

## Summary Tabulation 13.07.2021

Active Substance (High Level)		COVID-19 MRNA VACCINE MODERNA (CX-024414)		
Reaction SOC	Reaction PT	Serious	Non Serious	Total
Blood and lymphatic system disorders	Coagulopathy	4	1	5
	Lymph node pain	0	1	1
	Lymphadenitis	1	0	1
	Lymphadenopathy	10	1	11
	Splenic infarction	1	0	1
	Thrombocytopenia	4	0	4
Cardiac disorders	Angina pectoris	1	0	1
	Arrhythmia	1	1	2
	Atrial fibrillation	2	0	2
	Bradycardia	1	0	1
	Cardiac arrest	3	0	3
	Cardiac discomfort	1	0	1
	Cardiac failure	2	0	2
	Cardiovascular disorder	16	2	18
	Coronary artery occlusion	1	0	1
	Extrasystoles	1	0	1
	Palpitations	8	5	13
	Pericarditis	3	1	4
	Tachycardia	6	6	12
Ear and labyrinth disorders	Deafness	1	0	1
	Ear discomfort	1	0	1
	Ear pain	1	0	1
	Hyperacusis	3	0	3
	Tinnitus	7	3	10
	Vertigo	4	5	9
Endocrine disorders	Goitre	1	0	1
	Hypothyroidism	1	0	1
Eye disorders	Conjunctival haemorrhage	1	1	2
	Diplopia	0	1	1
	Eye oedema	0	1	1
	Eye pain	3	1	4
	Iridocyclitis	0	1	1
	Lacrimation increased	0	1	1
	Photophobia	2	0	2
	Scleritis	1	0	1
	Swelling of eyelid	0	1	1
Uveitis	0	1	1	

	Vision blurred	3	0	3
	Visual impairment	2	2	4
Gastrointestinal disorders	Abdominal discomfort	1	1	2
	Abdominal pain	8	2	10
	Abdominal pain upper	3	3	6
	Aphthous ulcer	1	0	1
	Diarrhoea	16	6	22
	Dyspepsia	1	0	1
	Gastrointestinal pain	1	0	1
	Haematochezia	1	0	1
	Hypoaesthesia oral	0	1	1
	Lip swelling	3	1	4
	Nausea	175	33	208
	Oesophageal spasm	1	0	1
	Paraesthesia oral	1	1	2
	Retching	0	1	1
	Swollen tongue	3	0	3
	Toothache	1	0	1
	Vomiting	27	7	34
General disorders and administration site conditions	Asthenia	16	6	22
	Axillary pain	0	6	6
	Chest discomfort	2	3	5
	Chest pain	6	4	10
	Chills	266	51	317
	Cyst	0	1	1
	Death	7	0	7
	Discomfort	2	0	2
	Extensive swelling of vaccinated limb	56	12	68
	Face oedema	1	1	2
	Fatigue	304	74	378
	Feeling abnormal	1	5	6
	Feeling cold	2	2	4
	Feeling hot	6	2	8
	Feeling of body temperature change	3	0	3
	Gait disturbance	4	0	4
	General physical health deterioration	1	0	1
	Hyperthermia	0	1	1
	Hypothermia	1	0	1
	Illness	1	0	1
	Inflammation	1	1	2
	Inflammatory pain	1	0	1
	Influenza like illness	47	7	54
	Injected limb mobility decreased	1	0	1
	Injection site bruising	1	0	1
	Injection site erythema	8	13	21
	Injection site haematoma	2	0	2
	Injection site hypersensitivity	0	2	2
	Injection site induration	2	5	7
	Injection site movement impairment	1	0	1
	Injection site necrosis	0	1	1

