On 14-JUL-2021patient has a mild inflammatory syndrome (CRP 38.6 mg/L) and the ultrasensitive troponin assay is negative (troponin I 11.6 ng/L, normal <60 ng/L). The ECG shows a regular sinus rhythm at 70/min, an isoelectric PR and ST segment and the absence of depolarization or repolarization disorders. Physical examination BP 122/71mmhg, pulse 75bpm, saturation 98% on room air	

Case ID	WW Identifier	Narrative	MAH Comment
		On 14-Jul-2021, patient undergone High sensitive troponin I, C-reactive protein, Leukocyte count, Electrocardiogram, Thorax X-ray and results were unknown. On 15-Jul-2021, patient undergone C-reactive protein, High sensitive troponin I, Creatine kinase and results were unknown. Most recent FOLLOW-UP information incorporated above includes: On 23-Sep-2021: Translation Document received on 28-Sep-2021 significant information that include lab data added, narrative updated.	
4.1(b)	4.1(b)	This case was received via 4.1(b) Pharmaceuticals (Reference number: 4.1(b)) on 15-Sep-2021 and was forwarded to Moderna on 27-Sep-2021. This case, initially reported to the 4.1(b)) by a physician, was received via the 4.1(b) (Ref, 4.1(b) On an unknown date, the patient received 1st dose of the vaccine. On an unknown date, body temperature before vaccination: 36.2 degrees Celsius. On 11-Sep-2021, at 11:30, the patient received 2nd dose of the vaccine. On 12-Sep-2021, at 08:00, the patient visited a nearby hospital with a complaint of chest pain on inspiration. Electrocardiogram showed that elevated ST was seen in wide range of leads, and blood test showed no elevated cardiac enzymes. The diagnosis of acute pericarditis was made. On 13-Sep-2021, the patient was hospitalized due to acute pericarditis. On 14-Sep-2021, it was confirmed that the symptom resolved.	28 years old male with unknown medical history who next day after the 2nd dose experienced chest pain and was diagnosed with pericarditis. Lab results showed elevated cardiac enzimes and abnormal EKG. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2.

Case ID	WW Identifier	Narrative	MAH Comment
		The outcome of acute pericarditis was reported as resolved. Follow-up investigation will be made. Company Comment: The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	
4.1(b)	4.1(b)	This case was received via 4.1(b) Pharmaceuticals (Reference number: 4.1(b)) on 17-Sep-2021 and was forwarded to Moderna on 28-Sep-2021. This case, initially reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref, 4.1(b) On an unknown date, the patient received the 1st dose of this vaccine. On an unknown date, body temperature before the vaccination: 36.6 degrees Celsius. On 18-Aug-2021, the patient received the 2nd dose of this vaccine. On 19-Aug-2021, chest pain occurred. Acute pericarditis developed. On 21-Aug-2021, the patient visited local doctor, and myocardial abnormalities were pointed out. The patient visited an emergency outpatient at this hospital. Elevated myocardial enzyme was noted. Electrocardiogram showed ST elevation in chest leads. The patient was hospitalized with a diagnosis of myocarditis. Late gadolinium enhancement (LGE) was observed in lateral wall on contrast-enhanced MRI. On an unknown date, the symptoms showed an improving tendency.	26 years old male with unknown medical history who next day after the 2nd dose experienced chest pain. The following day patient went to the hospital were he was diagnosed with myocarditis. Lab results showed elevated cardiac enzymes, and abnormal EKG and cMRI. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2.

Case ID	WW Identifier	Narrative	MAH Comment
		On 25-Aug-2021, improvement of symptoms was confirmed. The patient was discharged home. The outcome of acute pericarditis and myocarditis was reported as resolving. Follow-up investigation will be made. Company Comment: The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	
4.1(b)	4.1(b)	This case was received via 4.1(b) Pharmaceuticals (Reference number: 4.1(b)) on 17-Sep-2021 and was forwarded to Moderna on 28-Sep-2021. This case, initially reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref, 4.1(b) On an unknown date, the patient received the 1st dose of this vaccine. On an unknown date, body temperature before the vaccination: 36.6 degrees Celsius. On 18-Aug-2021, the patient received the 2nd dose of this vaccine. On 19-Aug-2021, chest pain occurred. Acute pericarditis developed. On 21-Aug-2021, the patient visited local doctor, and myocardial abnormalities were pointed out. The patient visited an emergency outpatient at this hospital. Elevated myocardial enzyme was noted. Electrocardiogram showed ST elevation in chest leads. The patient was hospitalized with a diagnosis of myocarditis. Late gadolinium enhancement (LGE) was observed in lateral wall on contrast-enhanced MRI.	26 years old male with unknown medical history who next day after the 2nd dose experienced chest pain. The following day patient went to the hospital were he was diagnosed with myocarditis. Lab results showed elevated cardiac enzymes, and abnormal EKG and cMRI. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2.

Case ID	WW Identifier	Narrative	MAH Comment
		On an unknown date, the symptoms showed an improving tendency. On 25-Aug-2021, improvement of symptoms was confirmed. The patient was discharged home. The outcome of acute pericarditis and myocarditis was reported as resolving. Follow-up investigation will be made. Company Comment: The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	
4.1(b)	4.1(b)	This case was received via 4.1(b) Pharmaceuticals (Reference number: 4.1(b)) on 17-Sep-2021 and was forwarded to Moderna on 28-Sep-2021. This case, initially reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref, 4.1(b) On 27-Jul-2021, the patient received the 1st dose of this vaccine. On an unknown date, body temperature before vaccination: 36.0 degrees Celsius. On 27-Aug-2021, at 13:00, the patient received the 2nd dose of this vaccine. The patient had pyrexia at night. On 29-Aug-2021, at 00:00, chest pain developed. The patient consulted a previous physician. There was extensive ST elevation in the electrocardiogram and myocardial enzyme elevation in the blood examination. On 30-Aug-2021, the patient was referred to our hospital and was admitted with acute myocarditis.	20 years old male with unknown medical history who 2 day after the 2nd dose experienced chest pain and pyrexia and was diagnosed the next day with myocarditis. Lab results showed elevated myocardial enzymes, and abnormal EKG. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2.

Case ID	WW Identifier	Narrative	MAH Comment
		On an unknown date, though there was the cardiac hypofunction temporarily, it was improved. On 04-Sep-2021, the patient's symptoms were considered to be improved. The patient was discharged from the hospital. The outcome of acute myocarditis was reported as resolving. Follow-up investigation will be made. Company Comment: The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	
4.1(b)	4.1(b)	This case was received via 4.1(b) Pharmaceuticals (Reference number: 4.1(b)) on 17-Sep-2021 and was forwarded to Moderna on 28-Sep-2021. This case, initially reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref, 4.1(b) On 18-Jul-2021, the patient received the 1st dose of this vaccine. On 22-Aug-2021, the patient received the 2nd dose of this vaccine. Pyrexia persisted from night (until the morning of 25-Aug-2021). On 25-Aug-2021, at 04:00, the patient visited the reporting hospital for subjective symptoms of chest pain and cold sweat. In the blood test, elevated cardiac enzymes and inflammatory reaction were found, and in the electrocardiogram, the ST elevation was noted. There was no coronary artery lesion in coronary ST, and the diagnosis of acute myocarditis was made. The patient was hospitalized. The patient was followed up, and the symtoms improved conservatively.	25 years old male with unknown medical history who 3 day after the 2nd dose experienced chest pain and cold sweat and was diagnosed with myocarditis. Lab results showed elevated myocardial enzymes, and abnormal EKG. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2.

Case ID	WW Identifier	Narrative	MAH Comment
		On 31-Aug-2021, the remission of the symptom was confirmed. The patient was discharged from the hospital. The outcome of acute myocarditis was reported as resolving. Follow-up investigation will be made. Company Comment: The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	
4.1(b)	4.1(b)	This case was received via 4.1(b) Pharmaceuticals (Reference number: 4.1(b) on 21-Sep-2021 and was forwarded to Moderna on 29-Sep-2021. This case, initially reported to the 4.1(b) by a pharmacist, was received via the 4.1(b) (Ref, 4.1(b)). The patient had an underlying condition of hemophilia B and an history of cedar pollen allergy. The patient was under treatment with eftrenonacog alfa for intravenous injection, sublingual tablet containing cedar pollen extract, ephedra, aconite and manchurian wildginger decoction, ambroxol hydrochloride, and mequitazine. On an unknown date, the patient received the 1st dose of the vaccine. On 01-Sep-2021, in the morning, the patient received the 2nd dose of the vaccine. The patient received 4000 U of eftrenonacog alfa on the same day. On 02-Sep-2021, in the morning, pyrexia and breathlessness developed. The patient was considered to experience acute myocarditis. On 03-Sep-2021, around noon, the patient noticed obvious chest pain	18 years old male with medical history of hemophilia B who next day after the 2nd dose experienced pyrexia and dyspnea. Next day pateint experienced chest pain and was diagnosed with myocarditis. Lab results showed elevated myocardial markers, abnormal EKG and abnormal MRI. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2.

Case ID	WW Identifier	Narrative	MAH Comment
		and was transported to another hospital. An electrocardiogram showed ST elevation in the leads of I and aVL and ST depression in III. Blood sampling found increases in myocardial biomarkers. The patient was emergently transported to the reporting hospital for detailed examinations and was hospitalized. On arrival, chest pain remained. BP (systolic) was 100-160 mmHg with HR of 80s and SpO2 of 98% (room). A blood test was performed to find CK of 1,238 mU/L, and an ECG was performed to show ST elevation in the leads of lateral and anterior wall and ST depression in III and aVF. UCG: eyeball EF was around 30% with akinesis in the basal inferior wall. Pericardial fluid was not apparently detected. An arterial line was placed, and the patient was placed on a care in ICU. Regarding nourishment, the patient was placed on fluid replacement with fasting. On 04-Sep-2021, UCG: eyeball EF was around 40%. No marked change was shown by ECG. There was a change in the blood tests that CK of 2,689 mU/L (the 1st time on the day) decreased to CK of 2,216 mU/L (the 2nd time), which was considered to have passed a peak. Acetaminophen (oral and drip infusion) was used for the treatment of chest pain. The patient began to have meals. On 05-Sep-2021, BP: 112/58 mmHg, HR: 75-85, and SpO2: 100% (O2: 2 L). ECG: ST in V4-6 move to the side of baseline with LI of around 1 mm, and ST itself returned to the baseline in I and aVF leads and changed to negative T wave. UCG: no change in EF, no pericardial fluid, and marked right ventricular enlargement. On 06-Sep-2021, UCG: eyeball EF was 40%-50% with mild mitral regurgitation (MR), and IVC was 10 mm in diameter with RC +. The result of a blood test showed CK decreased to the standard value.	

Case ID	WW Identifier	Narrative	MAH Comment
		Chest pain was relieved. As the patient was permitted to have meals, fluid replacement was finished. The course of the condition was favorable, and the patient was transferred to the general ward after the arterial line was removed. On 07-Sep-2021, chest pain disappeared. BP: 104/58 mmHg, HR: 62, and SpO2: 98% (room) without cardiac murmur. On 09-Sep-2021, BP: 105/59 mmHg, HR: 64, and SpO2: 99% (room). The result of a blood test found CK decreased to the standard value. MRI was performed to show high signal intensities in the inferior wall and septum in T2, and delayed image was found in the same region. Since FIXu was as decreased as 4.8%, administration of 4000 U of eftrenonacog alfa was ordered by a hematologic physician. On 10-Sep-2021, BP: 120/61 mmHg, HR: 68, and UCG: eyeball EF was 61%. On 11-Sep-2021, as cardiac function recovered and the clinical course was good, the patient was discharged from the hospital. On 16-Sep-2021, a coronary CT was performed to show no significant stenosis. On 17-Sep-2021, the patient visited the hospital as an outpatient, and there was no worsening of the symptom. No appreciable abnormalities were also found in a blood test. Resolution of the symptoms was confirmed, and treatments and follow-up were completed. The outcome of acute myocarditis was reposted as resolved. Follow-up investigation will be made. Company Comment:	

Case ID	WW Identifier	Narrative	MAH Comment
		The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	
4.1(b)	4.1(b)	This case was received via 4.1(b) Pharmaceuticals (Reference number: 4.1(b)) on 21-Sep-2021 and was forwarded to Moderna on 29-Sep-2021. This case was reported by a physician via the Drug Information Center. On 30-Aug-2021, the patient received the 1st dose of this vaccine. The patient experienced pyrexia. On an unknown date, pyrexia went down, and the patient recovered from pyrexia. On 15-Sep-2021, the patient received the 2nd dose of this vaccine. On 17-Sep-2021, the patient experienced pyrexia and chest pain. At 16:00, the patient visited the hospital. No detailed examination was possible. At 22:30, the patient visited the hospital. Chest pain, elevated ECG, and increase in CT883, CKMB66, and troponin I were observed. Myocardial infarction was ruled out by catheterization, and myocarditis was diagnosed. On an unknown date, the patient was hospitalized. On 21-Sep-2021, the patient's chest pain disappeared without medication. On 22-Sep-2021, the patient was scheduled to be discharged. The outcome of pyrexia after the 1st dose of this vaccine was reported as resolved. The outcome of pyrexia and myocarditis after the 2nd dose of this vaccine was unknown. Follow-up investigation will be made.	23 years old male with unknown medical history who 2 days after the 2nd dose experienced chest pain and pyrexia was diagnosed with myocarditis. Lab results showed elevated troponin, and abnormal EKG. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2.

Case ID	WW Identifier	Narrative	MAH Comment
		Company Comment: The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	
4.1(b)		This case was received via 4.1(b) (Reference number: 4.1(b) on 28-Sep-2021 and was forwarded to Moderna on 28-Sep-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of ABDOMINAL DISTENSION (bloating), C-REACTIVE PROTEIN INCREASED (C-reactive protein increased), CHEST DISCOMFORT (cracking chest pressure), CHEST PAIN (Chest pain), COUGH (Cough), DISCOMFORT (uncomfortable lying flat), DIZZINESS (lightheadedness), DYSPNOEA (SOB), EJECTION FRACTION DECREASED (Ejection fraction decreased), HYPERHIDROSIS (diaphoresis), MYOCARDITIS (Myocarditis), PAIN (Pain), PERICARDIAL EFFUSION (Pericardial effusion), PERICARDIAL FIBROSIS (Pericardial fibrosis), PERICARDITIS (Pericarditis), PYREXIA (Pyrexia), RED BLOOD CELL SEDIMENTATION RATE INCREASED (Red blood cell sedimentation rate increased), TROPONIN INCREASED (Troponin increased), MYALGIA (severe body aches), DEEP VEIN THROMBOSIS (unprovoked DVT), PAIN IN EXTREMITY (Pain of lower extremities) and PERIPHERAL SWELLING (swelling in his left lower extremity) in a 30-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 046C21A and 036C21A) for COVID-19 vaccination. The patient's past medical history included Dyslipidemia. On 10-Sep-2021, the patient received second dose of mRNA-1273	30 years old male with medical history of dyslipidemia who next day after the 2nd experienced chest discomfort, abdominal distension, chest pain, cough, dizziness, dypsnea, pain in extremities, peripheral swealling, and was diagnosed with myopericarditis as well as DVT. Lab results showed elevated troponin, elevated CRP, abnormal Echo and EKG. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2.

Case ID	WW Identifier	Narrative	MAH Comment
		(Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 10-Sep-2021, received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 11-Sep-2021, the patient experienced ABDOMINAL DISTENSION (bloating) (seriousness criterion hospitalization), C-REACTIVE PROTEIN INCREASED (C-reactive protein increased) (seriousness criterion hospitalization), CHEST DISCOMFORT (cracking chest pressure) (seriousness criterion hospitalization), CHEST PAIN (Chest pain) (seriousness criterion hospitalization), COUGH (Cough) (seriousness criterion hospitalization), DISCOMFORT (uncomfortable lying flat) (seriousness criterion hospitalization), DIZZINESS (lightheadedness) (seriousness criterion hospitalization), DYSPNOEA (SOB) (seriousness criterion hospitalization), EJECTION FRACTION DECREASED (Ejection fraction decreased) (seriousness criterion hospitalization), HYPERHIDROSIS (diaphoresis) (seriousness criterion hospitalization), MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant), PAIN (Pain) (seriousness criterion hospitalization), PERICARDIAL EFFUSION (Pericardial effusion) (seriousness criteria hospitalization and medically significant), PERICARDIAL FIBROSIS (Pericardial fibrosis) (seriousness criteria hospitalization and medically significant), PERICARDITIS (Pericarditis) (seriousness criteria hospitalization and medically significant), PYREXIA (Pyrexia) (seriousness criterion hospitalization), RED BLOOD CELL SEDIMENTATION RATE INCREASED (Red blood cell sedimentation rate increased) (seriousness criterion hospitalization) and TROPONIN INCREASED (Troponin increased) (seriousness criterion hospitalization). On an	

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

Case ID	WW Identifier	Narrative	MAH Comment
		For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Allergies: Sulfa antibiotics Other Meds : Xarelto Pt negative for covid. LFTs normal	
4.1(b)		This case was received via 4.1(b) (Reference number: 4.1(b) on 28-Sep-2021 and was forwarded to Moderna on 28-Sep-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of ABDOMINAL DISTENSION (bloating), C-REACTIVE PROTEIN INCREASED (C-reactive protein increased), CHEST DISCOMFORT (cracking chest pressure), CHEST PAIN (Chest pain), COUGH (Cough), DISCOMFORT (uncomfortable lying flat), DIZZINESS (lightheadedness), DYSPNOEA (SOB), EJECTION FRACTION DECREASED (Ejection fraction decreased), HYPERHIDROSIS (diaphoresis), MYOCARDITIS (Myocarditis), PAIN (Pain), PERICARDIAL EFFUSION (Pericardial effusion), PERICARDIAL FIBROSIS (Pericardial fibrosis), PERICARDITIS (Pericarditis), PYREXIA (Pyrexia), RED BLOOD CELL SEDIMENTATION RATE INCREASED (Red blood cell sedimentation rate increased), TROPONIN INCREASED (Troponin increased), MYALGIA (severe body aches), DEEP VEIN THROMBOSIS (unprovoked DVT), PAIN IN EXTREMITY (Pain of lower extremities) and PERIPHERAL SWELLING (swelling in his left lower extremity) in a 30-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 046C21A and 036C21A) for COVID-19 vaccination. The patient's past medical history included Dyslipidemia.	30 years old male with medical history of dyslipidemia who next day after the 2nd experienced chest discomfort, abdominal distension, chest pain, cough, dizziness, dypsnea, pain in extremities, peripheral swealling, and was diagnosed with myopericarditis as well as DVT. Lab results showed elevated troponin, elevated CRP, abnormal Echo and EKG. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2.

Case ID	WW Identifier	Narrative	MAH Comment
		On 10-Sep-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 10-Sep-2021, received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 11-Sep-2021, the patient experienced ABDOMINAL DISTENSION (bloating) (seriousness criterion hospitalization), C-REACTIVE PROTEIN INCREASED (C-reactive protein increased) (seriousness criterion hospitalization), CHEST DISCOMFORT (cracking chest pressure) (seriousness criterion hospitalization), CHEST PAIN (Chest pain) (seriousness criterion hospitalization), COUGH (Cough) (seriousness criterion hospitalization), DISCOMFORT (uncomfortable lying flat) (seriousness criterion hospitalization), DIZZINESS (lightheadedness) (seriousness criterion hospitalization), DYSPNOEA (SOB) (seriousness criterion hospitalization), EJECTION FRACTION DECREASED (Ejection fraction decreased) (seriousness criterion hospitalization), HYPERHIDROSIS (diaphoresis) (seriousness criterion hospitalization), MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant), PAIN (Pain) (seriousness criterion hospitalization), PERICARDIAL EFFUSION (Pericardial effusion) (seriousness criteria hospitalization and medically significant), PERICARDIAL FIBROSIS (Pericardial fibrosis) (seriousness criteria hospitalization and medically significant), PERICARDITIS (Pericarditis) (seriousness criteria hospitalization and medically significant), PYREXIA (Pyrexia) (seriousness criterion hospitalization), RED BLOOD CELL SEDIMENTATION RATE INCREASED (Red blood cell sedimentation rate increased) (seriousness criterion hospitalization)	

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

Case ID	WW Identifier	Narrative	MAH Comment
		depression (abnormal) pr segment depression and st segment elevation (abnormal) st segment elevation. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Allergies: Sulfa antibiotics Other Meds : Xarelto Pt negative for covid. LFTs normal	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 29-Sep-2021 and was forwarded to Moderna on 29-Sep-2021. This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (PERIMYOCARDITIS) in a 25-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3004498) for Vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Migraine and Revaccination with different COVID-19 vaccine. Previously administered products included for Vaccination: COMIRNATY. Concomitant products included VERAPAMIL (ISOPTIN [VERAPAMIL]) for Migraine. On 06-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 07-Sep-2021, the patient experienced MALAISE (MALAISE) and PYREXIA (FEVER). On 08-Sep-2021, the patient experienced CHEST PAIN (CHEST PAIN). On 09-Sep-2021, the patient experienced MYOCARDITIS (PERIMYOCARDITIS) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS	25 years old male with history of receiving the other mRNA vaccine as the 1st dose, and who 2 days after the 2nd dose experienced chest pain was diagnosed with myopericarditis. Lab results showed elevated troponin, and abnormal EKG and cMRI; Echo was normal. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. This report is confounded by the administration of the other mRNA vaccine

Case ID	WW Identifier	Narrative	MAH Comment
		(PERIMYOCARDITIS) was resolving and MALAISE (MALAISE), CHEST PAIN (CHEST PAIN) and PYREXIA (FEVER) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 09-Sep-2021, Echocardiogram: normal (normal) No pathology.. On 09-Sep-2021, Electrocardiogram: abnormal (abnormal) Typical changes as seen in pericarditis.. On 09-Sep-2021, Magnetic resonance imaging heart: abnormal (abnormal) Typical changes as seen in myocarditis, oedema and T1/T2 mapping, preserved ventricular function.. On 09-Sep-2021, Troponin T: 3962 (High) nanogram per litre. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Treatment information was not provided.	
4.1(b) [redacted]		This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Acute myocarditis) in a 24-year-old male patient who received mRNA-1273 (COVID 19 Vaccine Moderna) (batch no. 3003187) for COVID-19 vaccination. Concurrent medical conditions included Tobacco user. On 16-Jul-2021, the patient received second dose of mRNA-1273 (COVID 19 Vaccine Moderna) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (COVID 19 Vaccine Moderna) (unknown route) 1 dosage form. On 18-Jul-2021, after starting mRNA-1273 (COVID 19 Vaccine Moderna), the patient experienced MYOCARDITIS (Acute myocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Acute myocarditis) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 19-Jul-2021, Angiocardiogram: normal (normal) normale. On 19-Jul-2021, C-reactive protein (Unknown-5): 19.3 (High) 19.3 milligram per litre. On 19-Jul-2021, Echocardiogram: normal (normal) Normal left ventricular kinetics, 56% ejection fraction, no heart valve disease, no sign of PAH, no myocardial hypertrophy, no dilation of the aortic root, clear pericardium.. On 19-Jul-2021, Electrocardiogram: normal (normal) No ST elevation.	

