

Summary Tabulation 19-10-2021

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	7	1	8
	Increased tendency to bruise	1	2	3
	Lymph node pain	0	1	1
	Lymphadenitis	2	0	2
	Lymphadenopathy	32	10	42
	Splenic infarction	1	0	1
	Thrombocytopenia	5	1	6
Cardiac disorders	Acute myocardial infarction	2	0	2
	Angina pectoris	2	0	2
	Arrhythmia	4	1	5
	Atrial fibrillation	5	0	5
	Atrial flutter	1	0	1
	Bradycardia	1	0	1
	Cardiac arrest	3	0	3
	Cardiac discomfort	1	1	2
	Cardiac failure	2	0	2
	Cardiac tamponade	1	0	1
	Cardiovascular disorder	28	2	30
	Coronary artery occlusion	1	0	1
	Extrasystoles	5	0	5
	Heart alternation	1	0	1
	Myocardial ischaemia	1	0	1
	Myocarditis	5	0	5
	Palpitations	23	6	29
	Pericarditis	7	1	8
	Sinus bradycardia	1	0	1
	Supraventricular extrasystoles	1	0	1
Tachycardia	11	8	19	
Ventricular extrasystoles	1	0	1	
Congenital, familial and genetic disorders	Limb malformation	1	0	1
Ear and labyrinth disorders	Deafness	1	1	2
	Ear discomfort	5	1	6
	Ear pain	3	0	3
	Hyperacusis	4	1	5
	Inner ear disorder	0	1	1

	Tinnitus	9	4	13
	Vertigo	14	17	31
Endocrine disorders	Goitre	2	0	2
	Hypothyroidism	1	0	1
	Thyroiditis subacute	0	1	1
Eye disorders	Blindness	2	1	3
	Conjunctival haemorrhage	2	1	3
	Diplopia	3	1	4
	Dry eye	0	2	2
	Eye discharge	1	0	1
	Eye haemorrhage	1	0	1
	Eye oedema	0	1	1
	Eye pain	4	2	6
	Eye swelling	1	1	2
	Eyelid pain	0	1	1
	Eyelids pruritus	1	0	1
	Iridocyclitis	0	1	1
	Lacrimation increased	0	2	2
	Ocular discomfort	1	0	1
	Ocular hyperaemia	0	2	2
	Photophobia	4	1	5
	Retinal detachment	1	0	1
	Retinal vein thrombosis	0	1	1
	Scleritis	1	0	1
	Strabismus	1	0	1
	Swelling of eyelid	0	1	1
	Uveitis	0	1	1
	Vision blurred	6	0	6
	Visual impairment	5	6	11
Gastrointestinal disorders	Abdominal discomfort	4	2	6
	Abdominal distension	0	2	2
	Abdominal pain	15	7	22
	Abdominal pain lower	1	0	1
	Abdominal pain upper	13	5	18
	Abdominal rigidity	0	1	1
	Acute abdomen	1	0	1
	Aphthous ulcer	1	1	2
	Constipation	1	0	1
	Diarrhoea	30	10	40
	Dry mouth	2	0	2
	Dyspepsia	4	0	4
	Dysphagia	2	0	2
	Eructation	1	0	1
	Faeces discoloured	1	0	1
	Gastrointestinal disorder	0	1	1
	Gastrointestinal pain	1	0	1
	Haematemesis	1	0	1
	Haematochezia	1	0	1
	Haemorrhoids	1	1	2
	Hypoaesthesia oral	0	1	1

	Lip swelling	3	1	4
	Mouth swelling	0	1	1
	Nausea	431	116	547
	Odynophagia	1	0	1
	Oesophageal spasm	1	0	1
	Pancreatitis acute	1	0	1
	Paraesthesia oral	2	1	3
	Retching	0	2	2
	Swollen tongue	3	2	5
	Tongue oedema	0	1	1
	Toothache	2	0	2
	Vomiting	66	20	86
General disorders and administration site conditions	Asthenia	32	14	46
	Axillary pain	9	17	26
	Chest discomfort	8	6	14
	Chest pain	17	9	26
	Chills	577	177	754
	Condition aggravated	3	1	4
	Cyst	0	1	1
	Death	11	0	11
	Decreased activity	1	0	1
	Discomfort	6	3	9
	Disease recurrence	2	0	2
	Exercise tolerance decreased	0	1	1
	Extensive swelling of vaccinated limb	161	57	218
	Face oedema	1	1	2
	Facial pain	1	0	1
	Fatigue	725	268	993
	Feeling abnormal	6	9	15
	Feeling cold	17	5	22
	Feeling hot	15	5	20
	Feeling of body temperature change	7	1	8
	Gait disturbance	8	0	8
	General physical health deterioration	1	0	1
	Generalised oedema	0	1	1
	Hangover	3	0	3
	Hyperthermia	0	1	1
	Hypothermia	1	0	1
	Illness	2	2	4
	Induration	0	1	1
	Inflammation	1	1	2
	Inflammatory pain	1	0	1
	Influenza like illness	87	23	110
	Injected limb mobility decreased	1	0	1
	Injection site bruising	1	0	1
	Injection site dermatitis	1	0	1
	Injection site discomfort	1	0	1
	Injection site erythema	39	30	69
	Injection site haematoma	3	1	4
	Injection site hypersensitivity	1	2	3