	Injection site oedema	1	0	1
	Injection site pain	14	14	28
	Injection site paraesthesia	1	0	1
	Injection site pruritus	1	3	4
	Injection site reaction	228	46	274
	Injection site swelling	5	6	11
	Injection site warmth	1	0	1
	Malaise	185	43	228
	Mass	0	1	1
	Oedema peripheral	2	0	2
	Pain	7	6	13
	Peripheral swelling	17	10	27
	Pyrexia	319	69	388
	Sensitivity to weather change	0	1	1
	Sudden death	1	0	1
	Swelling	0	2	2
	Swelling face	2	1	3
	Terminal state	1	0	1
	Thirst	0	1	1
	Vaccination failure	1	0	1
	Vaccination site bruising	0	1	1
	Vaccination site erythema	2	7	9
	Vaccination site lymphadenopathy	0	2	2
	Vaccination site mass	1	2	3
	Vaccination site movement impairment	2	1	3
	Vaccination site pain	5	7	12
	Vaccination site reaction	0	1	1
	Vaccination site swelling	3	2	5
	Vaccination site warmth	0	2	2
Hepatobiliary disorders	Liver disorder	1	0	1
Immune system disorders	Allergy to vaccine	1	0	1
	Anaphylactic reaction	4	0	4
	Anaphylactic shock	2	0	2
	Autoimmune disorder	0	1	1
	Hypersensitivity	5	1	6
	Immune system disorder	0	1	1
Infections and infestations	COVID-19	17	0	17
	COVID-19 pneumonia	1	0	1
	Cellulitis	1	0	1
	Erysipelas	3	0	3
	Herpes zoster	4	16	20
	Infection	0	1	1
	Influenza	3	0	3
	Nasopharyngitis	1	0	1
	Peritonsillar abscess	1	0	1
	Pneumonia	2	0	2
	Vaccination site joint infection	1	0	1
Injury, poisoning and procedural complications	Airway burns	1	0	1
	Cartilage injury	1	0	1
	Contusion	0	5	5

	Exposure via breast milk	1	1	2
	Fall	1	1	2
	Heat stroke	0	1	1
	Inappropriate schedule of product administration	0	30	30
	Incorrect dose administered	0	1	1
	Off label use	0	1	1
	Product dose omission issue	2	0	2
	Vaccination complication	0	2	2
	Wound	0	1	1
	Wrong technique in product usage process	0	1	1
Investigations	Blood glucose increased	0	1	1
	Blood pressure decreased	3	2	5
	Blood pressure increased	0	2	2
	Body temperature abnormal	1	0	1
	Body temperature increased	1	1	2
	C-reactive protein increased	1	1	2
	Electrocardiogram ST segment elevation	1	0	1
	Fibrin D dimer increased	2	0	2
	Heart rate increased	3	1	4
	Heart rate irregular	0	1	1
	Liver function test abnormal	1	0	1
	Oxygen saturation decreased	3	1	4
	Platelet count decreased	1	0	1
	Red blood cell count decreased	1	0	1
	Troponin increased	1	0	1
	Weight decreased	0	1	1
	Weight increased	2	0	2
	White blood cell count decreased	1	0	1
Metabolism and nutrition disorders	Decreased appetite	16	2	18
Musculoskeletal and connective tissue disorders	Arthralgia	180	30	210
	Axillary mass	1	2	3
	Back pain	1	2	3
	Bone pain	1	0	1
	Joint stiffness	1	0	1
	Joint swelling	2	1	3
	Limb discomfort	5	3	8
	Muscle rigidity	2	0	2
	Muscle spasms	2	1	3
	Muscular weakness	6	3	9
	Musculoskeletal discomfort	2	0	2
	Musculoskeletal stiffness	6	3	9
	Myalgia	284	76	360
	Neck pain	3	2	5
	Pain in extremity	18	19	37
	Pain in jaw	1	0	1
	Periarthritis	1	0	1
	Polymyalgia rheumatica	0	1	1
Nervous system disorders	Ageusia	2	1	3
	Altered state of consciousness	1	0	1
	Amnesia	0	1	1

Anosmia	1	0	1
Aphasia	0	1	1
Balance disorder	3	1	4
Bell's palsy	0	1	1
Burning sensation	0	4	4
Central pain syndrome	1	0	1
Cerebral artery thrombosis	1	0	1
Cerebral thrombosis	1	0	1
Cerebrovascular accident	3	1	4
Cognitive disorder	1	0	1
Dizziness	25	7	32
Dizziness postural	1	0	1
Dysarthria	1	0	1
Dysgeusia	2	0	2
Dysstasia	0	1	1
Dystonia	1	0	1
Electric shock sensation	0	1	1
Facial paralysis	2	4	6
Haemorrhagic transformation stroke	1	0	1
Head discomfort	4	0	4
Headache	282	69	351
Hemianopia	0	1	1
Hyperaesthesia	1	1	2
Hypoaesthesia	4	3	7
Hypokinesia	1	0	1
Hyporeflexia	1	0	1
Ischaemic stroke	1	0	1
Loss of consciousness	5	1	6
Memory impairment	1	0	1
Migraine	8	2	10
Nervous system disorder	5	2	7
Neuralgia	1	0	1
Paraesthesia	5	4	9
Paralysis	1	0	1
Paraplegia	1	0	1
Paresis	1	0	1
Parosmia	2	0	2
Post herpetic neuralgia	0	1	1
Presyncope	2	2	4
Retinal migraine	0	1	1
Seizure	1	1	2
Sensorimotor disorder	1	0	1
Sleep deficit	2	0	2
Somnolence	3	0	3
Spinal artery embolism	1	0	1
Syncope	7	3	10
Taste disorder	3	0	3
Tension headache	0	1	1
Transient ischaemic attack	1	0	1
Tremor	2	1	3