Case ID	WW Identifier	Narrative	MAH Comment
		On 19-Jul-2021, Fibrin D dimer (Unknown-500): 280 (normal) 280 nanogram per millliiter. On 19-Jul-2021, Glomerular filtration rate: 105 (normal) 105 millilitre per minute. On 19-Jul-2021, Magnetic resonance imaging heart: abnormal (abnormal) Areas of basal inferolateral myocardial inflammation. Left and right cardiac ventricular functions considered normal. No pleural or pericardial effusion. No indirect sign of a mitro- aortic heart valve disease. After gadolinium injection, no transmural endocardial sequelae of infarction. Slight basal inferolateral subepicardial contrast and on lateral side of the LV, consistent with small inflammatory areas of myocarditis. (Fiesta MRI cine sequences. On 19-Jul-2021, Myoglobin blood (Unknown-72): 31 (normal) 31 nanogram per millliiter. On 19-Jul-2021, Troponin T (Unknown-15): 64 (High) 64 nanogram per litre. On 19-Jul-2021, White blood cell count (4000-9000): 10150 (High) 10150 per cubic millimetre. For mRNA-1273 (COVID 19 Vaccine Moderna) (Unknown), the reporter did not provide any causality assessments. Concomitant product use was not provided by the reporter. Patient experienced acute myocarditis with precordial pain after 2 days of receiving 2nd moderna vaccine and diagnosis made the next day on MRI. Managed with medication. Patient currently recovering. He was hospitalized for 2 days No treatment information was provided. 4.1(b) Sender's Case Safety Report Unique Identifier is 4.1(b) . Company comment Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. Most recent FOLLOW-UP information incorporated above includes: On 02-Aug-2021: Follow-up received on 06-Aug-2021 and laboratory data was added.	
4.1(b)		This case was initially received via European Medicines Agency (Reference number: 4.1(b)) on 03-Aug-2021. The most recent information was received on 04-Aug-2021 and was forwarded to Moderna on 04-Aug-2021. This regulatory authority case was reported by a physician and describes the occurrence of DYSPNOEA (4.1(b)), PALPITATIONS (4.1(b) and MYOCARDITIS (4.1(b) in a 27-year-old male patient who received mRNA-1273 (Spikevax) for Prophylactic vaccination. No Medical History information was reported. On 24-Jun-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 26-Jun-2021, the patient	

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

Case ID	WW Identifier	Narrative	MAH Comment
		DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 19-Jul-2021, Alanine aminotransferase: increased (High) 54 IU/L. On 19-Jul-2021, Aspartate aminotransferase: increased (High) 163 IU/L. On 19-Jul-2021, Catheterisation cardiac: normal (normal) Normal. On 19-Jul-2021, Ejection fraction: normal (normal) Normal. On 19-Jul-2021, Electrocardiogram: normal (normal) Normal and abnormal (abnormal) Mildly abnormal. On 19-Jul-2021, Liver function test: increased (High) Mildly elevated. On 19-Jul-2021, Troponin: high (High) Increased. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medications were reported. Treatment information is not given. The patient developed chest pain starting 48 hours after the 2nd dose of Moderna vaccine. Progressively worsened. Presented to the hospital 72 hours after the vaccine with mildly abnormal ECG and elevated troponin level. Underwent cardiac catheterization without coronary artery disease. Diagnosis of myocarditis made. No treatment information was provided. Based on the current available information and temporal association between the use of the product and the events, a causal relationship cannot be excluded. Most recent FOLLOW-UP information incorporated above includes: On 03-Aug-2021: Follow-up received contains additional laboratory data and events.	
4.1(b)		This case was received via 4.1(b) (Reference number: 4.1(b) on 03-Aug-2021 and was forwarded to Moderna on 03-Aug-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of CHEST CRUSHING (Chest crushing), HYPERDYNAMIC LEFT VENTRICLE (Hyperdynamic left ventricle), CHEST DISCOMFORT (Chest discomfort), CHEST PAIN (Chest pain), MYALGIA (Myalgia), PAINFUL RESPIRATION (Painful respiration), PLEURITIC PAIN (Pleuritic pain), PYREXIA (Pyrexia) and MYOCARDITIS (Myocarditis) in a 21-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 045C21A and 004C21A) for COVID-19 vaccination. Concurrent medical conditions included Asthma and Depression. On 20-Jul-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 20-Jul-2021, received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 22-Jul-2021, the patient experienced CHEST CRUSHING (Chest crushing) (seriousness criteria hospitalization and medically significant), HYPERDYNAMIC LEFT VENTRICLE (Hyperdynamic left ventricle)	

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

Case ID	WW Identifier	Narrative	MAH Comment
		received mRNA-1273 (Spikevax) (batch nos. 214012 and 3002620) for Prophylactic vaccination. No Medical History information was reported. On 25-Jun-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 17-Jul-2021, received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to 1 dosage form. On 20-Jul-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Myocarditis) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Troponin: 0.9 (Positive) Positive, the value was 0.9 ng/ml.. Concomitant medication was not reported. Treatment medications was not given. Lab data includes ECG: ST elevations II, III, aVF, positive troponin 0.9ng/mL and MRI: hypertensive change in rear wall TIRM sequence was reported. Myocardial infarction was excluded using a heart catheter was reported. Company Comment: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Awaiting SD Translation. Most recent FOLLOW-UP information incorporated above includes: On 04-Aug-2021: Translation includes sender comment 1st dose information updated, lab data added On 25-Aug-2021: Follow-up information included no new information	
4.1(b)	4.1(b)	This case was initially received via European Medicines Agency (Reference number: 4.1(b) on 04-Aug-2021. The most recent information was received on 25-Aug-2021 and was forwarded to Moderna on 25-Aug-2021. This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (Myocarditis) in a 20-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3002183) for Prophylactic vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Pollen allergy. On 01-Jul-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 05-Jul-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant), CHEST DISCOMFORT (Chest pressure sensation of), MALAISE (General malaise), ARTHRALGIA (Joint ache) and HEADACHE (Head pain). The patient was hospitalized from 07-Jul-2021 to 12-Jul-2021 due to MYOCARDITIS. On 12-Jul-2021, MYOCARDITIS (Myocarditis),	

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

Case ID	WW Identifier	Narrative	MAH Comment
		DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In 2021, Magnetic resonance imaging: myocarditis confirmed (abnormal) myocarditis confirmed. In 2021, Troponin: elevated (abnormal) Elevated. Concomitant product use was not provided by the reporter. Patient Occasionally some alcohol consumption, a glass of wine 2 days before vaccination. Laboratory detail was elevated troponin levels, myocarditis confirmed in the MRI scan. No treatment information was provided. Company Comment: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Most recent FOLLOW-UP information incorporated above includes: On 04-Aug-2021: Translation received on 30-Aug-21 included events and narrative were translated to English with elevated troponin levels and myocarditis confirmed in the MRI scan. On 25-Aug-2021: Follow up contains no new information.	
4.1(b)		This regulatory authority case was reported by a physician and describes the occurrence of CHEST PAIN (chest pain) and MYOCARDITIS (Myocarditis) in a 28-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Myocarditis and Chest pain. On 07-May-2021, the patient received first dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 28-Jul-2021, received second dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 28-Jul-2021, the patient experienced INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (Inappropriate schedule of vaccine administered). On 31-Jul-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). On an unknown date, the patient experienced CHEST PAIN (chest pain) (seriousness criterion hospitalization). At the time of the report, CHEST PAIN (chest pain) had resolved, MYOCARDITIS (Myocarditis) was resolving and INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (Inappropriate schedule of vaccine administered) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Angiogram: angiogram (normal) Normal coronary arteries on angiogram.	

Case ID	WW Identifier	Narrative	MAH Comment
		On an unknown date, Magnetic resonance imaging heart: cardiac mri (abnormal) Cardiac MRI showed likely myocarditis. On an unknown date, SARS-CoV-2 test: sars-cov-2 test (Negative) negative. On an unknown date, Troponin: troponin (Positive) Troponin positive in blood tests. For mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Concomitant product information was not provided by the reporter. Patient was received first dose of vaccine on 07-May-2021 and second dose on 28-Jul-2021 Patient was hospitalized with chest pain and checked troponin level in blood it was found to be 991 (positive). Had normal coronary arteries on angiogram. Showed myocarditis on cardiac MRI scan. Treatment information was not provided by the reporter. Company Comment This report refers to a case of Inappropriate schedule of product administration for mRNA-1273, lot # unknown with AEs. Based on the current available information and temporal association between the use of the product and the start date of the events Myocarditis and Chest pain, a causal relationship cannot be excluded.	
4.1(b)	4.1(b)	This case was received via 4.1(b) Pharmaceuticals (Reference number: 4.1(b) on 03-Aug-2021 and was forwarded to Moderna on 06-Aug-2021. This case, initially reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref, 4.1(b) On an unknown date, body temperature before the vaccination: 36.5 degrees Celsius. On 26-Jul-2021, the patient received the 2nd dose of this vaccine in the afternoon. On 27-Jul-2021, the patient became aware of pyrexia in the 38 degrees Celsius range and chest discomfort. On 28-Jul-2021, the patient's symptoms did not improve, and the patient was rushed to a hospital. On arrival at the hospital, the patient was diagnosed with acute myocarditis, with pyrexia of 38.8 degrees Celsius, chest discomfort, widespread ST-segment elevation on electrocardiography, elevated myocardial enzymes on blood test, and decreased wall motion on echocardiography. The outcome of acute myocarditis (pyrexia, chest discomfort, ST elevated, elevation of cardiac enzymes, decreased wall motion) was unknown. Follow-up investigation will be made.	

Case ID	WW Identifier	Narrative	MAH Comment
		Company Comment: The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	
4.1(b) [redacted]		This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Perimyocarditis) in a 21-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) (batch nos. 3003188 and 3003188) for COVID-19 vaccination. The patient's past medical history included Non-smoker. On 22-Jun-2021, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form. On 20-Jul-2021, received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) dosage was changed to 1 dosage form. On 21-Jul-2021, after starting mRNA-1273 (COVID-19 Vaccine Moderna), the patient experienced MYOCARDITIS (Perimyocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Perimyocarditis) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 24-Jul-2021, Blood creatine phosphokinase: high (High) 75mmol/L. On 24-Jul-2021, Echocardiogram: inconclusive (Inconclusive) widespread disorders in the movement of the wall, with slightly limited systolic pump function. On 24-Jul-2021, Magnetic resonance imaging: inconclusive (Inconclusive) findings consistent with myocarditis; function of the systolic pump still slightly compromised (47%). On 24-Jul-2021, Troponin I: high (High) High. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter did not provide any causality assessments. Concomitant products were not provided. Treatment medication were not reported. Company Comment: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. Case awaiting translation. FU translation received with additional information does not change the company comment. Most recent FOLLOW-UP information incorporated above includes: On 13-Aug-2021: Translation document received on 25-AUG-2021included sender's comment, relevant medical history and test result updated	
4.1(b) [redacted]		This case was received via 4.1(b) [redacted] (Reference number: 4.1(b) [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 CHEST PAIN (Chest pain) and MYOCARDITIS (Myocarditis) in an 18-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported.	

Case ID	WW Identifier	Narrative	MAH Comment
		On 29-Jul-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 01-Aug-2021, the patient experienced CHEST PAIN (Chest pain) (seriousness criterion hospitalization) and MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, CHEST PAIN (Chest pain) and MYOCARDITIS (Myocarditis) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 01-Aug-2021, Blood creatine phosphokinase: 634 (High) increased. On 01-Aug-2021, Blood creatine phosphokinase MB: 35.1 (High) increased. On 01-Aug-2021, C-reactive protein: 7.5 (High) increased. On 01-Aug-2021, Electrocardiogram: abnormal (abnormal) abnormal. On 01-Aug-2021, Myocardial necrosis marker: increased (High) increased. On 01-Aug-2021, Prohormone brain natriuretic peptide: 328 (High) Increased. On 01-Aug-2021, Troponin: 0.38 (High) increased. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medication information was provided. No treatment information was provided. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.	
4.1(b)		This regulatory authority case was reported by a physician and describes the occurrence of MYALGIA (4.1(b) PYREXIA (4.1(b)) and MYOCARDITIS (4.1(b)) in a 21-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) (batch no. 3004215) for COVID-19 vaccination. Concurrent medical conditions included Tobacco user (1 pack per day). In 2021, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form. On 23-Jul-2021, received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) dosage was changed to 1 dosage form. On 23-Jul-2021, the patient experienced MYALGIA (4.1(b) (seriousness criterion hospitalization) and PYREXIA (4.1(b)) (seriousness criterion hospitalization). On 27-Jul-2021, after starting mRNA-1273 (COVID-19 Vaccine Moderna), the patient experienced MYOCARDITIS (4.1(b)) (seriousness criteria hospitalization and medically significant). On 26-Jul-2021, MYALGIA (4.1(b) and PYREXIA (4.1(b) had resolved. At the time of the report, MYOCARDITIS (4.1(b)) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 27-Jul-2021, Echocardiogram: normal (normal) normal. On 27-Jul-2021, Electrocardiogram: normal (normal) With Non-abnormalities.	

Case ID	WW Identifier	Narrative	MAH Comment
		On 27-Jul-2021, Magnetic resonance imaging: abnormal (abnormal) Visible lesion, suggestive of myocarditis. On 27-Jul-2021, Troponin: 1000 (abnormal) 1000 ng/mL. On 27-Jul-2021, Viral test: negative (Negative) Negative. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter did not provide any causality assessments. The concomitant medications were not reported. The treatment information was not provided. Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. Most recent FOLLOW-UP information incorporated above includes: On 19-Aug-2021: Translation received on 24-AUG-21 and had significant information. Updated the lab results.	
4.1(b)		This case was received via 4.1(b) Pharmaceuticals (Reference number: 4.1(b) on 13-Aug-2021 and was forwarded to Moderna on 22-Aug-2021. This case, initially reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref, 4.1(b) On 29-Jun-2021, the patient received the 1st dose of the vaccine. On an unknown date, body temperature before the vaccination: 36.6 degrees Celsius. On 28-Jul-2021, the patient received the 2nd dose of the vaccine. On 29-Jul-2021, pyrexia developed. On 31-Jul-2021, chest pain developed. On 01-Aug-2021, at 05:02, as the symptoms continued, the patient visited this hospital. A wide range of ST elevation was shown in the electrocardiogram and increases in myocardial markers and inflammatory response were found as CK: 1120 U/L, troponin I: 19642 pg/mL, and CRP: 4.96 mg/dL. Echocardiography revealed no wall motion abnormality. The patient was diagnosed with myocarditis based on the symptoms and course of the disease and was admitted to the hospital to receive treatments. On 07-Aug-2021, the symptoms improved. The patient was discharged from the hospital. The outcome of myocarditis was reported as recovered. Follow-up investigation will be made. Company Comment: The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	

Case ID	WW Identifier	Narrative	MAH Comment
		Sender's comments : The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.	
4.1(b)		This case was received via 4.1(b) (Reference number: 4.1(b) on 24-Aug-2021 and was forwarded to Moderna on 24-Aug-2021. This regulatory authority case was reported by a health care professional and describes the occurrence of CHEST DISCOMFORT (Chest discomfort), CHEST PAIN (Chest pain), LEFT VENTRICULAR DYSFUNCTION (Left ventricular dysfunction), NASOPHARYNGITIS (Nasopharyngitis), SLEEP DISORDER (Sleep disorder), STRESS (Stress), MYOCARDITIS (Myocarditis) and PERICARDITIS (Pericarditis) in a 23-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The patient's past medical history included Depression. Concurrent medical conditions included Dyspnea (Three days prior to vaccine patient had slightly more than expected dyspnea trying to restart running after a hiatus of several months, attributed it to stress and deconditioning.) and Asthma (Mild). Concomitant products included 4.1(b) [SALBUTAMOL] for an unknown indication. On 03-Apr-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 05-Apr-2021, the patient experienced CHEST DISCOMFORT (Chest discomfort) (seriousness criterion hospitalization), CHEST PAIN (Chest pain) (seriousness criterion hospitalization), LEFT VENTRICULAR DYSFUNCTION (Left ventricular dysfunction) (seriousness criterion hospitalization), NASOPHARYNGITIS (Nasopharyngitis) (seriousness criterion hospitalization), SLEEP DISORDER (Sleep disorder) (seriousness criterion hospitalization), STRESS (Stress) (seriousness criterion hospitalization), MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant) and PERICARDITIS (Pericarditis) (seriousness criteria hospitalization and medically significant). The patient was treated with KETOROLAC TROMETHAMINE (TORADOL) at an unspecified dose and frequency and ASPIRIN [ACETYLSALICYLIC ACID] at an unspecified dose and frequency. At the time of the report, CHEST DISCOMFORT (Chest discomfort), CHEST PAIN (Chest pain), LEFT VENTRICULAR DYSFUNCTION (Left ventricular dysfunction), NASOPHARYNGITIS (Nasopharyngitis), SLEEP DISORDER (Sleep disorder), STRESS (Stress), MYOCARDITIS (Myocarditis) and PERICARDITIS (Pericarditis) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 05-Apr-2021, Aspartate aminotransferase: 51 (High) Increased. On 05-Apr-2021, Blood bilirubin: 1.6 (High) Increased. On 05-Apr-2021, C-reactive protein: 6.8 (High) Increased. On 05-Apr-2021, Cardiac imaging procedure: abnormal (abnormal) Demonstrated consistent with myopericarditis. On 05-Apr-2021, Chest X-ray: normal (normal) Normal. On 05-Apr-2021, Echocardiogram: abnormal (abnormal) Echocardiogram demonstrated mildly reduced LV systolic function..	

Case ID	WW Identifier	Narrative	MAH Comment
		On 05-Apr-2021, Haemoglobin: normal (normal) Normal. On 05-Apr-2021, Inflammatory marker test: increased (High) Increased. On 05-Apr-2021, Red blood cell sedimentation rate: 23 (High) increased. On 05-Apr-2021, SARS-CoV-2 test: negative (Negative) Negative. On 05-Apr-2021, Sinus rhythm: 57 (abnormal) 57 abnormal. On 05-Apr-2021, Troponin: increased ng/L (High) Troponin level at 6473 with a repeat of 8989, (reference range less than 45 ng/L). On 05-Apr-2021, White blood cell count: normal (normal) Normal. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Company comment: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.	
4.1(b) [redacted]	4.1(b) [redacted]	This case was received via 4.1(b) [redacted] (Reference number: 4.1(b) [redacted]) on 24-Aug-2021 and was forwarded to Moderna on 24-Aug-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCARDITIS (Myocarditis), CHEST PAIN (Chest pain), CHILLS (Chills), FATIGUE (Fatigue), MYALGIA (Myalgia) and NAUSEA (Nausea) in a 27-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. Concurrent medical conditions included Allergy to nuts. Concomitant products included BUPROPION for an unknown indication. On 15-Jun-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 19-Jun-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant), CHILLS (Chills) (seriousness criterion hospitalization), FATIGUE (Fatigue) (seriousness criterion hospitalization) and MYALGIA (Myalgia) (seriousness criterion hospitalization). On 19-Jun-2021 at 6:00 AM, the patient experienced CHEST PAIN (Chest pain) (seriousness criterion hospitalization) and NAUSEA (Nausea) (seriousness criterion hospitalization). At the time of the report, MYOCARDITIS (Myocarditis), CHEST PAIN (Chest pain), CHILLS (Chills), FATIGUE (Fatigue), MYALGIA (Myalgia) and NAUSEA (Nausea) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 19-Jun-2021, Catheterisation cardiac: normal (normal) resulted in no blockage. On 19-Jun-2021, Ejection fraction: decreased abnormal (Low) Ejection fraction deceased. On 19-Jun-2021, Electrocardiogram: abnormal (abnormal) ejection fraction between 40 and 45 %. On 19-Jun-2021, Magnetic resonance imaging heart: unknown (Inconclusive) unknown. On 19-Jun-2021, Scan with contrast: abnormal (abnormal) abnormal. On 19-Jul-2021, Magnetic resonance imaging heart: abnormal (abnormal) with and without contrast indicating ejection fraction of 41%.	

Case ID	WW Identifier	Narrative	MAH Comment
		For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. No Treatment information was received by the patient. After vaccination, initially the patient had symptoms of chills, fatigue, and muscle pain throughout body. These symptoms lasted about two days following his second dose of the Moderna vaccination. Symptoms subsided on the third day. On the fourth day following the vaccination he woke up at 6 am with nausea and chest pain. As a result patient was taken to the emergency room (ER) where he discovered that he had myocarditis. Company Comment: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.	
4.1(b)		This case was received via 4.1(b) Pharmaceuticals (Reference number: 4.1(b) on 18-Aug-2021 and was forwarded to Moderna on 26-Aug-2021. This case, initially reported to the 4.1(b) by a (physician), was received via the 4.1(b) (Ref, 4.1(b) On an unknown date, the patient received the 1st dose of this vaccine. On an unknown date, body temperature before the vaccination: Unknown. On 10-Aug-2021, the patient received the 2nd dose of this vaccine. At night, pyrexia of 38.0 degrees Celsius and headache developed. On 11-Aug-2021, in the morning, pyrexia persisted. Body temperature was 38.0 degrees Celsius. On 12-Aug-2021, at 06:30, body temperature was 36.6 degrees Celsius. At around 10:10, the patient was found lying unconscious on the floor. At 10:23, emergency call was made, and the patient was raced to a hospital in a state of cardio-respiratory arrest. Initial waveform was ventricular fibrillation. VA ECMO was introduced in ER, and cardiac catheterization was performed. There were no abnormal findings in the coronary artery. Elevated cardiac enzymes were observed, and the possibility that the patient developed myocarditis could not be ruled out. The patient was admitted to the hospital. The outcome of pyrexia, headache, cardio-respiratory arrest, elevated cardiac enzymes, ventricular fibrillation, and myocarditis was reported as ongoing and unchanged. Follow-up investigation will be made. Company Comment: The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	

Case ID	WW Identifier	Narrative	MAH Comment
4.1(b)	4.1(b)	This case was initially received via European Medicines Agency (Reference number: 4.1(b)) on 25-Aug-2021. The most recent information was received on 25-Aug-2021 and was forwarded to Moderna on 28-Aug-2021. This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (4.1(b) in a 29-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 214007) for Prophylactic vaccination. No Medical History information was reported. On 06-Jul-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 26-Jul-2021, received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to 1 dosage form. On 30-Jul-2021, the patient experienced MYOCARDITIS (4.1(b) (seriousness criteria hospitalization, medically significant and life threatening). At the time of the report, MYOCARDITIS (4.1(b) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Biopsy heart: abnormal The result was still excluded and has STEMI (acute ST-elevation myocardial infarction).. No relevant concomitant medications were reported. Treatment medication was not provided by the reporter. Lab data provided MRI Myocardial biopsy result is still excluded STEMI (acute ST-elevation myocardial infarction). Most recent FOLLOW-UP information incorporated above includes: On 25-Aug-2021: Follow Up received has no new information. On 25-Aug-2021: Translation received on 28-Aug-2021 and I narrative updated	
4.1(b)		This case was received via European Medicines Agency (Reference number: 4.1(b)) on 26-Aug-2021 and was forwarded to Moderna on 26-Aug-2021. This regulatory authority case was reported by a physician and describes the occurrence of CHEST PAIN (Chest pain) and MYOCARDITIS (Myocarditis) in a 28-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3004494) for COVID-19 vaccination. The patient's past medical history included Myocarditis (Admitted hospital June 2019 due to mild myocarditis, TnT max 396. Presumed virology. No arrhythmia. CT cor normal. Echocardiography with mild hypokinesia posterioapical, small MI. No pericardial fluid. Normalization of ventricular function at ctr after 1 month.) in June 2019 and Family history of cardiovascular disorder (Brother got myocarditis 6-7 years ago). Concurrent medical conditions included Pollen allergy (No drug allergy) and Non-smoker.	