	Injection site induration	8	8	16
	Injection site inflammation	2	2	4
	Injection site irritation	1	0	1
	Injection site lymphadenopathy	1	0	1
	Injection site macule	0	2	2
	Injection site movement impairment	7	0	7
	Injection site necrosis	0	1	1
	Injection site oedema	1	2	3
	Injection site pain	52	29	81
	Injection site paraesthesia	2	0	2
	Injection site plaque	2	1	3
	Injection site pruritus	10	5	15
	Injection site rash	2	0	2
	Injection site reaction	517	168	685
	Injection site swelling	23	19	42
	Injection site warmth	14	3	17
	Localised oedema	0	2	2
	Malaise	483	121	604
	Mass	0	1	1
	Oedema	1	0	1
	Oedema peripheral	5	2	7
	Pain	25	15	40
	Peripheral swelling	32	16	48
	Pyrexia	669	209	878
	Sense of oppression	2	1	3
	Sensitivity to weather change	0	1	1
	Sudden death	1	0	1
	Swelling	2	1	3
	Swelling face	2	2	4
	Systemic inflammatory response syndrome	1	1	2
	Terminal state	1	0	1
	Thirst	3	2	5
	Vaccination failure	1	0	1
	Vaccination site bruising	0	1	1
	Vaccination site erythema	2	12	14
	Vaccination site lymphadenopathy	0	2	2
	Vaccination site mass	1	2	3
	Vaccination site movement impairment	2	2	4
	Vaccination site pain	6	14	20
	Vaccination site plaque	0	1	1
	Vaccination site pruritus	0	1	1
	Vaccination site reaction	0	1	1
	Vaccination site swelling	3	3	6
	Vaccination site warmth	0	3	3
Hepatobiliary disorders	Cholestasis	1	0	1
	Drug-induced liver injury	1	0	1
	Hepatitis	1	1	2
	Liver disorder	3	1	4
	Ocular icterus	1	0	1
Immune system disorders	Allergy to vaccine	1	1	2

	Anaphylactic reaction	5	2	7
	Anaphylactic shock	4	1	5
	Autoimmune disorder	2	1	3
	Drug hypersensitivity	0	1	1
	Hypersensitivity	7	3	10
	Immune system disorder	0	1	1
Infections and infestations	Asymptomatic COVID-19	0	2	2
	Bronchitis	0	1	1
	COVID-19	21	5	26
	COVID-19 pneumonia	1	0	1
	Cellulitis	2	1	3
	Erysipelas	3	0	3
	Herpes virus infection	0	1	1
	Herpes zoster	8	25	33
	Herpes zoster meningoencephalitis	1	0	1
	Infection	0	1	1
	Influenza	5	0	5
	Localised infection	2	1	3
	Meningitis viral	1	0	1
	Mucosal infection	2	0	2
	Myelitis	1	0	1
	Nasopharyngitis	2	5	7
	Ophthalmic herpes zoster	1	0	1
	Oral herpes	1	0	1
	Peritonsillar abscess	1	0	1
	Pneumonia	3	0	3
	Sinusitis	1	0	1
	Skin infection	1	0	1
	Vaccination site joint infection	1	0	1
	Vaccination site pustule	0	1	1
	Vaccine breakthrough infection	0	2	2
	Viral infection	1	0	1
Injury, poisoning and procedural complications	Airway burns	1	0	1
	Cartilage injury	1	0	1
	Contusion	2	5	7
	Exposure via breast milk	1	1	2
	Fall	6	1	7
	Heat stroke	0	1	1
	Inappropriate schedule of product	0	31	31
	Incorrect dose administered	0	1	1
	Joint injury	1	1	2
	Limb injury	0	1	1
	Muscle rupture	0	1	1
	Musculoskeletal injury	1	0	1
	Off label use	0	2	2
	Product administered to patient of	0	1	1
	Product dose omission issue	2	3	5
	Tracheal injury	1	0	1
	Vaccination complication	3	5	8
	Wound	1	1	2