Pregnancy, puerperium and perinatal conditions	Abortion spontaneous	3	0	3
	Morning sickness	1	0	1
Psychiatric disorders	Abnormal dreams	1	0	1
	Apathy	1	0	1
	Confusional state	1	1	2
	Eating disorder	1	0	1
	Illusion	1	0	1
	Insomnia	5	1	6
	Nightmare	1	0	1
	Restlessness	1	0	1
	Sleep disorder	0	1	1
	Sleep disorder due to general medical condition, hypersomnia type	0	1	1
Renal and urinary disorders	Chromaturia	1	0	1
	Polyuria	1	0	1
	Renal disorder	1	0	1
	Renal pain	1	0	1
	Strangury	1	0	1
Reproductive system and breast disorders	Breast engorgement	1	0	1
	Breast mass	1	0	1
	Breast pain	2	0	2
	Breast swelling	1	0	1
	Dysmenorrhoea	2	0	2
	Heavy menstrual bleeding	1	3	4
	Intermenstrual bleeding	0	1	1
	Menstrual disorder	1	1	2
	Menstruation irregular	1	0	1
	Polymenorrhoea	1	0	1
Respiratory, thoracic and mediastinal disorders	Acute pulmonary oedema	1	0	1
	Apnoea	1	0	1
	Asphyxia	1	0	1
	Choking sensation	0	2	2
	Cough	6	3	9
	Dysphonia	1	0	1
	Dyspnoea	15	7	22
	Epistaxis	0	1	1
	Hypoxia	1	0	1
	Nasal congestion	2	0	2
	Nasal discomfort	1	0	1
	Nocturnal dyspnoea	1	1	2
	Oropharyngeal pain	11	0	11
	Pharyngeal swelling	2	0	2
	Pulmonary embolism	3	0	3
	Pulmonary infarction	1	0	1
	Pulmonary pain	0	1	1
	Respiration abnormal	1	0	1
	Respiratory disorder	15	3	18
	Rhinalgia	1	0	1
	Rhinorrhoea	1	0	1
	Sputum discoloured	1	0	1
	Wheezing	1	1	2

Skin and subcutaneous tissue disorders	Angioedema	1	0	1
	Blister	0	1	1
	Cold sweat	1	0	1
	Cutaneous sarcoidosis	1	0	1
	Erythema	5	6	11
	Erythema nodosum	1	0	1
	Hyperhidrosis	9	3	12
	Pain of skin	1	0	1
	Petechiae	1	0	1
	Pruritus	5	1	6
	Psoriasis	0	1	1
	Rash	3	4	7
	Rash erythematous	2	0	2
		Rash macular	0	2
Rash maculo-papular		1	0	1
Sensitive skin		0	2	2
Skin discolouration		0	1	1
Skin disorder		29	25	54
Skin reaction		1	1	2
Skin warm		0	1	1
Urticaria		5	2	7
Vascular disorders	Artery dissection	1	0	1
	Blood pressure fluctuation	2	2	4
	Cyanosis	1	0	1
	Deep vein thrombosis	1	0	1
	Diastolic hypertension	1	0	1
	Embolism	1	0	1
	Flushing	1	0	1
	Haematoma	1	1	2
	Haemorrhage	1	0	1
	Hot flush	1	2	3
	Hypertension	3	2	5
	Hypertensive crisis	1	0	1
	Hypotension	6	0	6
	Infarction	1	0	1
	Lymphoedema	1	0	1
	Pallor	2	2	4
	Thrombosis	1	2	3
	Varicose vein	0	1	1
	Vasculitis	1	0	1
Venous thrombosis	1	1	2	
<b>Total</b>		<b>3076</b>	<b>944</b>	<b>4.020</b>