Case ID	WW Identifier	Narrative	MAH Comment
		On 07-Aug-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 10-Aug-2021, the patient experienced CHEST PAIN (Chest pain) (seriousness criterion hospitalization) and MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, CHEST PAIN (Chest pain) and MYOCARDITIS (Myocarditis) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 10-Aug-2021, Blood pressure measurement: 115/64 (Low) 115/64. On 10-Aug-2021, Body temperature: 36.6 (normal) 36.6. On 10-Aug-2021, C-reactive protein: 21 - 11 (High) 21 - 11 High. On 10-Aug-2021, Cardiac telemetry: sr 50-96, mostly < 70 (Low) SR 50-96, mostly < 70. On 10-Aug-2021, Echocardiogram: normal (normal) VV systolic function in the lower normal range, EF estimated 50%. Otherwise normal findings.. On 10-Aug-2021, Electrocardiogram: high (High) SR 58 / min. Incomplete right branch block. High ST-departure globally.. On 10-Aug-2021, Haemoglobin: 14.2 (normal) 14.2 Normal. On 10-Aug-2021, Heart rate: 60 (normal) 60. On 10-Aug-2021, Platelet count: 196 (normal) 196 Normal. On 10-Aug-2021, Respiratory rate: 16 (normal) 16 Normal. On 10-Aug-2021, Troponin T: 181-182-135-173 (High) 181 - 182 - 135 - 173 High. On 10-Aug-2021, Visual analogue scale: 4-5 (High) 4 - 5. For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered CHEST PAIN (Chest pain) and MYOCARDITIS (Myocarditis) to be possibly related. No concomitant medication details was provided. No treatment medication details was provided. Most recent FOLLOW-UP information incorporated above includes: On 26-Aug-2021: Additional translation information received does not contain any new information (NNI)	
4.1(b) [redacted]		This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 26-Aug-2021 and was forwarded to Moderna on 26-Aug-2021. This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myocarditis), HYPERSENSITIVITY (Rash on right arm), PYREXIA (Fever), CHEST PAIN (Chest pain) and VACCINATION SITE LYMPHADENOPATHY (Vaccination site lymphadenopathy) in a 29-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3002623) for Routine childhood immunisation. No Medical History information was reported. On 04-Jun-2021 at 5:37 PM, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 05-Jun-2021 at 6:06 AM, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant), HYPERSENSITIVITY (Rash on right arm) (seriousness criterion hospitalization), PYREXIA (Fever) (seriousness	

Case ID	WW Identifier	Narrative	MAH Comment
		criterion hospitalization), CHEST PAIN (Chest pain) (seriousness criterion hospitalization) and VACCINATION SITE LYMPHADENOPATHY (Vaccination site lymphadenopathy) (seriousness criterion hospitalization). At the time of the report, MYOCARDITIS (Myocarditis), HYPERSENSITIVITY (Rash on right arm), PYREXIA (Fever), CHEST PAIN (Chest pain) and VACCINATION SITE LYMPHADENOPATHY (Vaccination site lymphadenopathy) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In June 2021, Body temperature: 39,0-39,4 (High) 39,0-39,4. In June 2021, Magnetic resonance imaging: abnormal (abnormal) myocarditis. For mRNA-1273 (Spikevax) (Unknown), the reporter considered MYOCARDITIS (Myocarditis) to be probably related and HYPERSENSITIVITY (Rash on right arm), PYREXIA (Fever), CHEST PAIN (Chest pain) and VACCINATION SITE LYMPHADENOPATHY (Vaccination site lymphadenopathy) to be possibly related. No concomitant medications are reported. No treatment medications are reported. Most recent FOLLOW-UP information incorporated above includes: On 26-Aug-2021: Translated doc received on 30AUG2021 includes no new information	
4.1(b)		This case was received via European Medicines Agency (Reference number: 4.1(b)) on 27-Aug-2021 and was forwarded to Moderna on 27-Aug-2021. This regulatory authority case was reported by a pharmacist and describes the occurrence of DYSPNOEA EXERTIONAL (Dyspnea exertional), CHEST PAIN (Chest pain), FATIGUE (Fatigue), PYREXIA (Fever) and MYOCARDITIS (Myocarditis) in a 21-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 3003659 and 3003606) for COVID-19 immunisation. Concurrent medical conditions included Pollen allergy, Food allergy (peanut allergy) and Tobacco user. Concomitant products included DESLORATADINE (AERIUS [DESLORATADINE]) for an unknown indication. On 08-Jul-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 05-Aug-2021, received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to 1 dosage form. On 05-Aug-2021, the patient experienced FATIGUE (Fatigue) (seriousness criterion hospitalization) and PYREXIA (Fever) (seriousness criterion hospitalization). On 06-Aug-2021, the patient experienced DYSPNOEA EXERTIONAL (Dyspnea exertional) (seriousness criterion hospitalization) and MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). On 07-Aug-2021, the patient experienced CHEST PAIN (Chest pain) (seriousness criterion hospitalization). At the time of the report, DYSPNOEA EXERTIONAL (Dyspnea exertional), CHEST PAIN (Chest pain), FATIGUE (Fatigue), PYREXIA (Fever) and MYOCARDITIS (Myocarditis) was resolving.	

Case ID	WW Identifier	Narrative	MAH Comment
		DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 05-Aug-2021, Body temperature: (High) fever. On 06-Aug-2021, Body temperature: (High) fever. On 07-Aug-2021, Angiocardiogram: Angiographically normal coronaries except for a discrete low flow of the tip of the IVA. No coronary disease. On 07-Aug-2021, Blood creatine phosphokinase (Unknown-190): 397. On 07-Aug-2021, Electrocardiogram: regular sinus rhythm with HR 80 beats/min, no conduction disorder, fine QRS, no repolarisation disorder, few changes with only a discrete concave ST elevation in V7-V9. On 07-Aug-2021, Troponin T (Unknown-0.014 nanogram per millliiter): 0.832 nanogram per millliiter. On 08-Aug-2021, Blood creatine phosphokinase (Unknown-190): 1650. On 08-Aug-2021, Electrocardiogram: regular sinus rhythm with HR 80 beats/min, no conduction disorder, fine QRS, no repolarisation disorder, with a discrete overshoot.. On 08-Aug-2021, Troponin T (Unknown-0.014 nanogram per millliiter): 4.47 nanogram per millliiter. On 09-Aug-2021, Blood creatine phosphokinase (Unknown-190): 361. On 09-Aug-2021, Electrocardiogram: regular sinus rhythm with HR 80 beats/min, no conduction disorder, fine QRS, no repolarisation disorder.. On 09-Aug-2021, Troponin T (Unknown-0.014 nanogram per millliiter): 3.9 nanogram per millliiter and 4.5 nanogram per millliiter. On 10-Aug-2021, Blood creatine phosphokinase (Unknown-190): 141. On 10-Aug-2021, Troponin T (Unknown-0.014 nanogram per millliiter): 2.91 nanogram per millliiter. In August 2021, Echocardiogram: non-dilated, non-hypertrophied left ventricle with moderate hypokinesia of the posterior wall and minimal hypokinesia of the inferobasal wall. LVEF 51%.. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No treatment medications were reported.	
4.1(b)		This case was received via 4.1(b) (Reference number: 4.1(b) on 29-Aug-2021 and was forwarded to Moderna on 29-Aug-2021. This regulatory authority case was reported by a non-health professional and describes the occurrence of FATIGUE (fatigue), MYOCARDIAL INFARCTION (heart attack), HYPERTENSION (hypertension), TREMOR (shaking), PAIN (pain), VOMITING (vomiting) and MYOCARDITIS (Myocarditis) in a 21-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) (batch no. 3003651) for COVID-19 vaccination. The patient's past medical history included Mood change and Pregnancy. Concurrent medical conditions included Hypertension. On 16-Aug-2021, the patient received second dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 19-Aug-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criterion medically significant). On an unknown date, the patient experienced FATIGUE (fatigue) (seriousness criterion life threatening), MYOCARDIAL INFARCTION (heart attack) (seriousness criteria medically significant and life threatening), HYPERTENSION (hypertension) (seriousness criterion life threatening),	

Case ID	WW Identifier	Narrative	MAH Comment
		TREMOR (shaking) (seriousness criterion life threatening), PAIN (pain) (seriousness criterion life threatening) and VOMITING (vomiting) (seriousness criterion life threatening). At the time of the report, FATIGUE (fatigue), MYOCARDIAL INFARCTION (heart attack), HYPERTENSION (hypertension), TREMOR (shaking), PAIN (pain), VOMITING (vomiting) and MYOCARDITIS (Myocarditis) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, SARS-CoV-2 test: negative Negative. The action taken with mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown Route) was unknown. Lab reports:the enzyme Tropin was reported at 7000 rising to 12000,Had x rays, many blood tests,CT scan, ultra sound scan. patient isnow on 3 types of medication for hypertension.	
4.1(b) [redacted]		This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS 4.1(b) [redacted])) and CHEST PAIN (4.1(b) [redacted] in a 17-year-old male patient who received mRNA-1273 (COVID 19 Vaccine Moderna) (batch no. 3001946) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Type I diabetes mellitus without mention of complication. Concomitant products included INSULIN for Type I diabetes mellitus without mention of complication. On 14-May-2021, the patient received second dose of mRNA-1273 (COVID 19 Vaccine Moderna) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (COVID 19 Vaccine Moderna) (unknown route) 1 dosage form. On	This is a 17 years old male with history if Diabetes Type 1 who the next day after the second dose of Spikevax developed chest pain and was diagnosed with myocarditis. Patient had abnormal echocardiogram and elevated troponin levels. Type 1 and type 2 diabetic patients are at increased risk of cardiomyopathy and heart failure is a major cause of death for these patients. Cardiomyopathy in diabetes is associated with a cluster of features including decreased diastolic compliance, interstitial fibrosis and myocyte hypertrophy. The mechanisms leading to diabetic cardiomyopathy remain uncertain. Diabetes is associated with most known risk factors for cardiac failure seen in the overall population, including obesity, dyslipidemia, thrombosis, infarction, hypertension, activation of multiple hormone and cytokine systems, autonomic neuropathy, endothelial dysfunction and coronary artery disease. This case is classify as Level 2 of diagnostic certainty according ot the Brighton Collaboration case classification, as Probable according to the CDC working definition, and as possible according to the WHO causality assessment.

Case ID	WW Identifier	Narrative	MAH Comment
		14-May-2021, the patient experienced PRODUCT ADMINISTERED TO PATIENT OF INAPPROPRIATE AGE (inappropriate age at vaccination (17 years)). On 15-May-2021, the patient experienced MYOCARDITIS [redacted] (seriousness criteria hospitalization and medically significant) and CHEST PAIN [redacted] (seriousness criterion hospitalization). On 14-May-2021, PRODUCT ADMINISTERED TO PATIENT OF INAPPROPRIATE AGE (inappropriate age at vaccination (17 years)) had resolved. On 28-May-2021, MYOCARDITIS [redacted] and CHEST PAIN [redacted] had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 15-May-2021, Blood creatine phosphokinase MB: increased (High) Increased. On 15-May-2021, Blood test: abnormal (abnormal) myopericarditis. On 15-May-2021, Electrocardiogram: abnormal (abnormal) abnormal. On 15-May-2021, Myoglobin blood: increased (High) Increased. On 15-May-2021, Troponin: increased (High) Increased. For mRNA-1273 (COVID 19 Vaccine Moderna) (Intramuscular), the reporter did not provide any causality assessments.	

Case ID	WW Identifier	Narrative	MAH Comment
		Treatment information was not provided. Company Comment: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship for the events Myocarditis and Chest pain cannot be excluded. Causality for the event Product administered to patient of inappropriate age is assessed as not applicable. The action taken for m-RNA-1273 Covid-19 Moderna Vaccine was not applicable. Most recent FOLLOW-UP information incorporated above includes: On 24-Jun-2021: Follow-Up received on 24-June-2021 included update in action taken and De-challenge for suspect product and updated narrative	
4.1(b)		This case was received via 4.1(b) (Reference number: 4.1(b) on 15-Jun-2021 and was forwarded to Moderna on 15-Jun-2021. This regulatory authority case was reported by a health care professional and describes the occurrence of CHEST PAIN (Chest pain), CHILLS (Chills), FATIGUE (Fatigue), TACHYCARDIA (Intermittent tachycardia), MYOCARDITIS (Myocarditis) and SARS-COV-2 TEST POSITIVE (COVID-19 IgG Ab positive) in a 15-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 002c21a) for COVID-19 vaccination. The patient's past medical history included Wolff-Parkinson-White syndrome. Concomitant products included HPV VACCINE VLP RL1 9V (YEAST) (GARDASIL 9) from 14-May-2021 to an unknown date for an unknown indication.	This is a 15 years old male with history if Wolff-Parkinson-White syndrome who the next day after the second dose of Spikevax developed chest pain and was diagnosed with myocarditis and COVID-19 infection. Patient had abnormal EKG, elevated troponin levels. Patient medical history including concurrent COVID-19 infection provides a more plausible explanation for the events reported by the patient. This case is classify as Level 1 of diagnostic certainty according ot the Brighton Collaboration case classification, as unassessable according to the CDC working definition, due to other identifiable cause of the symptoms, and as possible according to the WHO causality assessment.

Case ID	WW Identifier	Narrative	MAH Comment
		On 14-May-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 2 dosage form. On 15-May-2021, the patient experienced CHEST PAIN (Chest pain) (seriousness criterion hospitalization), CHILLS (Chills) (seriousness criterion hospitalization), FATIGUE (Fatigue) (seriousness criterion hospitalization), TACHYCARDIA (Intermittent tachycardia) (seriousness criterion hospitalization), MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant) and SARS-COV-2 TEST POSITIVE (COVID-19 IgG Ab positive) (seriousness criterion hospitalization). At the time of the report, CHEST PAIN (Chest pain), CHILLS (Chills), FATIGUE (Fatigue), TACHYCARDIA (Intermittent tachycardia), MYOCARDITIS (Myocarditis) and SARS-COV-2 TEST POSITIVE (COVID-19 IgG Ab positive) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 19-May-2021, C-reactive protein increased: 10.6 Increased. On 19-May-2021, COVID-19: positive (Positive) Positive. On 19-May-2021, Electrocardiogram: abnormal. On 19-May-2021, Electrocardiogram ST segment: abnormal. On 19-May-2021, Polymerase chain reaction: negative (Negative) Negative. On 19-May-2021, Troponin: 16.72 (High) 16.72. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medications were provided. Treatment medications was not provided.	

Case ID	WW Identifier	Narrative	MAH Comment
		Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Based on the mechanism of action of mRNA-1273, a causal association between the event of positive COVID-19 antibody test and mRNA-1273 is assessed as not applicable.	
4.1(b)	4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b) on 27-Jul-2021 and was forwarded to Moderna on 27-Jul-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCARDITIS (Myocarditis), CHEST PAIN (Chest pain), PALPITATIONS (Palpitations) and VACCINATION COMPLICATION (myocarditis related to COVID19 vaccine) in a 15-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Tic disorder, unspecified. Concomitant products included GUANFACINE for an unknown indication. On 05-Jul-2021, the patient received dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 06-Jul-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant), CHEST PAIN (Chest pain) (seriousness criterion hospitalization), PALPITATIONS (Palpitations) (seriousness criterion hospitalization) and VACCINATION COMPLICATION (myocarditis related to COVID19 vaccine) (seriousness criterion hospitalization). On an unknown date, the patient experienced PRODUCT	This is a 15 years old female with unknown medical history and Guanfacine as concomitant medication who the next day after an unknown dose of Spikevax experienced chest pain, palpitations and was diagnosed with myocarditis. Troponin levels were elevated in two different days. No other information was provided. This case is classify as Level 2 of diagnostic certainty according ot the Brighton Collaboration case classification, as probable according to the CDC working definition, and as probable according to the WHO causality assessment.

Case ID	WW Identifier	Narrative	MAH Comment
		ADMINISTERED TO PATIENT OF INAPPROPRIATE AGE (Inappropriate age at vaccine administration). At the time of the report, MYOCARDITIS (Myocarditis), CHEST PAIN (Chest pain), PALPITATIONS (Palpitations) and VACCINATION COMPLICATION (myocarditis related to COVID19 vaccine) had resolved and PRODUCT ADMINISTERED TO PATIENT OF INAPPROPRIATE AGE (Inappropriate age at vaccine administration) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 08-Jul-2021, Troponin: 77 (High) increased, 36 (normal) normal and 47 (High) increased. On 09-Jul-2021, Troponin: 69 (High) High. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown) was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. No treatment information was provided. Company comment: This report refers to a case of Inappropriate age at vaccine administration for mRNA-1273, lot # unknown, with associated AEs (Chest pain, Myocarditis, Palpitations, and Vaccination complication) for this 15-year-old female. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.	
4.1(b) [redacted]		This case was received via 4.1(b) [redacted] (Reference number: 4.1(b) [redacted] on 24-Aug-2021	This is a 17 years old male with unknown medical history and unknown concomitant medication who according to the report received

Case ID	WW Identifier	Narrative	MAH Comment
		and was forwarded to Moderna on 24-Aug-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of CHEST PAIN (Chest pain) and MYOCARDITIS (Myopericarditis) in a 17-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 016C21A and 016C21A) for COVID-19 vaccination. No Medical History information was reported. On 27-Jul-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 27-Jul-2021, received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 30-Jul-2021, the patient experienced CHEST PAIN (Chest pain) (seriousness criteria hospitalization and life threatening) and MYOCARDITIS (Myopericarditis) (seriousness criteria hospitalization, medically significant and life threatening). The patient was treated with IBUPROFEN (MOTRIN [IBUPROFEN]) for Chest pain, at an unspecified dose and frequency. At the time of the report, CHEST PAIN (Chest pain) and MYOCARDITIS (Myopericarditis) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 30-Jul-2021, Echocardiogram: normal normal. On 30-Jul-2021, Troponin: increased (High) ECG showed ST elevation and during follow up there is evidence of T wave inversion in lateral leads. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments.	by the the regulatory authority received both doses of Spikevax the same day. Patient 3 days later experienced chest pain and was diagnosed with myocarditis. Troponin levels were elevated and an ECG showed ST elevation and during follow up there is evidence of T wave inversion in lateral leads. No other information was provided. This case is classify as Level 2 of diagnostic certainty according ot the Brighton Collaboration case classification, as unassessable according to the CDC working definition, and as possible according to the WHO causality assessment.

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

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

Case ID	WW Identifier	Narrative	MAH Comment
		This regulatory authority case was reported by a physician and describes the occurrence of PERICARDITIS (Pericarditis), CHEST PAIN (Thoracic pain) and PYREXIA (Fever) in a 14-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 3005695 and 214013) for COVID-19 vaccination. No Medical History information was reported. On 29-Jul-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 26-Aug-2021, received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to 1 dosage form. On 27-Aug-2021, the patient experienced PERICARDITIS (Pericarditis) (seriousness criteria hospitalization prolonged and medically significant), CHEST PAIN (Thoracic pain) (seriousness criterion hospitalization prolonged) and PYREXIA (Fever) (seriousness criterion hospitalization prolonged). On 28-Aug-2021, PYREXIA (Fever) had resolved. At the time of the report, PERICARDITIS (Pericarditis) and CHEST PAIN (Thoracic pain) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 27-Aug-2021, Blood glucose: 102 mg/dl (normal) 102 mg/dL. On 27-Aug-2021, Blood urea: 36.7 mg/dl (High) 36.7 mg/dL. On 27-Aug-2021, Chest X-ray: No nodules or opacities are observed in the lung parenchyma. No signs of pleural disease are identified. Cardiothoracic ratio and mediastinum within the normal limit. No bone or soft tissue lesions are identified. No findings of pathological significance... On 27-Aug-2021, Coagulation test: abnormal (abnormal) Coagulation study: Patient (PT) 15.4 sec, Ratio (PT) 1.4 R, Activity (Quick Index)	line of pericardial effusion; EKG showed concave ST elevation, and slight decreased of PR segment. Pateint was tested for several microorganisms including COVID-19 and results were negative. No other informatin was provided. Important information is missing from this report.

Case ID	WW Identifier	Narrative	MAH Comment
		61(70-130)%, INR 1.4 INR, Patient (aPTT) 29.3 sec, Ratio (aPTT) 0.95, Derived fibrinogen 5.65(2-4)g/L, D-dimer 561(0-500)ngr/mL. On 27-Aug-2021, Echocardiogram: normal (normal) Echocardiogram: Fine line of pericardial effusion visible in the long axis and subcostal planes.. On 27-Aug-2021, Electrocardiogram: normal (normal) Sinus rhythm. HR: 78 bpm. Generalized concave ST elevation. Slight decrease of PR segment in derivation [cohort.] No signs of repolarization [disturbances].. On 27-Aug-2021, Full blood count: [redacted] 14.1 g/dL; [redacted] 5.01 10^6/microL; [redacted] 40.8 %. [redacted] 9.60 10^3/microL ([redacted] 64.0 % (40-62); [redacted] 19.5 % (19-48); [redacted] 15.3 % (3-10)). [redacted] 161.0 10^3/microL. VSG 13 mm (3-12).. On 27-Aug-2021, Laboratory test: [redacted] [redacted] 102 mg/dL, Urea 36.7 mg/dL, [redacted] ([redacted] 0.82 mg/dL, [redacted] 136 mmol/L, [redacted] 3.7 mmol/L, [redacted] 103 mmol/L, [redacted] [redacted] 0.45 mg/dL, GPT (ALT) 24.8 U/L, GOT (AST) 27.0 U/L, Gamma GT 13.0 U/L, [redacted] 71.0(74-390)U/L, CPK - [redacted] 193 U/L, PCR 5.75(0.5) mg/dL, [redacted] 0.27 ng/mL. [redacted] [redacted] 16.6(34)pg/mL, CK - MB Masa 0.60(<5.20)ng/mL. On 27-Aug-2021, Pharyngeal exudate: Bordetella pertussis [redacted] parapertussis, Chlamydia pneumoniae, Mycoplasma pneumoniae: [redacted] [redacted] RT-PCR [redacted] VRS ([redacted]), Virus Influenza A, Influenza B, Virus [redacted] Coronavirus: [redacted] [redacted] PCR [redacted] ADN [redacted] Adenovirus [redacted] ARN [redacted] Coronavirus (NL63, OC43, 229E, HKU1 y MERS-CoV), Enterovirus/Rinovirus, Metapneumovirus [redacted] Virus Parainfluenza (1, 2, 3 y 4): [redacted]	

Case ID	WW Identifier	Narrative	MAH Comment
		mRNA-1273 (Spikevax) (Intramuscular) was withdrawn on 29-Jul-2021. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medications were provided. No treatment information was provided. This case concerns a 14-year-old, male patient with no relevant medical history, who experienced the unexpected event of Chest pain and the expected events of Pericarditis, Pyrexia. The events occurred around 2 days after the second dose of Spikevax. The rechallenge was not applicable since no events were reported after the first dose. The events Pericarditis and Pyrexia consistent with the current understanding of the mechanism of action of the vaccine. The benefit-risk relationship of Spikevax is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 17-Sep-2021: Follow-Up received translation document, updating lab data result	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 16-Sep-2021 and was forwarded to Moderna on 16-Sep-2021. This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myopericarditis) in a 13-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 3005695 and 214016) for COVID-19 vaccination. No Medical History information was reported.	13-year-old, male patient with unknown medical history, who experienced chest pain, malaise an dpyrexia and wa diagnosed with myocarditis. The events fever and malaise occurred 2 days after the second dose of mRNA-1273 vaccine administration while the events myocarditis and chest pain occurred 4 days after the second dose. Laboratory information showed elevated troponin, EKG inconclusive. All other laboratory results were normal or inconclusive according to the report. No other information was provided.

Case ID	WW Identifier	Narrative	MAH Comment
		On 02-Aug-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 30-Aug-2021, received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to 1 dosage form. On 02-Sep-2021, after starting mRNA-1273 (Spikevax), the patient experienced MYOCARDITIS (Myopericarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Myopericarditis) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 02-Sep-2021, Alanine aminotransferase: 36.4 (Inconclusive) 36.4 U/L. On 02-Sep-2021, Aspartate aminotransferase: 68.0 (Inconclusive) 68.0 U/L. On 02-Sep-2021, Basophil count: 0.4 (Inconclusive) 0.4%. On 02-Sep-2021, Blood alkaline phosphatase: 194.0 (Inconclusive) 194.0 U/L. On 02-Sep-2021, Blood bilirubin: 0.38 (Inconclusive) 0.38 mg/dL. On 02-Sep-2021, Blood chloride: 105 (Inconclusive) 105 mmol/L. On 02-Sep-2021, Blood creatine phosphokinase: 639 (Inconclusive) 639 U/L. On 02-Sep-2021, Blood creatine phosphokinase MB: 25.20 (Inconclusive) 25.20 ng/mL. On 02-Sep-2021, Blood creatinine: 0.55 mg/dl (Inconclusive) 0.55 mg/dL. On 02-Sep-2021, Blood glucose: 94 mg/dl (Inconclusive) 94 mg/dL. On 02-Sep-2021, Blood potassium: 3.8 (Inconclusive) 3.8 mmol/L. On 02-Sep-2021, Blood sodium: 141 (Inconclusive) 141 mmol/L. On 02-Sep-2021, Blood urea: 16.4 (Inconclusive) 16.4 mg/dL. On 02-Sep-2021, C-reactive protein: 4.13 (Inconclusive) 4.13 mg/dL. On 02-Sep-2021, Electrocardiogram: inconclusive (Inconclusive) Sinus rhythm. Normal axis. Narrow PR (no clear depressions noted), narrow	

Case ID	WW Identifier	Narrative	MAH Comment
		QRS, concave ST-segment elevation in leads II, III, aVF, V3-6. Qtc 0.38.. On 02-Sep-2021, Eosinophil count: 3.10 (Inconclusive) 3.10 %. On 02-Sep-2021, Gamma-glutamyltransferase: 36.0 (Inconclusive) 36.0 U/L. On 02-Sep-2021, Haematocrit: 43.2 (Inconclusive) 43.%. On 02-Sep-2021, Haemoglobin: 14.6 (Inconclusive) Hemoglobin 14.6 g/dL. On 02-Sep-2021, Heart rate: 66 (Inconclusive) 66 bpm. On 02-Sep-2021, Lymphocyte count: 31.9 (Inconclusive) 31.9 %. On 02-Sep-2021, Mean cell haemoglobin: 27.40 (Inconclusive) 27.40 pg. On 02-Sep-2021, Mean cell haemoglobin concentration: 33.7 (Inconclusive) 33.7 g/dL. On 02-Sep-2021, Mean cell volume: 81.2 (Inconclusive) 81.2 fL. On 02-Sep-2021, Mean platelet volume: 8.8 (Inconclusive) 8.8 fL. On 02-Sep-2021, Monocyte count: 12.4 (Inconclusive) 12.4%. On 02-Sep-2021, Neutrophil count: 52.2 (Inconclusive) 52.2 %. On 02-Sep-2021, Platelet count: 253.0 (Inconclusive) 253.0 10^3/microL. On 02-Sep-2021, Red blood cell analysis: 13.3 (Inconclusive) 13.3%. On 02-Sep-2021, Red blood cell count: 5.32 (Inconclusive) 5.32 10^6 microL. On 02-Sep-2021, SARS-CoV-2 test: negative (Negative) Negative. On 02-Sep-2021, Troponin I: 6730.0 (Inconclusive) 6730.0 pg/mL. On 02-Sep-2021, White blood cell count: 8.20 (Inconclusive) 8.20 10^3/microL. mRNA-1273 (Spikevax) (Intramuscular) was withdrawn on 02-Aug-2021. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.	

Case ID	WW Identifier	Narrative	MAH Comment
		No concomitant medications reported. No treatment information provided. Company Comment: This case concerns a 13-year-old, male patient with no relevant medical history, who experienced the unexpected events of chest pain and malaise the expected events of myocarditis and pyrexia. The events fever and malaise occurred 2 days after the second dose of mRNA-1273 vaccine administration while the events myocarditis and chest pain occurred 4 days after the second dose of mRNA-1273 vaccine administration. The rechallenge was unknown as there's no information available about the first dose. No product report assessment was given from the reporter. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. RA SD events onset latency was captured from the first dose of mRNA-1273 vaccine administration rather than the second dose of mRNA-1273 vaccine administration. RA SD coding was maintained. Most recent FOLLOW-UP information incorporated above includes: On 16-Sep-2021: Translated document was received on SRD 22-Sep-2021 and laboratory information was updated.	
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 29-Sep-2021 and was forwarded to Moderna on 29-Sep-2021. This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (4.1(b) COVID-19 IMMUNISATION (4.1(b) and CHEST PAIN (4.1(b)) in a 17-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 3002616) for COVID-19 vaccination.	17 years old female with unknown medical history and who received the other mRNA vaccine as the 1st dose, and that the same day afte rthe 2nd dose with the MOderna vaccine expereince chest pain and was diagniosed with myocarditis. Troponin levels were elevated and EKG results were abniornal suggestive of mycarditis. No other information was provided.

Case ID	WW Identifier	Narrative	MAH Comment
		Previously administered products included for Vaccination: Comirnaty. On 15-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. In 2021, the patient experienced COVID-19 IMMUNISATION (4.1(b) (seriousness criterion hospitalization). On 15-Sep-2021, the patient experienced MYOCARDITIS (4.1(b) (seriousness criteria hospitalization and medically significant) and CHEST PAIN (4.1(b)) (seriousness criterion hospitalization). In 2021, COVID-19 IMMUNISATION (4.1(b) was resolving. On 21-Sep-2021, MYOCARDITIS (4.1(b) and CHEST PAIN (4.1(b) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In September 2021, Electrocardiogram: st-elevation (High) ST-elevation. In September 2021, Troponin: high (High) High. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medications reported No treatment medications provided	
4.1(b)		This case was initially received via an unknown source (no reference has been entered for a health authority or license partner) on 04-Jun-2021. The most recent information was received on 05-Jul-2021 and was forwarded to Moderna on 05-Jul-2021. This spontaneous case was reported by a consumer and describes the occurrence of MYOCARDITIS (Myocarditis/ acute myocarditis) in a 28-year-old male patient who received mRNA-1273 (Moderna	This is a 28 years old male with unknown medical history but who was taking Simvastatin, which suggest hypercholesterolemia. The patient 3 days after the 2nd dose of the vaccine developed chest pain and he was diagnosed with myocarditis. According to the CDC definition this case is a probable case of myocarditis; according to the Brigton collaboratuoin is a Level 4 case, and according to the WHO causality assessment, this case is considered

Case ID	WW Identifier	Narrative	MAH Comment
		COVID-19 Vaccine) (batch no. 006c21a) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concomitant products included FISH OIL from 05-Jan-2021 to an unknown date and SIMVASTATIN from 05-Jan-2021 to an unknown date for Cholesterol low, VITAMIN D [VITAMIN D NOS] from 10-Jan-2021 to an unknown date for Vitamin D increased. On 23-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 21-May-2021 at 8:30 AM, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 21-May-2021, the patient experienced MYALGIA (Body ache), CHILLS (Chills) and PYREXIA (Fever). On 24-May-2021, the patient experienced MYOCARDITIS (Myocarditis/ acute myocarditis) (seriousness criteria hospitalization and medically significant). The patient was hospitalized on 24-May-2021 due to CHEST PAIN and MYOCARDITIS. On 23-May-2021, MYALGIA (Body ache), CHILLS (Chills) and PYREXIA (Fever) had resolved. On 25-May-2021, MYOCARDITIS (Myocarditis/ acute myocarditis) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 25-Apr-2021, Magnetic resonance imaging: inconclusive (Inconclusive) Results are Unknown. On 24-May-2021, Angiogram: inconclusive (Inconclusive) Results are Unknown. On 24-May-2021, Electrocardiogram: abnormal (abnormal) Abnormal. On 24-May-2021, Ultrasound scan: inconclusive (Inconclusive) Results are Unknown. On an unknown date, SARS-CoV-2 test: negative (Negative) Negative.	possible. Important risk factors associated with this report is the medical history of hypercholesteronemia as well as use of Simvastatin, which is labelled for myopathy manifested as muscle pain, tenderness or weakness with creatine kinase (CK) above ten times the upper limit of normal (ULN).

Case ID	WW Identifier	Narrative	MAH Comment
		By that evening, patient felt the usual symptoms of fever, body ache and chills, which continued for the next 48 hours. By Sunday, 05/23, he was feeling back to normal and in good health. The next morning, Monday, 05/24, he woke up with chest pain, a crushing pain in his heart and to the ER(4.1(b)). An EKG was taken, and the cardiologist mentioned that it was abnormal and that a catheter angiogram needed to be done to check the arteries. Treatment included overnight monitoring by the cardiology team. Next morning, the cardiologist told the patient that he has myocarditis, and that it is showing up in younger adults who have taken the vaccine. He is currently on medication over the course of the next month, till his follow up visit with the cardiologist. (Per source document). No treatment information was provided. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Further information has been requested. Most recent FOLLOW-UP information incorporated above includes: On 05-Jul-2021: Updated Concomitant medication, lab data COVID- 19 test and event of Myocarditis end date were provided.	
4.1(b)		This spontaneous case was reported by a consumer and describes the occurrence of CARDIAC ARREST (Cardiac arrest) and MYOCARDITIS (Myocarditis (inflammation of heart tissue)) in a 55-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) (batch nos. 3002914 and 3001658) for COVID-19	This is a 55 years old male with medical history of hypertension who 3 days after the 2nd dose of the vaccine developed cardiac arrest and the next day was diagnosed with myocarditis. According to the CDC definition this case is probable; according to the Brigton collaboration is a Level 1 case, and according to

Case ID	WW Identifier	Narrative	MAH Comment
		vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Blood pressure high. On 18-Apr-2021, the patient received first dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (Intramuscular) 1 dosage form. On 17-Jun-2021, received second dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 17-Jun-2021, the patient experienced INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (Inappropriate schedule of vaccine administered). On 18-Jun-2021, after starting mRNA-1273 (Moderna CoviD-19 Vaccine), the patient experienced VACCINATION COMPLICATION (Common symptoms of vaccine) and PYREXIA (Fever). On 20-Jun-2021, the patient experienced CARDIAC ARREST (Cardiac arrest) (seriousness criteria hospitalization, medically significant and life threatening). On 21-Jun-2021, the patient experienced MYOCARDITIS (Myocarditis (inflammation of heart tissue)) (seriousness criteria hospitalization and medically significant). The patient was hospitalized from 20-Jun-2021 to 23-Jun-2021 due to CARDIAC ARREST and MYOCARDITIS. On 17-Jun-2021, INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (Inappropriate schedule of vaccine administered) had resolved. At the time of the report, CARDIAC ARREST (Cardiac arrest), MYOCARDITIS (Myocarditis (inflammation of heart tissue)), VACCINATION COMPLICATION (Common symptoms of vaccine) and PYREXIA (Fever) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):	the WHO causality assessment, this case is considered possible. Important risks factors for this report included the pateint's age and the history of hypertension with no other deatil sprovided including concurrent medications. In the analysis of this case report, the main concern here is the lack of information on the patient's full medical history and concomitant medications history. There is also important information missing regarding other laboratory tests conducted, treatment, medical course, etc.

Case ID	WW Identifier	Narrative	MAH Comment
		On 20-Jun-2021, Blood pressure measurement: high (High) High. On 20-Jun-2021, Myocardial necrosis marker: elevated (High) Elevated levels. On 21-Jun-2021, Angiogram: myocarditis (abnormal) Myocarditis (inflammation of heart tissue). No concomitant information as provided. Treatment information was not provided. The caller reported that patient had all types of symptoms. It was reported that the patient said that since that day has been recovering every day and that it's strength was seriously depleted. The patient reported the cardiologist said that there was a correlation between the myocarditis and the vaccine. The causality for the event Inappropriate schedule of vaccine administered is not applicable.Regarding the other adverse events, based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Most recent FOLLOW-UP information incorporated above includes: On 09-Jul-2021: Event of inappropriate schedule of vaccine administered added from Follow-up 1. On 15-Jul-2021: NNI received On 15-Jul-2021: other email addre ss provided On 15-Jul-2021: Follow up document received contains no significant information (NNI).	
4.1(b) [redacted]		This case was received via 4.1(b) [redacted] (Reference number: 4.1(b) [redacted] on 06-Jul-2021 and was forwarded to Moderna on 06-Jul-2021.	This is a 19 years old male with concurrent medical history of diabetes and dyslipidemia, and concurrent medication of simvastatin, who the next day afterreceiving the

Case ID	WW Identifier	Narrative	MAH Comment
		This regulatory authority case was reported by an other health care professional and describes the occurrence of CHEST PAIN (Chest pain), MYOCARDITIS (Myocarditis) and PYREXIA (Pyrexia) in a 19-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. Concurrent medical conditions included Type 1 diabetes mellitus and Dyslipidemia. Concomitant products included INSULIN GLARGINE, INSULIN BOVINE (INSULIN REGULAR [INSULIN BOVINE]) and SIMVASTATIN (ZOCOR) for an unknown indication. On 19-Jun-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 20-Jun-2021, the patient experienced CHEST PAIN (Chest pain) (seriousness criterion hospitalization), MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant) and PYREXIA (Pyrexia) (seriousness criterion hospitalization). At the time of the report, CHEST PAIN (Chest pain), MYOCARDITIS (Myocarditis) and PYREXIA (Pyrexia) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 20-Jun-2021, C-reactive protein: increased (High) increased. On 20-Jun-2021, Cardiac imaging procedure: abnormal (abnormal) abnormal. On 20-Jun-2021, Electrocardiogram: abnormal (abnormal) ST segment elevation.	2nd dose of the vaccine, experienced chest pain and pyrexia and was diagnosed with myocarditis. According to the CDC definition this case is considered a confirmed case; according to the Brigton collaboration is a Level 1 case, and according to the WHO causality assessment, this case is considered possible. Important risk factors included history of diabetes and dyslipidemia.

Case ID	WW Identifier	Narrative	MAH Comment
		On 20-Jun-2021, Red blood cell sedimentation rate: increased (High) increased. On 20-Jun-2021, Troponin: increased (High) increased. On 24-Jun-2021, Magnetic resonance imaging heart: myocarditis (abnormal) consistent with Myocarditis. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. An echocardiogram was performed on 20June2021, results not provided. Additional laboratory tests included troponin levels (on 21JUN2021 and 24JUN2021), sedimentation rate (on 22JUN2021) and EKG (21JUN2021 and 22JUN2021) with results not provided for all. Treatment details were not provided. Company comment: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. No further information is expected at this time.	
4.1(b)		This case was received via 4.1(b) (Reference number: 4.1(b) on 13-Jul-2021 and was forwarded to Moderna on 13-Jul-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCARDITIS (Myocarditis) in a 23-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. C44C21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Gouty pain. Concomitant products included COLCHICINE for Gouty pain,	This is a 23 years old male with history of gout and very limited information provided who 2 days after receiving the 2nd dose of the vaccine patient was diagnosed with myocarditis. According to the CDC definition this case is probable; according to the Brigton collaboration is a Level 2 case, and according to the WHO causality assessment, this case is considered possible. In the analysis of this case report, the main concern here is the lack of information on the patient's full medical history and concomitant medications history. There is also important information missing regarding other laboratory tests conducted, treatment, medical course, etc.

Case ID	WW Identifier	Narrative	MAH Comment
		FAMOTIDINE for an unknown indication. On 21-Jun-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 23-Jun-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criterion medically significant) and CHEST PAIN (Chest pain). At the time of the report, MYOCARDITIS (Myocarditis) and CHEST PAIN (Chest pain) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 23-Jun-2021, Troponin: increased (Inconclusive) increased. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Patient was observed under telemetry unit. Treatment information was not provided. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.	
4.1(b)		This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS 4.1(b) in a 36-year-old male patient who received mRNA-1273 (COVID 19 Vaccine Moderna) (batch nos. 3003183 and 3002183) for COVID-19 vaccination. No Medical History information was reported.	This is a 23 years old male with history of gout and very limited information provided who 2 days after receiving the 2nd dose of the vaccine patient was diagnosed with myocarditis. According to the CDC definition this case is probable; according to the Brigton collaboration is a Level 2 case, and according to the WHO causality assessment, this case is considered possible. In the

Case ID	WW Identifier	Narrative	MAH Comment
		On 11-May-2021, the patient received first dose of mRNA-1273 (COVID 19 Vaccine Moderna) (unknown route) 1 dosage form. On 22-Jun-2021, received second dose of mRNA-1273 (COVID 19 Vaccine Moderna) (unknown route) dosage was changed to 1 dosage form. On 24-Jun-2021, after starting mRNA-1273 (COVID 19 Vaccine Moderna), the patient experienced MYOCARDITIS [redacted] (seriousness criteria hospitalization, medically significant and life threatening). At the time of the report, MYOCARDITIS [redacted] had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In 2021, Troponin: elevated (High) troponin elevation. The concomitant medications were not reported. The treatment information was not provided. The lab tests were reported as ecocardiogram and elevated troponin performed on an unspecified date confirmed the suspected myocarditis in the patient. Myocardial infarction and NSTEMI were ruled out. Most recent FOLLOW-UP information incorporated above includes: On 13-Jul-2021: Translation document was received on 20 July 2021 and had significant information. Added DOB of patient and batch number of first dose of drug, Lab data.	analysis of this case report, the main concern here is the lack of information on the patient's full medical history and concomitant medications history. There is also important information missing regarding other laboratory tests conducted, treatment, medical course, etc.
[redacted]		This case was received via [redacted] (Reference number: [redacted]) on 13-Jul-2021 and was forwarded to Moderna on 13-Jul-2021.	This is a 75 years old male with history of hypertension and hyperlipidemia who the same day after receiving the 2nd dose of the vaccine patient experience chest pain, pleuritic pain and was

Case ID	WW Identifier	Narrative	MAH Comment
		This regulatory authority case was reported by an other health care professional and describes the occurrence of PERICARDITIS (Pericarditis), PERICARDIAL EFFUSION (Pericardial effusion), PLEURITIC PAIN (Pleuritic pain) and CHEST PAIN (Chest pain) in a 75-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No medical history was provided by the reporter. Concurrent medical conditions included Allergic rhinitis, Hypertension and Hyperlipidemia. Concomitant products included ATENOLOL, MONTELUKAST, ROSUVASTATIN, OLMESARTAN, TAMSULOSIN and ACETYLSALICYLIC ACID for an unknown indication. On 02-Mar-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 02-Mar-2021, the patient experienced PERICARDITIS (Pericarditis) (seriousness criteria hospitalization and medically significant), PERICARDIAL EFFUSION (Pericardial effusion) (seriousness criteria hospitalization and medically significant), PLEURITIC PAIN (Pleuritic pain) (seriousness criterion hospitalization) and CHEST PAIN (Chest pain) (seriousness criterion hospitalization). The patient was hospitalized on 23-Jun-2021 due to CHEST PAIN, PERICARDIAL EFFUSION, PERICARDITIS and PLEURITIC PAIN. At the time of the report, PERICARDITIS (Pericarditis), PERICARDIAL EFFUSION (Pericardial effusion), PLEURITIC PAIN (Pleuritic pain) and CHEST PAIN (Chest pain) had resolved.	diagnosed with pericarditis and pericardial effusion. According to the CDC definition this case is classify as acute pericarditis; according to the Brigton collaboration is a Level 2 case, and according to the WHO causality assessment, this case is considered possible.Important risk factors for this report are the patient's advance age, an dhis history of hypertension and hyperlipidemia. There is also important information missing regarding other laboratory tests conducted, treatment, medical course, etc.

Case ID	WW Identifier	Narrative	MAH Comment
		DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 02-Mar-2021, C-reactive protein: 135 (normal) normal. On 02-Mar-2021, Computerised tomogram thorax: abnormal (abnormal) 1 cm pericardial effusion - no PE.. On 02-Mar-2021, Echocardiogram: abnormal (abnormal) abnormal. On 02-Mar-2021, Electrocardiogram ST segment: elevated (High) elevated. On 02-Mar-2021, Troponin: negative (Negative) Negative. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. The patient experienced sudden onset of pleuritic left precordial pain that increased with supine position. Treatment information was not provided. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.	
4.1(b)		This case was received via 4.1(b) (Reference number: 4.1(b) on 20-Jul-2021 and was forwarded to Moderna on 20-Jul-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCARDITIS (Myocarditis), DYSPNOEA (Dyspnoea), MALAISE (Malaise) and PYREXIA (Fever) in a 37-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. Concurrent medical conditions included Factor V Leiden carrier and Penicillin allergy.	This is a 37 years old male with history of Factor V Leiden and very limited information provided who the same day after receiving the 2nd dose of the vaccine patient experienced dyspnea, malaise, pyrexia, and was diagnosed with myocarditis. According to the CDC definition this case is confirmed; according to the Brigton collaboration is a Level 1 case, and according to the WHO causality assessment, this case is considered conditional. This report is confounded by the patient's medical history of Factor V Leiden. There is also important information missing regarding other laboratory tests conducted, treatment, medical course, etc.

Case ID	WW Identifier	Narrative	MAH Comment
		Concomitant products included PARACETAMOL (TYLENOL) for an unknown indication. On 03-Jul-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 03-Jul-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant) and DYSPNOEA (Dyspnoea) (seriousness criterion hospitalization). 03-Jul-2021, the patient experienced MALAISE (Malaise) (seriousness criterion hospitalization) and PYREXIA (Fever) (seriousness criterion hospitalization). The patient was treated with ASPIRIN [ACETYLSALICYLIC ACID] ongoing from 03-Jul-2021 for Myocarditis, at an unspecified dose and frequency and COLCHICINE ongoing from 03-Jul-2021 for Myocarditis, at an unspecified dose and frequency. At the time of the report, MYOCARDITIS (Myocarditis), DYSPNOEA (Dyspnoea), MALAISE (Malaise) and PYREXIA (Fever) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 03-Jul-2021, C-reactive protein: 3.29 (High) Increased. On 03-Jul-2021, Computerised tomogram: equivocal (Inconclusive) equivocal. On 03-Jul-2021, Ejection fraction: 60% (normal) 60%. On 03-Jul-2021, Fibrin D dimer: 821 (High) 821. On 03-Jul-2021, Magnetic resonance imaging heart: abnormal (abnormal) EF 60%, no ischemia. Small amount of late gadolinium enhancement in the epicardium at the base of the inferior well and in the distal segment. Also epicardial gadolinium	

Case ID	WW Identifier	Narrative	MAH Comment
		enhancement in the basal lateral wall and along the distal lateral wall. Findings consistent with myocarditis. On 03-Jul-2021, Troponin: 2.15 (Inconclusive) 2.15. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. The patient developed fevers and malaise within 10 hours of the vaccine and then subsequently developed progressive shortness of breath and presented to the emergency department (ED) locally. Was thought to have a pulmonary embolism (PE) and underwent CT images which was equivocal. The patient was transferred to hospital where an MRI cardiac stress indicated myocarditis. The patient started on aspirin and colchicine and will require cardiology outpatient follow up. Patient was feeling better at the time of the report. Based on the current available inform ation and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.	
4.1(b)		This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myocarditis), DYSPNOEA (Dyspnea), CHEST PAIN (oppressive chest pain that does not respond to analgesics) and PYREXIA (Fever) in a 28-year-old male patient who received mRNA-1273 (COVID 19 Vaccine Moderna) (batch nos. 3003655 and 3002545) for COVID-19 vaccination. Concurrent medical conditions included Hypertension arterial. Concomitant products included RAMIPRIL for Hypertension. On 30-May-2021, the patient received first dose of mRNA-1273	This is a 28 years old male with history of hypertension and no other information provided who the same day after receiving the 2nd dose of the vaccine patient experienced chest pain, dypsnea, and pyrexia and was diagnosed with myocarditis. According to the CDC definition this case is probable; according to the Brigton collaboration is a Level 2 case, and according to the WHO causality assessment, this case is considered possible. In the analysis of this case report, the main concern here is the lack of information on the patient's full medical history and concomitant medications history. There is also important information missing regarding other laboratory tests conducted, treatment, medical course, etc.

Case ID	WW Identifier	Narrative	MAH Comment
		(COVID 19 Vaccine Moderna) (unknown route) .5 milliliter. On 05-Jul-2021, received second dose of mRNA-1273 (COVID 19 Vaccine Moderna) (Intramuscular) dosage was changed to 1 dosage form. On 05-Jul-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant), DYSPNOEA (Dyspnea) (seriousness criterion hospitalization), CHEST PAIN (oppressive chest pain that does not respond to analgesics) (seriousness criterion hospitalization) and PYREXIA (Fever) (seriousness criterion hospitalization). At the time of the report, MYOCARDITIS (Myocarditis), DYSPNOEA (Dyspnea), CHEST PAIN (oppressive chest pain that does not respond to analgesics) and PYREXIA (Fever) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Electrocardiogram: high (High) ECG elevated. For mRNA-1273 (COVID 19 Vaccine Moderna) (Intramuscular), the reporter did not provide any causality assessments. Laboratory investigation reported, on 08-JUL-2021 patient done Troponin I, White blood cells, C-reactive protein result were not provided. on an unknown date TnI , result reported 2629->3750. There was no treatment medication reported. 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:	

Case ID	WW Identifier	Narrative	MAH Comment
		On 27-Jul-2021: Translated document received on 27-JUL-2021 contains significant information, Laboratory investigation and Anatomical Location, batch number for dose one updated. On 27-Jul-2021: Follow-up received on 27-JUL-2021 Contain No new information.	
4.1(b)		This case was received via 4.1(b) (Reference number: 4.1(b) on 27-Jul-2021 and was forwarded to Moderna on 27-Jul-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCARDITIS (Myocarditis) in a 21-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. Concurrent medical conditions included Asthma (mild and well controlled). On 07-Jul-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 09-Jul-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Myocarditis) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 09-Jul-2021, Cardiac imaging procedure: abnormal (abnormal) abnormal. On 09-Jul-2021, Troponin: increased (High) Increased. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter	This is a 21 years old male with history of mild and well control asthma and not other information provided who 2 days after receiving the 2nd dose of the vaccine patient was diagnosed with myocarditis. According to the CDC definition this case is probable; according to the Brigton collaboration is a Level 4 case, and according to the WHO causality assessment, this case is considered conditional. In the analysis of this case report, the main concern here is the lack of information on the patient's full medical history and concomitant medications history. There is also important information missing regarding other laboratory tests conducted, treatment, medical course, etc.

Case ID	WW Identifier	Narrative	MAH Comment
		did not provide any causality assessments. Concomitant product use was not provided by the reporter. On 09Jul2021, an Angiocardiogram and Echocardiogram were performed (results not provided). Reportedly, myocarditis with troponin elevation was verified on cardiac MRI. Treatment information was not provided.	
4.1(b)		This case was received via 4.1(b) (Reference number: 4.1(b) on 27-Jul-2021 and was forwarded to Moderna on 27-Jul-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of PERICARDITIS (Pericarditis), ARRHYTHMIA (Arrhythmia), ATRIAL FIBRILLATION (Atrial fibrillation), CARDIAC FLUTTER (Cardiac flutter), CHEST PAIN (Chest pain) and DIZZINESS (Dizziness) in a 51-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The patient's past medical history included Cardiac pacemaker insertion on 02-May-2021. Concomitant products included ATORVASTATIN CALCIUM (LIPITOR) for an unknown indication. On 27-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 PERICARDITIS (Pericarditis) (seriousness criteria hospitalization and medically significant). 02-May-2021, the patient experienced ARRHYTHMIA	This is a 51 years old male with very limited information provided who 5 days after receiving the 2nd dose of the vaccine patient experienced arrhythmia, atrial fibrillation, cardiac flutter, chest pain and dizziness and was diagnosed with pericarditis. According to the CDC definition this case is not assessable; according to the Brigton collaboration is a Level 4 case, and according to the WHO causality assessment, this case is considered conditional. In the analysis of this case report, the main concern here is the lack of information on the patient's full medical history and concomitant medications history. There is also important information missing regarding other laboratory tests conducted, treatment, medical course, etc.

Case ID	WW Identifier	Narrative	MAH Comment
		(Arrhythmia) (seriousness criteria hospitalization and medically significant), ATRIAL FIBRILLATION (Atrial fibrillation) (seriousness criteria hospitalization and medically significant), CARDIAC FLUTTER (Cardiac flutter) (seriousness criteria hospitalization and medically significant), CHEST PAIN (Chest pain) (seriousness criterion hospitalization) and DIZZINESS (Dizziness) (seriousness criterion hospitalization). At the time of the report, PERICARDITIS (Pericarditis), ARRHYTHMIA (Arrhythmia), ATRIAL FIBRILLATION (Atrial fibrillation), CARDIAC FLUTTER (Cardiac flutter), CHEST PAIN (Chest pain) and DIZZINESS (Dizziness) had not resolved. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Treatment done while patient was hospitalized were not reported. Patient stated that various lab tests were ran and the results are unknown	
4.1(b)		This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myocarditis) in a 73-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination. Co-suspect product included non-company product PEMBROLIZUMAB for an unknown indication. The patient's past medical history included Melanoma (4.1(b) 2021) in January 2021. On 26-Mar-2021, the patient started PEMBROLIZUMAB (unknown route) 1 dosage form. On 02-Apr-2021, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form.	This is a 73 years old male with history of melanoma and very limited information provided who 3 days after receiving the 2nd dose of the vaccine patient was diagnosed with myocarditis. According to the CDC definition this case is probable; according to the Brigton collaboration is a Level 4 case, and according to the WHO causality assessment, this case is considered possible. In the analysis of this case report, the main concern here is the lack of information on the patient's full medical history and concomitant medications history. There is also important information missing regarding other laboratory tests conducted, treatment, medical course, etc.

Case ID	WW Identifier	Narrative	MAH Comment
		On 16-Apr-2021, PEMBROLIZUMAB (unknown route) dosage was changed to 1 dosage form. On 30-Apr-2021, received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) dosage was changed to 1 dosage form. On 03-May-2021, after starting mRNA-1273 (COVID-19 Vaccine Moderna), the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Myocarditis) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 07-May-2021, Blood creatine phosphokinase: 4.1(b) (High) 1650 U/L (v.n. <190). On 07-May-2021, Troponin: 4.1(b) (High) 205 ng/mL (v.n. < 14 ng/mL). For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered MYOCARDITIS (Myocarditis) to be possibly related. No concomitant medications were provided by the reporter. No treatment information was provided by the reporter.	
4.1(b)		This case was initially received via 4.1(b) (Reference number: 4.1(b)) on 01-Nov-2021. The most recent information was received on 02-Nov-2021 and was forwarded to Moderna on 02-Nov-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of CHEST PAIN (Chest Pain), DYSPNOEA (Dyspnoea) and MYOCARDITIS (Myocarditis) in a 29-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for COVID-19 vaccination.	29 years old male with unknown medical history who 4 days after the 2nd dose experienced chest pain and dyspnoea and was found to have elevated troponin, abnormal EGC, abnormal Echo and was diagnosed with myocarditis. Pending cMRI results. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the

Case ID	WW Identifier	Narrative	MAH Comment
		No Medical History information was reported. On 05-Oct-2021, the patient received second dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 09-Oct-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). On an unknown date, the patient experienced CHEST PAIN (Chest Pain) (seriousness criterion hospitalization) and DYSPNOEA (Dyspnoea) (seriousness criterion hospitalization). At the time of the report, CHEST PAIN (Chest Pain) and DYSPNOEA (Dyspnoea) outcome was unknown and MYOCARDITIS (Myocarditis) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 09-Oct-2021, Electrocardiogram: abnormal (abnormal) ST elevation inferior leads.. On 09-Oct-2021, Troponin: 686 ng/l (High) Troponin- 686 ng/l. On an unknown date, SARS-CoV-2 test: negative (Negative) Negative. On an unknown date, Troponin: 689 (High) 689 and 383 (High) 383. For mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. The patient's relevant investigations or tests conducted included blood tests, echo cardiogram done on 10-Oct-2021, result ST elevation inferior lead, Troponin was measured on 10-Oct-2021, were high with peak value 686ng/L(normal range-normal less than 15 for males) troponin serial values were 686/689/ 383. The patient was admitted to hospital 09-Oct-2021 with chest pain, diagnosed myocarditis, awaited outpatient MRI.	elevated troponin and ECG results; a causal relationship cannot be excluded due to the lack of other information.

Case ID	WW Identifier	Narrative	MAH Comment
		He was admitted to hospital on 09-Oct-2021 with chest pain for 3 days. Treatment information included NSAID's. Company comment: This is a regulatory case concerns a 29-year old, male subject with no relevant medical history, who experienced the serious expected event of Myocarditis(AESI) and the serious unexpected events of Chest pain and Dyspnoea. The event Myocarditis occurred 4 days after the second dose of Moderna COVID-19 vaccine while events Chest pain and Dyspnoea occurred unknown number of days after the second dose of Moderna COVID-19 vaccine. Rechallenge is not applicable (no more doses are expected) relevant lab data: troponin values: 686 ng/ml (9 Oct) and 689, 383 (unk dates). The benefit-risk relationship of Moderna COVID-19 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 02-Nov-2021: Lab data added. Action taken updated as not applicable.	
4.1(b)		This case was received via European Medicines Agency (Reference number: 4.1(b)) on 02-Nov-2021 and was forwarded to Moderna on 02-Nov-2021. This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (suspected myocarditis) in a 33-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 214008) for Prophylactic vaccination. No Medical History information was reported. On 13-Aug-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 14-Aug-2021, the patient experienced MYOCARDITIS	33 years old female with unknown medical history who next days after the 2nd dose was diagnosed with myocarditis. Test results were not provided. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events; a causal relationship cannot be excluded due to the lack of other information.

Case ID	WW Identifier	Narrative	MAH Comment
		(suspected myocarditis) (seriousness criteria hospitalization, medically significant and life threatening). At the time of the report, MYOCARDITIS (suspected myocarditis) had not resolved. Concomitant medications were not reported . Treatment information was not provided. The patient had the 1st dose of Spikevax on 02/07/2021 (3003609). Laboratory data include ECG, laboratory, transthoracic echocardiography, cardiac catheter DD excluded: STEMI. Company Comment: This case concerns a 33-year-old, female patient with no relevant medical history, who experienced the expected AESI of myocarditis. The event, which was life-threatening and resulted in hospitalization, occurred 1 day after administration of the second dose of the Moderna COVID-19 Vaccine. The rechallenge was not applicable as no additional dosing will be given. The benefit-risk relationship of the Moderna COVID-19 Vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 02-Nov-2021: Translation document received on 04-Nov-2021. Reaction/event as reported by primary source is updated. Sender's comments are updated.	
4.1(b)		This case was received via 4.1(b) (Reference number: 4.1(b) on 02-Nov-2021 and was forwarded to Moderna on 02-Nov-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of PERICARDITIS (Pericarditis) in a 20-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 019F21A) for COVID-19 vaccination. The occurrence of	20 years old female with medical history of aspergillosis (unknown TTO) hypertension, and SLE, who next day after the 2nd dose experienced chest pain, pleuritic pain, and was found to have abnormal MRI of the heart, and was diagnosed with pericarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. This report is confounded by the

Case ID	WW Identifier	Narrative	MAH Comment
		additional non-serious events is detailed below. The patient's past medical history included Aspergillosis. Concurrent medical conditions included Allergy to antibiotic (Red cell antibody allergy), Hypertension and Lupus nephritis. Concomitant products included LISINOPRIL for Product used for unknown indication, MYCOPHENOLATE MOFETIL (CELLCEPT [MYCOPHENOLATE MOFETIL]), HYDROXYCHLOROQUINE PHOSPHATE (PLAQUENIL [HYDROXYCHLOROQUINE PHOSPHATE]), AMLODIPINE, CARVEDILOL, HYDRALAZINE and ISAVUCONAZONIUM SULFATE (CRESEMBA) for an unknown indication. On 30-Sep-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 01-Oct-2021, the patient experienced PERICARDITIS (Pericarditis) (seriousness criterion medically significant), CHEST PAIN (Chest pain) and PLEURITIC PAIN (Pleuritic pain). At the time of the report, PERICARDITIS (Pericarditis), CHEST PAIN (Chest pain) and PLEURITIC PAIN (Pleuritic pain) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 15-Oct-2021, Magnetic resonance imaging heart: abnormal (abnormal) There was circumferential late gadolinium enhancement of the pericardium consistent with active inflammation (pericarditis). For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments.	associated risk factor of this patient including her medical history of SLE, given that pericarditis is the most common heart problem associated with active lupus an doccurs in about 25% of people with SLE. Hypertension in such a young person is also a very important risk factor, as well as her history of aspergillosis for which there is no information related to when this comorbidity occurred. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the MRI results; a causal relationship cannot be excluded.

Case ID	WW Identifier	Narrative	MAH Comment
		The patient had symptoms of pericarditis with pleuritic chest pain and chest pain when lying flat occurring a couple days after administration of covid-19 vaccine. Patient was undergoing treatment for pericarditis. Company Comment : This case concerns a 20-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) with relevant medical history of HTN and Lupus nephritis who experienced the serious expected event of pericarditis one day after the second dose of the vaccine. Medical history of HTN and lupus nephritis are confounding factors. Rechallenge is not applicable, since no further dosing is expected. The benefit-risk relationship is not affected by this report	
4.1(b)		This case was received via an unknown source (no reference has been entered for a health authority or license partner) on 03-Nov-2021 and was forwarded to Moderna on 03-Nov-2021. This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myocarditis) in an 18-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for SARS-CoV-2 immunisation. No Medical History information was reported. In 2021, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form. On 21-Oct-2021, received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) dosage was changed to 1 dosage form. On 24-Oct-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report,	18 years old male with unknown medical history who 3 days after the 2nd dose experienced chest pain, radiating to his left shoulder and back, and was found to have elevated CRP, troponin, abnormal Echo, and EKG, and SARS-CoV-2 test negative. He was diagnosed with myopericarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including results B19, CMV, etc, that were nopt provided. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and EKG, and Echo results; a causal relationship cannot be excluded due to the missing information.

Case ID	WW Identifier	Narrative	MAH Comment
		MYOCARDITIS (Myocarditis) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 24-Oct-2021, Blood creatine phosphokinase (47-222): 374 (High) 374. On 24-Oct-2021, C-reactive protein (0-10): 13 (High) mg/L. On 24-Oct-2021, Electrocardiogram: abnormal (abnormal) ST ascendant v3-v4-v5. On 24-Oct-2021, Troponin (Unknown-90 nanogram per litre): 494 nanogram per litre High. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered MYOCARDITIS (Myocarditis) to be possibly related. No concomitant medications were provided. On 24 Oct 2021, he went to the Emergency Room for sudden-onset left-sided chest pain, that woke him up, reproducible on palpation and radiating into the left shoulder plus back, assessed at 7/10. An electrocardiogram showed ST elevation in v3-v4-v5. The laboratory tests show CRP of 13 mg/L, CK at a max of 374 U/L and still increasing troponins, currently at 494 ng/L. Transthoracic echocardiography shows a preserved left ventricular ejection fraction, with a mild pericardial effusion over the right ventricle. The Covid swab result is negative. The diagnosis of myocarditis was retained, and the patient was hospitalized for heart-rate monitoring with analgesic treatment with paracetamol + tramadol. In terms of etiological investigation, HIV, HCV, B19, CMV, EBV and HHV6 serological tests still need to be performed, and a cardiac MRI is pending. Company Comment : This case concerns an 18-year-old male patient	

Case ID	WW Identifier	Narrative	MAH Comment
		with no medical history, who experienced the serious expected (AESI) of Myocarditis. The event occurred three days after the second dose of Moderna COVID-19 vaccine. Lab data of high blood creatine phosphokinase, high C-reactive protein, high troponin and an abnormal Electrocardiogram all support the diagnosis. The rechallenge was not applicable, as the event occurred after the second dose. The benefit-risk relationship of Moderna COVID-19 vaccine is not affected by this report. Event seriousness assessed as per Regulatory Authority reporting and retained for consistency with the RA report. Most recent FOLLOW-UP information incorporated above includes: On 03-Nov-2021: Translation received on 5-Nov-2021.Case narrative were translated treatment drugs were added. No new information	
4.1(b)		This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Suspected myopericarditis), CHEST PAIN (Progressive-onset stabbing retrosternal pain radiating into the back), MYALGIA (Myalgia) and FEELING OF BODY TEMPERATURE CHANGE (Sensation of warmth/cold) in a 29-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for SARS-CoV-2 immunization. The patient's past medical history included 4.1(b) abuse, episodic use on 21-Oct-2021. Concurrent medical conditions included Alcohol abuse, unspecified drinking behavior and Smoker (15 UPA). In 2021, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form.	29 years old male with unknown medical history and concomitant use of 4.1(b) alcohol abuse and smoker who 2 days after the 2nd dose experienced chest pain, fever, and myalgias, and was found to have elevated troponin, CK, abnormal EKG and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted including SARS-CoV. The use of 4.1(b) and alcohol abuse are important conmfounders in this report. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and ECG results; a causal relationship cannot be excluded due to the lack of some information.

Case ID	WW Identifier	Narrative	MAH Comment
		On 23-Oct-2021, received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) dosage was changed to 1 dosage form.T60. At the time of the report, MYOCARDITIS (Suspected myopericarditis) and CHEST PAIN (Progressive-onset stabbing retrosternal pain radiating into the back) had not resolved and MYALGIA (Myalgia) and FEELING OF BODY TEMPERATURE CHANGE (Sensation of warmth/cold) had resolved. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered MYALGIA (Myalgia) and FEELING OF BODY TEMPERATURE CHANGE (Sensation of warmth/cold) to be probably related and MYOCARDITIS (Suspected myopericarditis) and CHEST PAIN (Progressive-onset stabbing retrosternal pain radiating into the back) to be possibly related. An electrocardiogram of patient showed depression of the PR segment in II, III and V3-V6, and a submillimeter ST segment depression in the same leads. The laboratory workup of patient on 26-OCT-2021 showed troponins of up to 298 ng/l, creatinine kinases of up to 290 U/l and an inflammatory syndrome with no leukocytosis. A cardiac ultrasound and cardiac magnetic resonance imaging tests were pending. Concomitant medication and treatment medication were not reported. Patient was in usual good health, Habits of patient included High-risk alcohol consumption and Active smoking habit at 15 pack-years occasional 4.1(b) consumption. Patient had received 2 injections of the Spikevax. The second injection was administered on 23-OCT-2021, after which the patient was presented with myalgia and a sensation of	

Case ID	WW Identifier	Narrative	MAH Comment
		warmth/cold which spontaneously resolved in 24 hours. During the evening of 25-OCT-2021, patient presented at the Emergency Department with progressive-onset stabbing retrosternal pain radiating into the back. The patient was currently in hospital within a context of suspected myo-pericarditis for cardiac rhythm monitoring. This case concerns a 29 year-old male patient with a history of alcohol and 4.1(b) abuse and tobacco smoker who experienced the unexpected serious events of myocarditis, an AESI, myalgia, and chest pain. The event of myalgia and sensation of warmth and cold occurred during the first day after the second dose of Moderna COVID-19 Vaccine. The event myocarditis occurred approximately 2 days after the second dose of Moderna COVID-19 Vaccine. The date of the first dose of the vaccine was not provided. The rechallenge was not applicable as no additional dosing will be administered. The medical history of alcohol and 4.1(b) abuse and tobacco smoking remain confounders for myocarditis and chest pain. The benefit-risk relationship of Moderna COVID-19 Vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 03-Nov-2021: Translation document received on 05-NOV-2021 contains: Dosage text updated, event verbatim updated and senders comments which contains lab details and event information added in narrative.	
4.1(b)		This case was initially received via 4.1(b) (Reference number: 4.1(b)) on 02-Nov-2021. The most recent information was received on 10-Nov-2021 and was forwarded to Moderna on 10-Nov-2021. This regulatory authority case was reported by an other health care professional and describes the	30 years old female with medical history of migraines and previously receving Cominarty who 4 days after the 3rd dose of Spikevax experienced chest pain, tachycardia, palpitations, dyspnoea, fatigue, and pain and was found to have elevated troponin, and abnormal EGC, and was diagnosed with myocarditis. No other information was provided. Important information

Case ID	WW Identifier	Narrative	MAH Comment
		occurrence of MYOCARDITIS (Myocarditis), TACHYCARDIA (Tachycardia), PALPITATIONS (Palpitations), DYSPNOEA (Dyspnoea), CHEST PAIN (Chest Pain), PAIN (Pain) and FATIGUE (Fatigue) in a 30-year-old female patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) (batch no. 3004674) for COVID-19 vaccination. Concurrent medical conditions included Migraine. Concomitant products included AMITRIPTYLINE for Migraine, TOZINAMERAN (COVID-19 MRNA VACCINE BNT162B2) for an unknown indication. On 28-Oct-2021, the patient received third dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 01-Nov-2021, after starting mRNA-1273 (Moderna CoviD-19 Vaccine), the patient experienced MYOCARDITIS (Myocarditis) (seriousness criterion medically significant). On an unknown date, the patient experienced TACHYCARDIA (Tachycardia) (seriousness criterion medically significant), PALPITATIONS (Palpitations) (seriousness criterion medically significant), DYSPNOEA (Dyspnoea) (seriousness criterion medically significant), CHEST PAIN (Chest Pain) (seriousness criterion medically significant), PAIN (Pain) (seriousness criterion medically significant) and FATIGUE (Fatigue) (seriousness criterion medically significant). At the time of the report, MYOCARDITIS (Myocarditis) had not resolved and TACHYCARDIA (Tachycardia), PALPITATIONS (Palpitations), DYSPNOEA (Dyspnoea), CHEST PAIN (Chest Pain), PAIN (Pain) and FATIGUE (Fatigue) outcome was unknown.	is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and ECG results; a causal relationship cannot be excluded due to the lack of other information.

Case ID	WW Identifier	Narrative	MAH Comment
		DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 01-Nov-2021, Chest X-ray: normal (normal) Normal Clear. On 01-Nov-2021, Electrocardiogram: abnormal (abnormal) Abnormal. The action taken with mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown) was unknown. For mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Lab test included Troponin on 1-Nov-2021 with value 3. Patient has not tested positive for COVID-19 since having the vaccine. Patient is not enrolled in clinical trial. Patient experienced pericarditis.It was reported that 4 days after the vaccination the symptoms occurred. The patient was diagnosed with heart inflammation and she had a abnormal ECG. she reported that she still had pain and she was taking strong anti inflammatory, pain killer. Due to pain she woke up in the sleep. Treatment medications prescribed as anti inflammatories and pain relief. Company Comment: This case concerns a 30-year-old, female with relevant medical history of previous vaccination with COVID-19 mRNA vaccine BIONTECH, who experienced the serious unexpected events of Tachycardia, Palpitations, Chest pain, Dyspnoea and Fatigue and the serious expected (AESI) of Myocarditis. The event Myocarditis occurred approximately 4 days after the 3rd dose of mRNA-1273, the events of Tachycardia, Palpitations, Chest pain, Dyspnoea and Fatigue occurred on an unknown date after the 3rd dose of mRNA-1273. The benefit-risk relationship of mRNA-1273 is not affected by this report.	

Case ID	WW Identifier	Narrative	MAH Comment
		Event seriousness assessed as per Regulatory Authority reporting and retained for consistency with the RA report. Most recent FOLLOW-UP information incorporated above includes: On 04-Nov-2021: Follow up received as lab data results are added. On 10-Nov-2021: Follow up document received contains, medical history were added. Event (chest pain) outcome, action taken and l narrative were updated.	
4.1(b)		This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myopericarditis) in a 35-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination. The patient's past medical history included Viral myocarditis in 2020. Concurrent medical conditions included Smoker (10 pack-years) and Alcohol allergy (Alcohol occasional). On 20-Sep-2021, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form. On 19-Oct-2021, received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) dosage was changed to 1 dosage form. On 22-Oct-2021, after starting mRNA-1273 (COVID-19 Vaccine Moderna), the patient experienced MYOCARDITIS (Myopericarditis) (seriousness criterion hospitalization). At the time of the report, MYOCARDITIS (Myopericarditis) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 24-Oct-2021, Echocardiogram: reduced by 46% (abnormal) Abnormal. On 24-Oct-2021, Electrocardiogram: normal (normal) Normal Test was on 23-OCT-2021.	35 years old male with medical history of viral myocarditis a year before and a smoker who 3 days after the 2nd dose experienced myalgia, arthralgia and self-limiting chills, as well as respiration-dependent retrosternal pain, which worsened with movement. He was hospitalized and found to have elevated troponin, Ck, NT-proBNP, abnormal EGC, abnormal Echo and was diagnosed with myopericarditis. Patient was treated with ASA and lisinooril and was discharged 2 days later. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated laboratory results including troponin and ECG and Echo results; a causal relationship cannot be excluded due to the lack of other information.

Case ID	WW Identifier	Narrative	MAH Comment
		On an unknown date, Electrocardiogram: abnormal (abnormal) Abnormal Test was on 25-OCT-2021. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered MYOCARDITIS (Myopericarditis) to be probably related. No concomitant medication reported. No Treatment Medication reported. Based on Medical Review, the event of inappropriate schedule of vaccine administered is applicable as dose 1 and dose 2 are 20 days apart. A little while after the vaccination, patient presented symptoms of myalgia, arthralgia and self-limiting chills. On 22 Oct 2021 he experienced respiration-dependent retrosternal pain, which worsened when he moved, leading him to consult a physician on 23 Oct 2021. Vital signs on admission showed heart rate (HR) of 85 bpm, blood pressure (BP) of 113/80 mmHg, 100% saturation in ambient air, and a temperature of 35.9°C. The laboratory test done on 24 Oct 2021 showed troponin T at 498 ng/L, CK at 186 U/L (spike at 312 U/L) as well as NT proBNP at 361 ng/L. A search for FAN and myositis DOT came back negative. The pain decreased with acetylsalicylic acid (Aspegic®). Due to the LVEF reduction, treatment with lisinopril was introduced. The patient could go home on 25 Oct 2021. On 24 Oct 2021 Troponin T, Creatine kinase and NT-proBNP were performed with unknown results. Company comment: This case concerns a 35 year-old male patient with a history of viral myocarditis in 2020, tobacco smoking, overweight and allergy to alcohol who experienced the unexpected event of myocarditis. The event occurred	

Case ID	WW Identifier	Narrative	MAH Comment
		approximately 3 days after the second dose of Moderna COVID-19 Vaccine. The rechallenge was not applicable as no additional dosing will be administered. The medical history of viral myocarditis in 2020, and tobacco smoking remain confounders. The benefit-risk relationship of Moderna COVID-19 Vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 04-Nov-2021: Translation document received on 05 Nov 2021 contains Translated text for relevant Medical history, Test results, Case Narrative updated and Events verbatim updated.	
4.1(b) [redacted]		This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 05-Nov-2021 and was forwarded to Moderna on 05-Nov-2021. This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Perimyocarditis) in a 15-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. No Medical History information was reported. On 27-Aug-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 29-Aug-2021, after starting mRNA-1273 (Spikevax), the patient experienced MYOCARDITIS (Perimyocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Perimyocarditis) had resolved. For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered MYOCARDITIS (Perimyocarditis) to be probably related.	15 years old male with unknown medical history who 2 days after the 2nd dose was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events. A causal relationship cannot be excluded due to the lack of any information.

Case ID	WW Identifier	Narrative	MAH Comment
		The concomitant medication was not reported. The Treatment history was not reported. Company Comment: This case concerns a 15-year-old, male patient with no relevant medical history, who experienced the expected AESI of myocarditis. The event, which resulted in hospitalization, occurred 2 days after administration of the second dose of the Moderna COVID-19 Vaccine. The rechallenge was not applicable as no additional dosing will be given. The patient's gender remains a confounder. The benefit-risk relationship of the Moderna COVID-19 Vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 05-Nov-2021: Translation received on 07-Nov-2021, which contains dosage text information and event verbatim in English language were updated.	
4.1(b)		This case was received via European Medicines Agency (Reference number: 4.1(b)) on 05-Nov-2021 and was forwarded to Moderna on 05-Nov-2021. This regulatory authority case was reported by a physician and describes the occurrence of PERICARDITIS (Pericarditis) in a 26-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3004671) for Prophylactic vaccination. Previously administered products included for Product used for unknown indication: COVID-19 Vaccine Moderna dispersion for injectionCOVID-19 mRNA Vaccine (nucleoside modified)SpykeVax on 21-Jul-2021. Past adverse reactions to the above products included No adverse event with COVID-19 Vaccine Moderna dispersion for injectionCOVID-19	26 years old male with unknown medical history who 14 days after the 2nd dose was diagnosed with pericarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events. A causal relationship cannot be excluded due to the lack of any information.

Case ID	WW Identifier	Narrative	MAH Comment
		mRNA Vaccine (nucleoside modified)SpykeVax. On 25-Aug-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 08-Sep-2021, after starting mRNA-1273 (Spikevax), the patient experienced PERICARDITIS (Pericarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, PERICARDITIS (Pericarditis) had not resolved. For mRNA-1273 (Spikevax) (Unknown), the reporter considered PERICARDITIS (Pericarditis) to be possibly related. No concomitant medications were provided. No treatment medications were provided. Company comment: This case concerns a 26-year-old, male patient with no relevant medical history, who experienced the expected AESI of pericarditis. The event, which resulted in hospitalization, occurred 2 weeks after administration of the second dose of the Moderna COVID-19 Vaccine. The rechallenge was not applicable as no additional dosing will be given. The patient's gender remains a confounder. The benefit-risk relationship of the Moderna COVID-19 Vaccine is not affected by this report.	
4.1(b)		This case was received via European Medicines Agency (Reference number: 4.1(b)) on 05-Nov-2021 and was forwarded to Moderna on 05-Nov-2021. This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDITIS (Perimyocarditis) in a 19-year-old male patient who received mRNA-1273 (Spikevax)	19 years old male with medical history of PTSD and concomitant use of quetiapine (myocarditis is in the PI as an ADR in post-marketing) who 3 days after the 2nd dose experienced thoracic pressure, and was found to have elevated troponin, Ck, proBNP, D-dimer, abnormal Echo, and was diagnosed with myopericarditis. No other information was provided. Important information is missing in the report including patient's full

Case ID	WW Identifier	Narrative	MAH Comment
		(batch no. 3004671) for Prophylactic vaccination. No Medical History information was reported. On 08-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 11-Sep-2021, the patient experienced MYOCARDITIS (Perimyocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, MYOCARDITIS (Perimyocarditis) had resolved. Patient had medical history of posttraumatic stress disorder and drug allergy of quetiapine 25 mg. Gastrointestinal infection several weeks ago has been reported. Labs reported as Trop 3,000 pg/mL, proBNP 637 ng/L, D-dimer 0.333 mg/L. Cardiovascular: 12- lead ECG, echocardiograph initially showed normal pumping function with echo-rich pericardium. Ultrasound cardiograph showed mildly impaired pump function with global hypokinesis. Chemistry tests showed a significantly decreasing trend of cardiac integrity markers. On 13-Sep-2021 echocardiography showed non-hypertrophic LV with mildly impaired systolic LV pump function (EF: 47% biplane, acc. to Simpson) with global hypokinesis. Right atrium: narrow. Mitral valve: morphologically and functionally unremarkable. Aortic valve: aortic valve morphologically and functionally unremarkable. Tricuspid valve: VCI collapses completely. Ascending aorta but the examination had to be discontinued due to claustrophobia of the patient. Patient was hospitalized from 11-Sep-2021 to 14-Sep-2021, due to thoracic pressure since yesterday evening. Patient was diagnosed with peri myocarditis with ST elevations in I, II, III, aVF, V2-V6. Treatment medication was mentioned as intensive monitoring Infusion ASA	medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and ECG and Echo results; a causal relationship cannot be excluded due to the missing information and the other confounders.

Case ID	WW Identifier	Narrative	MAH Comment
		300 mg IV , Heparin 5,000 I.U., 600 mg ibuprofen. Taking quetiapine DD with status post viral infection; ibuprofen therapy was initiated. This case concerns a 19 year-old male patient with a history of post-traumatic stress disorder on quetiapine who experienced the expected, serious adverse event of special interest of myocarditis. The event occurred approximately 4 after the second dose of mRNA-1273. The rechallenge was not applicable as no additional dosing will be administered. The use of concomitant medication quetiapine remains a confounder. The benefit-risk relationship of mRNA-1273 is not affected by this report. The case's Regulatory Authority narrative reports the patient as having received Biontech vaccine and mRNA-1273. Most recent FOLLOW-UP information incorporated above includes: On 05-Nov-2021: Translation received on 7 Nov 2021 and it contains significant information of patient history, lab data and treatment medication along with hospitalization start date and stop date.	
4.1(b)		This case was received via European Medicines Agency (Reference number: 4.1(b)) on 05-Nov-2021 and was forwarded to Moderna on 05-Nov-2021. This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myocarditis) in an 18-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. No Medical History information was reported. On 07-Sep-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 05-Oct-2021, received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. On 07-	18 years old male with unknown medical history who 2 days after the 2nd dose was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events. A causal relationship cannot be excluded due to the lack of information.

Case ID	WW Identifier	Narrative	MAH Comment
		Oct-2021, after starting mRNA-1273 (Spikevax), the patient experienced MYOCARDITIS (Myocarditis) (seriousness criterion medically significant). At the time of the report, MYOCARDITIS (Myocarditis) had not resolved. For mRNA-1273 (Spikevax) (Unknown), the reporter considered MYOCARDITIS (Myocarditis) to be possibly related. Concomitant product use was not provided by the reporter. Treatment information was not provided. Company Comment: This case concerns an 18-year-old, male patient with no relevant medical history, who experienced the expected AESI of myocarditis. The event occurred 2 days after administration of the second dose of the Moderna COVID-19 Vaccine. The rechallenge was not applicable as no additional dosing will be given. The patient's gender remains a confounder. The benefit-risk relationship of the Moderna COVID-19 Vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 05-Nov-2021: Translation received on 08-Nov-2021, contains no new information. On 08-Nov-2021: Secondary reporter details were added. On 24-Nov-2021: non-significant follow up appended	
4.1(b)		This case was received via European Medicines Agency (Reference number: 4.1(b)) on 05-Nov-2021 and was forwarded to Moderna on 05-Nov-2021. This regulatory authority case was reported by a physician and describes the occurrence of PERICARDITIS (SUSPECTED PERICARDITIS) in an 18-year-old	18 years old male with unknown medical history who 16 days after the 2nd dose was diagnosed with pericarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality

Case ID	WW Identifier	Narrative	MAH Comment
		male patient who received mRNA-1273 (Spikevax) (batch nos. 3005242 and 3004218) for COVID-19 vaccination. No Medical History information was reported. On 10-Aug-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 14-Sep-2021, received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. On 30-Sep-2021, after starting mRNA-1273 (Spikevax), the patient experienced PERICARDITIS (SUSPECTED PERICARDITIS) (seriousness criteria hospitalization and medically significant). At the time of the report, PERICARDITIS (SUSPECTED PERICARDITIS) was resolving. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. No concomitant medications were mentioned. No treatment details were reported. This is a regulatory case concerning a 18 year-old male patient with no relevant medical history reported, who experienced the serious expected and AESI event of PERICARDITIS 17 days after receiving the second dose of proper vaccination schedule with mRNA-1273 .The benefit-risk relationship of mRNA-1273 is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 05-Nov-2021: Translation document received on 08-Nov-2021 included suspect product dosage form and event as reported by primary source updated. On 08-Nov-2021: Significant follow-up document were received on 08-	assessment this report is possible based on temporal association between the use of the product and the start of the events. A causal relationship cannot be excluded due to the lack of information.

Case ID	WW Identifier	Narrative	MAH Comment
		Nov-2021, Dose 1 details and batch number for both doses were Updated. On 08-Nov-2021: Translation received on 09-Nov-2021 dosage text updated.	
4.1(b)		This case was received via European Medicines Agency (Reference number: 4.1(b) on 05-Nov-2021 and was forwarded to Moderna on 05-Nov-2021. This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (Myocarditis) in a 22-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3005238.) for COVID-19 vaccination. No Medical History information was reported. On 02-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 05-Sep-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criterion hospitalization). At the time of the report, MYOCARDITIS (Myocarditis) had resolved. For mRNA-1273 (Spikevax) (Unknown), the reporter considered MYOCARDITIS (Myocarditis) to be possibly related. No concomitant medications were reported. No treatment medications were reported. pharmaceutical dosage form-Solution for injection, dispersion. Company Comment : This case concerns a 22-year-old, male patient with no relevant medical history, who experienced the expected AESI of myocarditis. The event, which resulted in hospitalization, occurred 3 days after administration of the second dose of the Moderna COVID-19 Vaccine. The rechallenge was not applicable as no additional dosing will	22 years old male with unknown medical history who 3 days after the 2nd dose was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events. A causal relationship cannot be excluded due to the lack of information.

Case ID	WW Identifier	Narrative	MAH Comment
		be given. The patient's gender remains a confounder. The benefit-risk relationship of the Moderna COVID-19 Vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 05-Nov-2021: Translation doc received on 08-Nov-2021 and narrative were updated	
4.1(b)		This case was received via European Medicines Agency (Reference number: 4.1(b)) on 05-Nov-2021 and was forwarded to Moderna on 05-Nov-2021. This regulatory authority case was reported by a consumer and describes the occurrence of PERICARDITIS (Symptoms of cardiac inflammation), MYOCARDITIS (Symptoms of heart muscle inflammation), MUSCULOSKELETAL PAIN (Pain in the left shoulder blade), DYSPNOEA (Respiratory distress), CHEST PAIN (Sharp pain on the left side around the heart) and HEART RATE INCREASED (High pulse) in a 20-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3005835) for COVID-19 vaccination. No Medical History information was reported. On 01-Oct-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 02-Oct-2021, the patient experienced PERICARDITIS (Symptoms of cardiac inflammation) (seriousness criteria disability and medically significant), MYOCARDITIS (Symptoms of heart muscle inflammation) (seriousness criteria disability and medically significant), MUSCULOSKELETAL PAIN (Pain in the left shoulder blade) (seriousness criterion disability), DYSPNOEA (Respiratory distress) (seriousness criterion disability), CHEST PAIN (Sharp pain on the left side around the heart) (seriousness criterion	20 years old male with unknown medical history who next day after the 2nd dose experienced musculoskeletal pain, dyspnoea, chest pain and heart rate increased, and was diagnosed with myopericarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events. A causal relationship cannot be excluded due to the lack of information.

Case ID	WW Identifier	Narrative	MAH Comment
		disability) and HEART RATE INCREASED (High pulse) (seriousness criterion disability). At the time of the report, PERICARDITIS (Symptoms of cardiac inflammation), MYOCARDITIS (Symptoms of heart muscle inflammation), MUSCULOSKELETAL PAIN (Pain in the left shoulder blade), DYSPNOEA (Respiratory distress), CHEST PAIN (Sharp pain on the left side around the heart) and HEART RATE INCREASED (High pulse) had not resolved. Concomitant medication was not reported. Treatment information was not reported. Company comment: This case concerns a 20 year-old male patient with no reported medical history who experienced the expected serious adverse events of special interest of myocarditis and pericarditis, as well as the unexpected serious events of musculoskeletal pain, dyspnea and increased heart rate. The events occurred approximately 2 days after the second dose of mRNA-1273. The rechallenge was not applicable as no additional dosing will be administered. The benefit-risk relationship of mRNA-1273 is not affected by this report. Event seriousness assessed as per Regulatory Authority reporting, however there was no information in the source document supporting that the events resulted in a persistent or permanent incapacity. Most recent FOLLOW-UP information incorporated above includes: On 05-Nov-2021: Translation received on 08-Nov-2021, which contains updated event verbatim.	
4.1(b) [redacted]		This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 05-Nov-2021 and was forwarded to Moderna on 05-Nov-2021.	40 years old male unknown medical history previously vaccinated with Cominarty who 34 days after the 2nd dose of Spikevax was diagnosed with pericarditis. Patient had an abnormal Echo. No other information was

Case ID	WW Identifier	Narrative	MAH Comment
		This regulatory authority case was reported by a physician and describes the occurrence of PERICARDITIS (Pericarditis) in a 40-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3004498) for Vaccination. The occurrence of additional non-serious events is detailed below. Previously administered products included for Vaccination: COMIRNATY. Past adverse reactions to the above products included No adverse event with COMIRNATY. On 10-Sep-2021 at 12:00 PM, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 10-Sep-2021, the patient experienced COVID-19 IMMUNISATION (REVACCINATION WITH DIFFERENT COVID-19 VACCINE). On 15-Oct-2021, the patient experienced PERICARDITIS (Pericarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, PERICARDITIS (Pericarditis) outcome was unknown and COVID-19 IMMUNISATION (REVACCINATION WITH DIFFERENT COVID-19 VACCINE) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 15-Oct-2021, Echocardiogram: abnormal (abnormal) Pericarditis. For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered PERICARDITIS (Pericarditis) and COVID-19 IMMUNISATION (REVACCINATION WITH DIFFERENT COVID-19 VACCINE) to be possibly related. Concomitant product was not provided by the reporter	provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events. A causal relationship cannot be excluded due to the lack of information.

Case ID	WW Identifier	Narrative	MAH Comment
		Treatment product was not provided by the reporter. Company comment: This case concerns a 40 year-old male patient with a history of vaccination with a different COVID-19 vaccine tozinameran who experienced the expected serious adverse events of special interest of pericarditis. The event occurred approximately 1 month, 6 days after vaccination with mRNA-1273 vaccine. The rechallenge was unknown as only one dose of mRNA-1273 was administered. The medical history of vaccination with COVID-19 vaccine tozinameran remain a confounder for pericarditis. The benefit-risk relationship of mRNA-1273 is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 05-Nov-2021: Translation received on 08 Nov 2021 with verbatim was translated and senders comment updated	
4.1(b) [redacted]		This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 08-Nov-2021 and was forwarded to Moderna on 08-Nov-2021. This regulatory authority case was reported by a physician in a 27-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3004498) for Vaccination. The patient's past medical history included Overweight. On 10-Sep-2021 at 12:00 PM, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 13-Sep-2021, the patient experienced HEAD DISCOMFORT (Decreased general condition, asthenia, strange sensation in the body, reduced appetite, unwell after physical activity. Palpitations/sensation of pressure in the chest) (seriousness criterion hospitalization), DIZZINESS (Decreased general condition,	27 years old male with medical history of overweight who 3 days after the 2nd dose experienced general symptoms including malaise, asthenia, dizzines, palpitations, etc. Patient was evaluated but blood test (no other information provided) were all normal. 30 days later the patient experienced palpitations, cold sweat, and chest pain and after evaluation was found to have elevated troponin but all other tests were normal, including EKG and Echo. Patient was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's full medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events. A causal relationship cannot be excluded due to the lack of information.

Case ID	WW Identifier	Narrative	MAH Comment
		asthenia, strange sensation in the body, reduced appetite, unwell after physical activity. Palpitations/sensation of pressure in the chest) (seriousness criterion hospitalization), GENERAL PHYSICAL HEALTH DETERIORATION (Decreased general condition, asthenia, strange sensation in the body, reduced appetite, unwell after physical activity. Palpitations/sensation of pressure in the chest) (seriousness criterion hospitalization), MALAISE (Decreased general condition, asthenia, strange sensation in the body, reduced appetite, unwell after physical activity. Palpitations/sensation of pressure in the chest) (seriousness criterion hospitalization), DISCOMFORT (Decreased general condition, asthenia, strange sensation in the body, reduced appetite, unwell after physical activity. Palpitations/sensation of pressure in the chest) (seriousness criterion hospitalization), DECREASED APPETITE (Decreased general condition, asthenia, strange sensation in the body, reduced appetite, unwell after physical activity. Palpitations/sensation of pressure in the chest) (seriousness criterion hospitalization), ASTHENIA (Decreased general condition, asthenia, strange sensation in the body, reduced appetite, unwell after physical activity. Palpitations/sensation of pressure in the chest) (seriousness criterion hospitalization), DYSPNOEA (Decreased general condition, asthenia, strange sensation in the body, reduced appetite, unwell after physical activity. Palpitations/sensation of pressure in the chest) (seriousness criterion hospitalization), MUSCULOSKELETAL STIFFNESS (Decreased general condition, asthenia, strange sensation in the body, reduced appetite, unwell after physical activity. Palpitations/sensation of pressure in	

Case ID	WW Identifier	Narrative	MAH Comment
		the chest) (seriousness criterion hospitalization) and MYOCARDITIS (Decreased general condition, asthenia, strange sensation in the body, reduced appetite, unwell after physical activity. Palpitations/sensation of pressure in the chest) (seriousness criteria hospitalization and medically significant). On 12-Oct-2021, the patient experienced PALPITATIONS (Decreased general condition, asthenia, strange sensation in the body, reduced appetite, unwell after physical activity. Palpitations/sensation of pressure in the chest) (seriousness criterion hospitalization), CHEST DISCOMFORT (Decreased general condition, asthenia, strange sensation in the body, reduced appetite, unwell after physical activity. Palpitations/sensation of pressure in the chest) (seriousness criterion hospitalization), COLD SWEAT (Decreased general condition, asthenia, strange sensation in the body, reduced appetite, unwell after physical activity. Palpitations/sensation of pressure in the chest) (seriousness criterion hospitalization) and CHEST PAIN (Decreased general condition, asthenia, strange sensation in the body, reduced appetite, unwell after physical activity. Palpitations/sensation of pressure in the chest) (seriousness criterion hospitalization). At the time of the report, HEAD DISCOMFORT (Decreased general condition, asthenia, strange sensation in the body, reduced appetite, unwell after physical activity. Palpitations/sensation of pressure in the chest), PALPITATIONS (Decreased general condition, asthenia, strange sensation in the body, reduced appetite, unwell after physical activity. Palpitations/sensation of pressure in the chest), DIZZINESS (Decreased general condition, asthenia, strange sensation in the body, reduced appetite, unwell after physical activity.	

Case ID	WW Identifier	Narrative	MAH Comment
		Palpitations/sensation of pressure in the chest), CHEST DISCOMFORT (Decreased general condition, asthenia, strange sensation in the body, reduced appetite, unwell after physical activity. Palpitations/sensation of pressure in the chest), GENERAL PHYSICAL HEALTH DETERIORATION (Decreased general condition, asthenia, strange sensation in the body, reduced appetite, unwell after physical activity. Palpitations/sensation of pressure in the chest), MALAISE (Decreased general condition, asthenia, strange sensation in the body, reduced appetite, unwell after physical activity. Palpitations/sensation of pressure in the chest), DISCOMFORT (Decreased general condition, asthenia, strange sensation in the body, reduced appetite, unwell after physical activity. Palpitations/sensation of pressure in the chest), DECREASED APPETITE (Decreased general condition, asthenia, strange sensation in the body, reduced appetite, unwell after physical activity. Palpitations/sensation of pressure in the chest), COLD SWEAT (Decreased general condition, asthenia, strange sensation in the body, reduced appetite, unwell after physical activity. Palpitations/sensation of pressure in the chest), ASTHENIA (Decreased general condition, asthenia, strange sensation in the body, reduced appetite, unwell after physical activity. Palpitations/sensation of pressure in the chest), DYSPNOEA (Decreased general condition, asthenia, strange sensation in the body, reduced appetite, unwell after physical activity. Palpitations/sensation of pressure in the chest), MUSCULOSKELETAL STIFFNESS (Decreased general condition, asthenia, strange sensation in the body, reduced appetite, unwell after physical activity. Palpitations/sensation of pressure in the chest), CHEST PAIN (Decreased general condition, asthenia, strange	

Case ID	WW Identifier	Narrative	MAH Comment
		sensation in the body, reduced appetite, unwell after physical activity. Palpitations/sensation of pressure in the chest) and MYOCARDITIS (Decreased general condition, asthenia, strange sensation in the body, reduced appetite, unwell after physical activity. Palpitations/sensation of pressure in the chest) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 13-Sep-2021, Blood test: normal (normal) Normal findings. On 13-Oct-2021, Chest X-ray: normal (normal) No focal densities, no signs of congestion or pleural effusion. Slim mediastinum and normal-sized heart. Normal skeletal parts. X-ray was compared to X-ray from 21-Sep-2014.. On 13-Oct-2021, Investigation: inconclusive (Inconclusive) Blood pressure 153/79 mmHg, pulse rate 84 bpm, respiratory frequence 14, oxygen saturation 100% Collum: No jugular vein congestion. No stenosis sounds over the carotids. Can place the chin on the chest. Thorax: Normal configuration and movement. Coronary: Regular action, no heart murmur, no heart rate deficit. Pulmonary: Vesicular respiratory sound, no foreign sounds. Upper extremities: A little tremor bilaterally, had since vaccination. Lower extremities: Equal and warm, good pulse in ADP and ATP. No edema. Electrocardiography: sinus rythm, frequence 78 Lab: PS-Creatinine 105; Pt-GFR, estimated 83; PS-Sodium 140; P-Potassium 3.7; B-Hemoglobin 14.9; B-Platelets 291; B-Leukocytes 6.2; P-Troponin T 30- 27- 26- 12; B-Glucose 4.9; PS-CRP 1- 0. On 15-Oct-2021, Computerised tomogram coronary artery: normal (normal) No findings of coronary stenosis.. In October 2021, Echocardiogram: normal (normal) Normal findings. In October 2021, Troponin: 30-27-26-12 (normal) 30-27-26-12 ng/L..	

Case ID	WW Identifier	Narrative	MAH Comment
		For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered HEAD DISCOMFORT (Decreased general condition, asthenia, strange sensation in the body, reduced appetite, unwell after physical activity. Palpitations/sensation of pressure in the chest), PALPITATIONS (Decreased general condition, asthenia, strange sensation in the body, reduced appetite,	
4.1(b)		This case was received via European Medicines Agency (Reference number: 4.1(b) on 08-Nov-2021 and was forwarded to Moderna on 08-Nov-2021. This regulatory authority case was reported by a physician and describes the occurrence of PERICARDITIS (Pericarditis) in a 25-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 3003604) for Vaccination. No medical history was reported. Previously administered products included for Vaccination: Spikevax. Past adverse reactions to the above products included No adverse event with Spikevax. On 26-Aug-2021 at 2:00 PM, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 28-Aug-2021, the patient experienced PERICARDITIS (Pericarditis) (seriousness criterion hospitalization). At the time of the report, PERICARDITIS (Pericarditis) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 14-Oct-2021, Computerised tomogram thorax: normal (normal) No pulmonary embolism.	25 years old female with unknown medical history who 2 days after the 2nd dose was diagnosed with pericarditis. CAT of thorax was normal, Echo showed pericardial fluid and fibrin d-dimer was negative. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events as well as the Echo test results. A causal relationship cannot be excluded due to the lack of information.

Case ID	WW Identifier	Narrative	MAH Comment
		On 14-Oct-2021, Echocardiogram: pericarditis (abnormal) Pericarditis, Pericardial fluid. On 14-Oct-2021, Fibrin D dimer: negative (Negative) Negative. For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered PERICARDITIS (Pericarditis) to be possibly related. No concomitant medication was reported. No treatment medication use was reported. Company Comment: This case concerns a 25-year-old, female patient with no relevant medical history, who experienced the expected AESI of pericarditis. The event, which resulted in hospitalization, occurred 2 days after administration of the second dose of the Moderna COVID-19 Vaccine. Echocardiography done on 14Oct2021 showed 'pericarditis, pericardial fluid'. The Computerized Tomography of the Chest showed 'no pulmonary embolism' and the Fibrin D dimer test was 'negative'. The event had not resolved at the time of the report. The rechallenge was not applicable as no additional dosing will be given. The benefit-risk relationship of the Moderna COVID-19 Vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 08-Nov-2021: Translation received on 10-Nov-2021 and contains No New Information.	
4.1(b)		This case was received via 4.1(b) Pharmaceuticals (Reference number: 4.1(b)) on 05-Nov-2021 and was forwarded to Moderna on 09-Nov-2021. This case, initially reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref, 4.1(b)	29 years old male with unknown medical history who 3 days after the 2nd dose experienced chest pain and was found to have elevated troponin, normal Ck and CK-MB, normal Echo, abnormal EKG and abnormal cMRI. Pending results for blood tests that were conducted to excluded viral myocarditis. Patient was diagnosed with myocarditis. No other information was provided. Important information

Case ID	WW Identifier	Narrative	MAH Comment
		The patient had a pollinosis and took an over-the-counter fexofenadine hydrochloride depending on the season. On an unknown date, the patient received the 1st dose of this vaccine. On 01-Oct-2021, the patient received the 2nd dose of this vaccine. On 03-Oct-2021, the patient had a pyrexia of the highest 39.1 degrees Celsius. The event was considered to be a side effect and was treated with antipyretics. Subsequently, the fever went down. On 04-Oct-2021, around 06:00, acute myocarditis developed. Chest pain was noted. The patient visited the previous physician. High sensitive troponin I was positive, and post-vaccination myocarditis was suspected, and the patient was referred to and visited the reporting hospital. At the time of medical examination, precordial discomfort was persisted, electrocardiogram showed suspected slight ST elevation in V3-6. There was no increase in CK or CK-MB, but the value of sensitive troponin was high as 4,000 pg/mL. The patient was hospitalized on the purpose of follow-up and medical treatment. Medical treatment with ACE inhibitor and ibuprofen was started. On an unknown date, no abnormal findings were found at the time of hospitalization on echocardiography. Thereafter, no new findings were noted. Coronary artery CT was performed, but there was no significant stenosis. On 08-Oct-2021, the patient was doing well and was discharged from the hospital. On 26-Oct-2021, the resolution of the symptoms was confirmed. The outcome of pyrexia and acute myocarditis was reported as resolved. Follow-up investigation will be made. Reporter comments continuation:	is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and the EKG and cMRI results. A causal relationship cannot be excluded due to the missing information.

Case ID	WW Identifier	Narrative	MAH Comment
		Blood tests were submitted to exclude viral myocarditis, but the results have not been reported. The cardiac contrast-enhanced MRI performed after discharge from the hospital showed myocardial edema and late gadolinium enhancement, which was consistent with myocarditis. If viral myocarditis is excluded, the event falls into the CDC's confirmed case" of post-COVID-19 mRNA vaccination myocarditis. Company Comment: The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	
4.1(b)		This case was received via 4.1(b) Pharmaceuticals (Reference number: 4.1(b) on 05-Nov-2021 and was forwarded to Moderna on 10-Nov-2021. This case, initially reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref 4.1(b) The patient was under treatment with 1 tablet of perampanel hydrate 4 mg, 6 tablets of levetiracetam 500 mg, and 1 tablet of sodium valproate 200 mg. On an unknown date, the patient received the 1st dose of the vaccine. On an unknown date, body temperature before the vaccination: 36.2 degrees Celsius. On 17-Oct-2021, the patient received the 2nd dose of the vaccine. On 30-Oct-2021, in the early evening, the patient was aware of malaise, pyrexia of 38s degrees Celsius, and chills. Around 20:00, the patient experienced anterior chest pain, which was gradually exacerbated.	22 years old female with unknown medical history and concomitant medications including levetiracetam (indicated for the treatment of partial seizures), perampanel hydrate (also indicated for the treatment of partialseizures) and valproate sodium (also indicated for the treatment of seizures and for migraines prophylaxis) who 16 days after the 2nd dose experienced pyrexia, malaise and chest pain. Patient was evaluated at that time and EKG and blood test were found to be within normal limits. Two days later as symptoms did not improved, patient went back tot he hospital were she was found to have elevated troponin, abnormal EKG, normal Echo. Additonal test results were not provided. Patient was diagnosed with acute myocarditis. Symptoms were resolving within 2 days. No other information was provided. Important information is missing in the report including patient's full medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events as well as the results of elevated

Case ID	WW Identifier	Narrative	MAH Comment
		On 31-Oct-2021, as the symptom did not improve, the patient called an ambulance and was transported to a nearby hospital. Blood sampling, electrocardiogram, and CT inspection showed no abnormal findings, and the patient was prescribed acetaminophen and returned home. On 02-Nov-2021, as there was no improvement of the symptom, the patient visited the reporting hospital. Electrocardiogram showed negative T-waves in III and V4- V6, and the result of blood sampling showed high level of troponin I of 2,789 pg/mL. Although echocardiography did not show reduced cardiac function, a diagnosis of acute myocarditis was made based on the course of the disease and the results of electrocardiogram and blood sampling. The patient was hospitalized on the same day. On an unknown date, after the hospitalization, the symptom showed a tendency of improvement. On 04-Nov-2021, troponin I also decreased to around 300 in 2 days, and the symptom was confirmed to be resolving. The outcome of acute myocarditis was reported as resolving. Follow-up investigation will be made. Company Comment: The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	troponin and the EKG results. A causal relationship cannot be excluded due to the missing information.
4.1(b)		This case was received via 4.1(b) Pharmaceuticals (Reference number: 4.1(b) on 05-Nov-2021 and was forwarded to Moderna on 10-Nov-2021. This case, initially reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref, 4.1(b)	34 years old male with unknown medical history who 2 days after the 2nd dose experienced pyrexia and chest pain and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted. According to the WHO causality

Case ID	WW Identifier	Narrative	MAH Comment
		On an unknown date, the patient received the 1st dose of the vaccine. On an unknown date, body temperature before the vaccination: 36.5 degrees Celsius. On 29-Oct-2021, at 19:30, the patient received the 2nd dose of the vaccine. At 23:00, acute myocarditis developed. On 31-Oct-2021, in the morning, the patient had pyrexia. At night, chest pain developed, and thus the patient was emergently transported. The patient was diagnosed with acute myocarditis from blood collection and electrocardiogram and hospitalized for treatment. The outcome of acute myocarditis was unknown. Follow-up investigation will be made. Company Comment: The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	assessment this report is conditional based onthe lack of information; a causal relationship cannot be excluded due to the lack of information.
4.1(b)		This case was received via 4.1(b) (Reference number: 4.1(b) on 09-Nov-2021 and was forwarded to Moderna on 09-Nov-2021. This regulatory authority case was reported by an other health care professional and describes the occurrence of CARDIOMYOPATHY (Cardiomyopathy), MYOCARDITIS (Myocarditis), OEDEMA (Oedema) and CHEST PAIN (Chest pain) in a 22-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 017f21a) for COVID-19 vaccination. The patient's past medical history included Hepatic steatosis and COVID-19 in August 2020. Concurrent medical conditions included Allergy to antibiotic	22 years old male with medical history of hepatic steatosis and COVID-19 one year before who 6 days after the 2nd dose experienced chest pain and was found to have elevated CRP, troponin I, d-dimer, abnormal EKG, abnormal Echo with low ejection fraction, and abnormal cMRI suggestive of acute myocarditis and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's full medical history as well as any other laboratory test conducted. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and EKG, cMRI and Echo results; a causal relationship cannot be excluded.

Case ID	WW Identifier	Narrative	MAH Comment
		(Amoxicillin), Depression, Anxiety and Vitamin D deficiency. Concomitant products included ESCITALOPRAM OXALATE, VITAMIN D [VITAMIN D NOS], MULTIVITAMIN [VITAMINS NOS] and LINUM USITATISSIMUM SEED OIL (FLAX OIL) for an unknown indication. On 22-Oct-2021, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 25-Oct-2021, the patient experienced CHEST PAIN (Chest pain) (seriousness criterion hospitalization). On 28-Oct-2021, the patient experienced CARDIOMYOPATHY (Cardiomyopathy) (seriousness criteria hospitalization and medically significant), MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant) and OEDEMA (Oedema) (seriousness criterion hospitalization). At the time of the report, CARDIOMYOPATHY (Cardiomyopathy), MYOCARDITIS (Myocarditis), OEDEMA (Oedema) and CHEST PAIN (Chest pain) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 25-Oct-2021, C-reactive protein: 1.710 (High) 1.710 mg/dL. On 25-Oct-2021, Chest X-ray: normal (normal) Normal. On 25-Oct-2021, Electrocardiogram: st-t segment abnormal (abnormal) ST-T segment abnormal and normal (normal) Normal. On 25-Oct-2021, Fibrin D dimer: 0.27 (normal) less than 0.27 ug/mL. On 25-Oct-2021, Red blood cell sedimentation rate: 7 (normal) 7 mm/hr. On 25-Oct-2021, Troponin I: 1.85 (High) 1.85 ng/mL and 3.22 (High) 3.22 ng/mL. On 26-Oct-2021, Echocardiogram: normal (normal) Normal.	

Case ID	WW Identifier	Narrative	MAH Comment
		On 26-Oct-2021, Ejection fraction: 59 (Low) 59%. On 26-Oct-2021, Troponin I: 2.47 (High) 2.47 ng/mL, 2.78 (High) 2.78 ng/mL and 3.47 (High) 3.47 ng/mL. On 27-Oct-2021, Troponin I: 2757 (High) 2757 ng/L. On 28-Oct-2021, Magnetic resonance imaging heart: acute myocarditis (abnormal) Non-ischemic pattern of edema/ hyperemia suggestive of acute myocarditis. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No treatment information provided. Company Comment: This case concerns a 22-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) with history of hepatic steatosis who experienced the serious unexpected event of cardiomyopathy and serious expected event (AESI) of myocarditis 6 days after the first dose of the vaccine. Rechallenge is not applicable, since no further dosing is expected. The benefit-risk relationship is not affected by this report	
4.1(b)		This case was received via 4.1(b) Pharmaceuticals (Reference number: 4.1(b) on 05-Nov-2021 and was forwarded to Moderna on 10-Nov-2021. This case, initially reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref, 4.1(b) On an unknown date, the patient received the 1st dose of the vaccine. On 22-Oct-2021, at 10:00, the patient received the 2nd dose of the vaccine. On 25-Oct-2021, at 05:00, myocarditis developed. The patient was emergently transported with a	37 years old male with unknown medical history who 3 days after the 2nd dose experienced chest pain and was found to have elevated troponin, and abnormal EKG and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including SARS-CoV-2 test. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and EKG results; a causal relationship cannot be excluded due to the lack of other information.

Case ID	WW Identifier	Narrative	MAH Comment
		major complaint of chest pain. On arrival, a wide range of ST elevation was shown by 12-lead electrocardiogram, and high-sensitive troponin I was found to be strongly positive in the results of blood sampling. An emergency coronary catheterization was performed to show no significant stenosis, and thus myocardial infarction was ruled out. The patient was hospitalized. On an unknown date, as cardiac MRI after hospitalization revealed high signal intensities at T2* in cardiac muscles and myocardial edema, the patient was diagnosed with myocarditis. On 02-Nov-2021, the symptom was confirmed to be resolving, and the patient was discharged from the hospital. The outcome of myocarditis was reported as resolving. Follow-up investigation will be made. Company Comment: The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	
4.1(b)		This case was received via 4.1(b) Pharmaceuticals (Reference number: 4.1(b)) on 03-Nov-2021 and was forwarded to Moderna on 10-Nov-2021. This case, initially reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref, 4.1(b) On an unknown date, the patient received the 1st dose of this vaccine. On 28-Oct-2021, at 11:00, the patient received the 2nd dose of the vaccine. In the evening, the patient developed pyrexia and it persisted. occurred	15 years old male with unknown medical history who the same day after the 2nd dose experienced pyrexia, and two days later experienced chest discomfort and was found to have elevated troponin, and CK-MB, and abnormal EKG, and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and

Case ID	WW Identifier	Narrative	MAH Comment
		On 30-Oct-2021, around 16:00, discomfort around the throat to chest and difficulty breathing were noted. Electrocardiogram showed ST elevation of 1, 2, 3, AVF, and V3 -6, elevation of troponin I, elevation of CKMB, and elevation of inflammatory reaction. The patient was diagnosed with myocarditis. The patient was hospitalized. The outcome of pyrexia and myocarditis was reported as unknown. Follow-up investigation will be made . Company Comment: The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship.	EKG results; a causal relationship cannot be excluded.
4.1(b)		This case was received via 4.1(b) Pharmaceuticals (Reference number: 4.1(b)) on 06-Nov-2021 and was forwarded to Moderna on 11-Nov-2021. This case, initially reported to the 4.1(b) by a pharmacist, was received via the 4.1(b) (Ref, 4.1(b) On an unknown date, the patient received the 1st dose of this vaccine. On 17-Oct-2021, the patient received the 2nd dose of this vaccine. On 20-Oct-2021, around 12:00, myocarditis developed. Chest pain and difficulty breathing developed, and an ambulance was called. The patient was transported to the reporting hospital as an emergency visit. On arrival, pyrexia of 37.6 degrees Celsius was observed. Acute myocarditis due to this vaccine was suspected from electrocardiogram and echocardiography, and the patient was hospitalized for further examination and follow-up.	16 years old male with unknown medical history who 3 days after the 2nd dose experienced experienced chest pain and dyspnea and was diagnosed with myocarditis. Test results were not provided, No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events; a causal relationship cannot be excluded.

Case ID	WW Identifier	Narrative	MAH Comment
		On an unknown date, after hospitalization, the symptoms improved with infusion of sodium chloride/potassium chloride/calcium chloride hydrate/sodium acetate hydrate, intravenous infusion of acetaminophen, aspirin, and lansoprazole. On 24-Oct-2021, resolution of the symptoms was confirmed, and the patient was discharged from the hospital. The outcome of myocarditis was reported as recovered. Follow-up investigation will be made. The event developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship. Company comment: This case concerns a 16-year-old, male patient with no relevant medical history, who experienced the expected event of myocarditis. The event myocarditis occurred 3 days after the second dose of Moderna Covid-19 vaccine administration. The rechallenge was not applicable. The patient's age and gender remain confounders. The benefit-risk relationship of Moderna Covid-19 vaccine is not affected by this report.	
4.1(b) [redacted]		This case was received via 4.1(b) Pharmaceuticals (Reference number: 4.1(b) [redacted]) on 06-Nov-2021 and was forwarded to Moderna on 11-Nov-2021. This case, initially reported to the 4.1(b) [redacted] by a (physician), was received via the 4.1(b) (Ref, 4.1(b) [redacted] On an unknown date, the patient received the 1st dose of this vaccine. On 26-Sep-2021, the patient received the 2nd dose of this vaccine. Pyrexia developed.	27 years old male with unknown medical history who the same day after the 2nd dose experienced pyrexia, the next day the patient was found unconcious and was taken to the hospital were myocarditis was suspected. Information provided is confusing as it reports that the patient was on cardio-respiratory arrest for 44 minutes which seems to be too long. Tests result information was not provided in detail, only the EKG which was abnormal. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test

Case ID	WW Identifier	Narrative	MAH Comment
		On 27-Sep-2021, the patient was aware of chest pain. On 28-Sep-2021, at 02:38, myocarditis developed. At 02:45, the family member noticed the patient's groan. The patient did not respond, so CPR was started, and an emergency call was made. The initial waveform was VF, and PCPS was established with an estimated cardio-respiratory arrest time of 44 minutes. Myocarditis was strongly suspected from rapidly elevated cardiac enzymes in CAG vitals. The diagnosis was confirmed by findings of myocardial oedema and cardiac swelling in the VCG. Hypoxic encephalopathy was prolonged, and the consciousness did not recover. The patient was hospitalized. The outcome of pyrexia, VF, myocarditis, and hypoxic encephalopathy was unknown. Follow-up investigation will be made. Company Comment: The events developed after the administration of COVID-19 vaccine mRNA (mRNA 1273) and there is temporal relationship..	conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the abnormal results of the EKG; a causal relationship cannot be excluded.
4.1(b)		This case was received via European Medicines Agency (Reference number: 4.1(b)) 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 PYREXIA (Pyrexia), FATIGUE (Fatigue) and MYOCARDITIS (Inpatient stay due to acute myocarditis since Oct 29, 2021 (2nd dose of the vaccination on Oct 26, 2021 [rhlatn])) in a 34-year-old male patient who received mRNA-1273 (Spikevax) for Prophylactic vaccination.	34 years old male with unknown medical history who same day after the 2nd dose experienced malaise, headache, pyrexia, chills, chest discomfort and 3 days later was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events. A causal relationship cannot be

Case ID	WW Identifier	Narrative	MAH Comment
		No Medical History information was reported. On 26-Oct-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 27-Oct-2021, the patient experienced PYREXIA (Pyrexia) (seriousness criterion hospitalization), FATIGUE (Fatigue) (seriousness criterion hospitalization) and MYOCARDITIS (Inpatient stay due to acute myocarditis since Oct 29, 2021 (2nd dose of the vaccination on Oct 26, 2021 [rhlatn])) (seriousness criteria hospitalization and medically significant). At the time of the report, PYREXIA (Pyrexia) and MYOCARDITIS (Inpatient stay due to acute myocarditis since Oct 29, 2021 (2nd dose of the vaccination on Oct 26, 2021 [rhlatn])) was resolving and FATIGUE (Fatigue) outcome was unknown. On Oct 26, 2021, Patient had 2nd vaccination, he received 1st dose at the end of September, since the night of the vaccination, aching limbs, headaches, fever, chills, pressure on the chest. On Jul 29, 2021, Inpatient stay, during which acute myocarditis was diagnosed, Inpatient stay until Nov 1, 2021. No concomitant medication was provided by reporter. No treatment drug was provided by reporter. Company Comment - This case concerns a 34-year-old, male patient with no relevant medical history reported, who experienced the unexpected serious events of PYREXIA, FATIGUE, and the expected serious event of MYOCARDITIS. The events occurred the following day of the second dose of mRNA-1273. The rechallenge was not applicable, as no information about additional dosing was	excluded due to the lack of information.

Case ID	WW Identifier	Narrative	MAH Comment
		disclosed. 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 received on 14-Nov-2021. Event verbatim and Sender's comment were updated.	
4.1(b)		This case was initially received via European Medicines Agency (Reference number: 4.1(b)) on 10-Nov-2021. The most recent information was received on 24-Nov-2021 and was forwarded to Moderna on 24-Nov-2021. This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (4.1(b)) in a 27-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 3005835 and 3004218) for COVID-19 vaccination. Concurrent medical conditions included Cold induced asthma, Overactive bladder and Micturition urgency. Concomitant products included ALFUZOSIN HYDROCHLORIDE (ALFUZOSIN ORION), BUDESONIDE (GIONA), FESOTERODINE FUMARATE (TOVIAZ) and SALBUTAMOL SULFATE (BUVENTOL) for an unknown indication. On 29-Jul-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 22-Sep-2021, received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. On 15-Oct-2021, after starting mRNA-1273 (Spikevax), the patient experienced MYOCARDITIS (4.1(b)) (seriousness criterion hospitalization). At the time of the report, MYOCARDITIS (4.1(b)) was resolving.	27 years old male with medical history of asthma and overactive bladder who 23 days after the 2nd dose was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events. A causal relationship cannot be excluded due to the lack of information.

Case ID	WW Identifier	Narrative	MAH Comment
		For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. Patient took Buventol Easyhaler at a dose of 100-200 microgram. No treatment medications provided by the reporter. There was no report of late second dose due to an oversight by the patient or HCP (e.g. missed appointment, misunderstood/misinterpreted dosing schedule); however, the second dose was administered more than the recommended window of 25 to 35 days after the first dose. Company Comment : This regulatory case concerns a 27-year-old, male patient with no relevant medical history, who experienced the expected AESI of myocarditis. The event, which resulted in hospitalization, occurred 23 days after administration of the second dose of the Moderna mRNA-1273. No treatment information was provided. However, the event was resolving at the time of the report. The rechallenge was not applicable as no additional dosing will be given. The patient's gender remains a confounder. The benefit-risk relationship of the Moderna mRNA-1273 is not affected by this report. Of note, there was no report of late second dose due to an oversight by the patient or HCP (e.g. missed appointment, misunderstood/misinterpreted dosing schedule); however, the second dose was administered more than the recommended window of 25 to 35 days after the first dose. Most recent FOLLOW-UP information incorporated above includes: On 10-Nov-2021: Translation document received on 12 Nov 2021. Translated event verbatim and dosage text was updated. On 24-Nov-2021: Follow up received on 24-NOV-2021 contained significant information Medical History, Concomitant product, Event start date was updated	

Case ID	WW Identifier	Narrative	MAH Comment
4.1(b)		This case was received via European Medicines Agency (Reference number: 4.1(b)) on 10-Nov-2021 and was forwarded to Moderna on 10-Nov-2021. This regulatory authority case was reported by a physician and describes the occurrence of PERICARDITIS (Pericarditis) in a 31-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3005835) for COVID-19 vaccination. No Medical History information was reported. On 13-Oct-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 17-Oct-2021, after starting mRNA-1273 (Spikevax), the patient experienced PERICARDITIS (Pericarditis) (seriousness criterion medically significant). At the time of the report, PERICARDITIS (Pericarditis) had not resolved. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. No concomitant medications were provided. No treatment information was provided. Follow-up received on 10-NOV-2021 included no new information. Company comment: This regulatory case concerns a 31-year-old, male patient with no relevant medical history, who experienced the expected AESI of pericarditis. The event occurred 4 days after administration of the second dose of the Moderna mRNA-1273. The rechallenge was not applicable as no additional dosing will be given. The patient's gender remains a	31 years old male with unknown medical history who 4 days after the 2nd dose was diagnosed with pericarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events. A causal relationship cannot be excluded due to the lack of information.

Case ID	WW Identifier	Narrative	MAH Comment
		confounder. The benefit-risk relationship of the Moderna mRNA-1273 is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 10-Nov-2021: Translation document received on 12 Nov 2021 includes reaction/event as reported by primary source,dosage text and dosage form translated.	
4.1(b)		This case was received via European Medicines Agency (Reference number: 4.1(b)) on 11-Nov-2021 and was forwarded to Moderna on 11-Nov-2021. This regulatory authority case was reported by a physician and describes the occurrence of CHEST PAIN (Retrosternal pain), MYOCARDIAL NECROSIS MARKER INCREASED (Cardiac enzymes NOS abnormal) and MYOCARDITIS (Acute myocarditis) in a 28-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 immunisation. No Medical History information was reported. On 27-Sep-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 28-Sep-2021, the patient experienced CHEST PAIN (Retrosternal pain) (seriousness criterion medically significant). On 30-Sep-2021, the patient experienced MYOCARDITIS (Acute myocarditis) (seriousness criterion medically significant). On an unknown date, the patient experienced MYOCARDIAL NECROSIS MARKER INCREASED (Cardiac enzymes NOS abnormal) (seriousness criterion medically significant). At the time of the report, CHEST PAIN (Retrosternal pain), MYOCARDIAL NECROSIS MARKER INCREASED (Cardiac enzymes NOS abnormal) and MYOCARDITIS (Acute myocarditis) was resolving.	28 years old male with unknown medical history who 3 days after the 2nd dose experienced chest pain and was found to have elevated myocardial necrosis marker increased (no additional information provided) and cMRI abnormal and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the test results and the cMRI results. A causal relationship cannot be excluded due to the incomplete of information.

Case ID	WW Identifier	Narrative	MAH Comment
		DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 14-Oct-2021, Magnetic resonance imaging heart: abnormal (abnormal) ABNORMAL: ACUTE MYOCARDITIS. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. No concomitant medication was reported. No treatment medication use was reported. The action taken for Moderna COVID-19 vaccine was Not Applicable. Company Comment: This case concerns a 28-year-old male patient with no relevant medical history provided who experienced serious unexpected events of Chest pain and Myocardial necrosis marker increased and serious expected event of special interest Myocarditis. The events occurred approximately one or three days after the second dose of mRNA-1273. The rechallenge was not applicable as the events occurred following the second dose of the vaccine. It was reported that cardiac MRI findings were consistent with myocarditis, however, very limited information regarding clinical course of the events has been provided at this time. At the time of the report the events were resolving. The benefit risk relationship of mRNA-1273 is not affected by this report.	
4.1(b)		This regulatory authority case was reported by an other health care professional and describes the occurrence of CHEST DISCOMFORT (Chest discomfort) and MYOCARDITIS (myocarditis) in a 20-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination.	20 years old male with unknown medical history who at an unknown TTO after the 2nd dose experienced chest discomfort and 4 days after the 2nd dose was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted,

Case ID	WW Identifier	Narrative	MAH Comment
		The patient's past medical history included Cardiac catheterization on 25-Oct-2021. On 21-Oct-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) .5 ml. In October 2021, the patient experienced CHEST DISCOMFORT (Chest discomfort) (seriousness criterion hospitalization prolonged). On 25-Oct-2021, the patient experienced MYOCARDITIS (myocarditis) (seriousness criteria hospitalization prolonged and medically significant). The patient was hospitalized on 25-Oct-2021 due to CHEST DISCOMFORT and MYOCARDITIS. At the time of the report, CHEST DISCOMFORT (Chest discomfort) and MYOCARDITIS (myocarditis) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In 2021, Alanine aminotransferase: 60 (abnormal) 60 U/L. In 2021, Aspartate aminotransferase: 50 (abnormal) 50 U/L. In 2021, Blood creatine: 0.8 (abnormal) 0.8 mg/dL. In 2021, Blood potassium: 4.1 (abnormal) 4.1 mmol/L. In 2021, Blood sodium: 138 (abnormal) 138 mmol/L. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. The concomitant history was not reported. The treatment history was not provided. Company comment This case concerns a 20 year old male patient with medical history of cardiac catheterization, who experienced the expected event of myocarditis and the unexpected	including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events. A causal relationship cannot be excluded due to the lack of information.

Case ID	WW Identifier	Narrative	MAH Comment
		event of chest pain leading to prolonged hospitalization. The event myocarditis occurred approximately 4 days after the second dose of mRNA-1273 vaccine. The event chest pain occurred on an unknown date in the month of October. The rechallenge was unknown. Patient's medical history of cardiac catheterization remains a confounder. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report.	
4.1(b) [redacted]		This case was initially received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 11-Nov-2021. The most recent information was received on 25-Nov-2021 and was forwarded to Moderna on 25-Nov-2021. This regulatory authority case was reported by a physician and describes the occurrence of PERICARDITIS (PERICARDITIS) in a 17-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 3005697 and 3005242) for an unknown indication. Concurrent medical conditions included ADHD. Concomitant products included METHYLPHENIDATE HYDROCHLORIDE (RITALIN) from 08-May-2018 to an unknown date, MELATONIN (MELATONIN AGB) from 07-Jul-2021 to an unknown date and HYDROXYZINE HYDROCHLORIDE (ATARAX [HYDROXYZINE HYDROCHLORIDE]) from 07-Jul-2021 to an unknown date for an unknown indication. On 27-Aug-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 01-Oct-2021, received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. On 08-Oct-2021, after starting mRNA-1273 (Spikevax), the patient experienced PERICARDITIS (PERICARDITIS) (seriousness criterion medically significant). At the time of the report,	17 years old male with medical history of ADHD who 7 days after the 2nd dose was diagnosed with pericarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events. A causal relationship cannot be excluded due to the lack of information.

Case ID	WW Identifier	Narrative	MAH Comment
		PERICARDITIS (PERICARDITIS) was resolving. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. No treatment medications were provided by reporter. Company comment- This regulatory case concerns a 17-year-old, male patient with no relevant medical history, who experienced the expected AESI of pericarditis. The event occurred 1 week after administration of the second dose of the Moderna mRNA-1273. The rechallenge was not applicable as no additional dosing will be given. The patient's gender remains a confounder. The benefit-risk relationship of the Moderna mRNA-1273 is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 11-Nov-2021: Translation document received on 12-Nov-2021. Description as reported for event was updated. On 25-Nov-2021: Follow-up received contains additional and updated concomitant medication details.	
4.1(b)		This case was received via European Medicines Agency (Reference number: 4.1(b)) on 11-Nov-2021 and was forwarded to Moderna on 11-Nov-2021. This regulatory authority case was reported by a physician and describes the occurrence of TROPONIN INCREASED (Cardiac troponin increased), BLOOD CREATINE PHOSPHOKINASE INCREASED (Creatine kinase increased) and MYOCARDITIS (Myocarditis) in an 18-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 214015) for Prophylactic vaccination. Previously administered products included for COVID-19 vaccination: COVID-19 Vaccine Moderna	18 years old male with unknown medical history who same day after the 2nd dose was found to have elevated troponin, and CK and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin. A causal relationship cannot be excluded due to the lack of information.

Case ID	WW Identifier	Narrative	MAH Comment
		dispersion for injectionCOVID-19 mRNA Vaccine (nucleoside modified)SpykeVax on 03-Sep-2021. Past adverse reactions to the above products included No adverse event with COVID-19 Vaccine Moderna dispersion for injectionCOVID-19 mRNA Vaccine (nucleoside modified)SpykeVax. On 15-Oct-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 15-Oct-2021, the patient experienced TROPONIN INCREASED (Cardiac troponin increased) (seriousness criterion hospitalization), BLOOD CREATINE PHOSPHOKINASE INCREASED (Creatine kinase increased) (seriousness criterion hospitalization) and MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant). At the time of the report, TROPONIN INCREASED (Cardiac troponin increased), BLOOD CREATINE PHOSPHOKINASE INCREASED (Creatine kinase increased) and MYOCARDITIS (Myocarditis) had not resolved. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. Concomitant medications were not reported. Treatment medications were not reported. Company comment: This case concerns a 18 year old male patient with no relevant medical history, who experienced the expected events of myocarditis and the unexpected events of troponin increased and blood creatine phosphokinase increased, requiring hospitalization. The events occurred on the same day after the second dose of mRNA-1273 vaccine. The rechallenge was unknown. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report.	

Case ID	WW Identifier	Narrative	MAH Comment
4.1(b)		This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCARDITIS (Vaccine myocarditis) and CHEST PAIN (Chest pain) in a 23-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 019G21A_1101115-CDC) for COVID-19 vaccination. No Medical History information was reported. On 14-Jul-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 01-Nov-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to .5 milliliter. On 02-Nov-2021, the patient experienced MYOCARDITIS (Vaccine myocarditis) (seriousness criteria hospitalization and medically significant) and CHEST PAIN (Chest pain) (seriousness criterion hospitalization). The patient was hospitalized on 02-Nov-2021 due to CHEST PAIN and MYOCARDITIS. At the time of the report, MYOCARDITIS (Vaccine myocarditis) and CHEST PAIN (Chest pain) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 02-Nov-2021, Fibrin D dimer: 277 (abnormal) 277. On 02-Nov-2021, Platelet aggregation test: 236 (abnormal) 236. On 02-Nov-2021, Polymerase chain reaction: negative (Negative) Negative. On 02-Nov-2021, SARS-CoV-2 test: negative (Negative) Negative. On 02-Nov-2021, Troponin I: 0.13 (abnormal) 0.13. On 02-Nov-2021, White blood cell count: 12600 (abnormal) 12600.	23 years old male with unknown medical history who the next day after the 2nd dose experienced chest pain an dwas found to have elevated troponin I, fibrin d-dimer, negative SARS-CoV-2 and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events as well as the elevated troponin. A causal relationship cannot be excluded due to the missing information.

Case ID	WW Identifier	Narrative	MAH Comment
		For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No concomitant and treatment medication was reported by patient. No chronic diseases were reported by patient. On 3 nov 2021 it was reported that Anti-PF4 test was submitted. Patient was diagnosed with vaccine myocarditis, and was admitted to the ICU for treatment. Company Comment : This case concerns a 23-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) with no relevant medical history who experienced the serious expected event (AESI) of myocarditis one day after the second dose of the vaccine. Rechallenge is not applicable, since no further dosing is expected. The benefit-risk relationship is not affected by this report	
4.1(b)		This regulatory authority case was reported by a pharmacist and describes the occurrence of MYOCARDITIS (Perimyocarditis) in a 19-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 immunisation. No Medical History information was reported. On 13-Oct-2021, the patient received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) dosage was changed to 100 microgram. On an unknown date, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 100 microgram. On 15-Oct-2021, after starting mRNA-1273 (COVID-19 Vaccine Moderna), the patient experienced MYOCARDITIS (Perimyocarditis) (seriousness criteria hospitalization and medically significant). The patient	19 years old male with unknown medical history who 2 days after the 2nd dose experienced chest pain and was found to have elevated troponin, Ck, NT-proBNP, abnormal EGC, normal Echo and was diagnosed with myocarditis. No other information was provided. Important information is missing in the report including patient's medical history as well as any other laboratory test conducted, including testing for SARS-CoV-2. According to the WHO causality assessment this report is possible based on temporal association between the use of the product and the start of the events, as well as the elevated troponin and ECG results; a causal relationship cannot be excluded due to the missing of other information.

Case ID	WW Identifier	Narrative	MAH Comment
		was hospitalized on 16-Oct-2021 due to MYOCARDITIS. At the time of the report, MYOCARDITIS (Perimyocarditis) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 17-Oct-2021, Blood creatine phosphokinase: 397 u/l (High) Elevated. On 17-Oct-2021, C-reactive protein increased: 27 mg/dl (High) Elevated. On 17-Oct-2021, Echocardiogram: normal (normal) Normal pumping function of the heart with unremarkable wall motion; no pericardial effusion was found.. On 17-Oct-2021, Electrocardiogram: abnormal (abnormal) revealed discrete ST elevations in leads V5, V6, and II.. On 17-Oct-2021, N-terminal prohormone brain natriuretic peptide: 1098 nanogram per litre (High) Increased. On 17-Oct-2021, Troponin: 439 microgram per litre (High) Elevated. On 17-Oct-2021, White blood cell count: 9 gram per litre (normal) normal. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered MYOCARDITIS (Perimyocarditis) to be possibly related. No concomitant medications were reported. On 15-Oct-2021, the patient felt stabbing and pressure pain in his left chest, radiating to his back. Since the night before administration, the stabbing pain intensified and had become much stronger (to VAS 7/10), the pain had not been provoked. Treatment with Ponstan (mefenamic acid, dose unknown) helped only slightly. The next day, the patient presented to an emergency department and was hospitalized. Patient presented in good general	

Case ID	WW Identifier	Narrative	MAH Comment
		and nutritional condition. He was hemodynamically stable and afebrile (HR 119/78 mmHg, P 74/min, T 36.8°C, SpO2 99%). There was an increase in heart rate to 110/min on mild exertion (standing up). Auscultation revealed a "crackle" in the right upper lobe, otherwise vesicular breath sounds in the remaining lung fields. Cardiac action was rhythmic, heart sounds pure, peripheral pulses palpable on all sides. There was no peripheral edema, no neck venous congestion. In addition, a macular red exanthema at the level of the clavicles was noticed. The remaining status was unremarkable according to age. This was interpreted as an adverse effect of Spikevax vaccination. A therapy with NSAIDs (substance, commercial preparation and dosage unknown) was started, under which the symptoms rapidly regressed. Cardiopulmonary monitoring was always unremarkable, and evidence of cardiac arrhythmia was not evident on telemetric monitoring. Company Comment: This case concerns a 19-year-old, female patient with no relevant medical history, who experienced the expected event of myocarditis, which required hospitalization. Since the night before administration, the stabbing pain intensified and had become much stronger (to VAS 7/10), the pain had not been provoked. The event occurred approximately 2 days after the second dose of mRNA-1273. The patient was hospitalized and electrocardiogram revealed discrete ST elevations in leads V5, V6, and II and troponin was high....Continued in company comment. Most recent FOLLOW-UP information incorporated above includes: On 12-Nov-2021: Translated document received on 15-NOV-2021 contains updated event verbatim, lab data and narrative.	