	Wrong technique in product usage process	0	1	1
Investigations	Antibody test negative	0	1	1
	Arteriogram carotid abnormal	1	0	1
	Biopsy artery	1	0	1
	Blood fibrinogen increased	1	0	1
	Blood glucose increased	0	1	1
	Blood pressure decreased	6	3	9
	Blood pressure increased	2	4	6
	Blood prolactin decreased	1	0	1
	Body temperature abnormal	1	0	1
	Body temperature decreased	1	0	1
	Body temperature fluctuation	2	0	2
	Body temperature increased	2	1	3
	C-reactive protein increased	6	1	7
	Carbohydrate antigen 19-9 increased	0	1	1
	Ejection fraction decreased	1	0	1
	Electrocardiogram ST segment elevation	2	0	2
	Fibrin D dimer increased	5	0	5
	Heart rate decreased	1	0	1
	Heart rate increased	10	3	13
	Heart rate irregular	1	1	2
	Hormone level abnormal	0	4	4
	Liver function test abnormal	2	0	2
	Oxygen saturation decreased	4	1	5
	Platelet count decreased	1	0	1
	Red blood cell count decreased	1	0	1
	Red blood cell sedimentation rate increased	1	0	1
	Respiratory rate increased	2	0	2
	SARS-CoV-2 antibody test positive	1	0	1
	SARS-CoV-2 test negative	2	0	2
	SARS-CoV-2 test positive	3	1	4
	Serum ferritin increased	1	0	1
	Troponin increased	4	0	4
	Weight decreased	5	3	8
Weight increased	2	0	2	
White blood cell count decreased	1	0	1	
Metabolism and nutrition disorders	Decreased appetite	30	8	38
	Dehydration	0	3	3
	Folate deficiency	1	0	1
	Lactic acidosis	1	0	1
	Vitamin B12 deficiency	1	0	1
Musculoskeletal and connective tissue disorders	Arthralgia	382	113	495
	Axillary mass	3	5	8
	Back pain	20	8	28
	Bone pain	3	0	3
	Groin pain	1	1	2
	Joint stiffness	1	0	1
	Joint swelling	3	3	6
	Limb discomfort	13	10	23
	Muscle fatigue	0	1	1

	Muscle rigidity	3	0	3
	Muscle spasms	4	4	8
	Muscle twitching	1	0	1
	Muscular weakness	12	4	16
	Musculoskeletal chest pain	0	1	1
	Musculoskeletal discomfort	2	0	2
	Musculoskeletal stiffness	23	8	31
	Myalgia	639	240	879
	Neck pain	8	6	14
	Pain in extremity	65	38	103
	Pain in jaw	1	0	1
	Periarthritis	1	2	3
	Polymyalgia rheumatica	0	1	1
	Rheumatic disorder	1	0	1
	Tendonitis	0	1	1
	Torticollis	2	0	2
Nervous system disorders	Ageusia	5	2	7
	Altered state of consciousness	1	0	1
	Amnesia	0	1	1
	Anosmia	1	0	1
	Aphasia	1	1	2
	Balance disorder	4	3	7
	Bell's palsy	0	1	1
	Burning sensation	4	5	9
	Central pain syndrome	1	0	1
	Cerebral artery thrombosis	1	0	1
	Cerebral haemorrhage	1	0	1
	Cerebral thrombosis	1	0	1
	Cerebral venous sinus thrombosis	1	0	1
	Cerebrovascular accident	5	1	6
	Cervicobrachial syndrome	0	1	1
	Cognitive disorder	1	0	1
	Coordination abnormal	3	0	3
	Diplegia	1	0	1
	Disturbance in attention	7	1	8
	Dizziness	44	13	57
	Dizziness postural	1	0	1
	Dysarthria	1	0	1
	Dysgeusia	2	0	2
	Dysstasia	3	1	4
	Dystonia	1	0	1
	Electric shock sensation	0	1	1
	Epilepsy	1	0	1
	Facial paralysis	5	4	9
	Formication	1	0	1
	Guillain-Barre syndrome	2	0	2
	Haemorrhagic transformation stroke	1	0	1
	Head discomfort	6	1	7
	Headache	664	218	882
	Hemianopia	0	1	1

Hemiparesis	1	0	1
Hemiplegia	2	0	2
Hyperaesthesia	2	2	4
Hypersomnia	0	1	1
Hypoaesthesia	10	7	17
Hypokinesia	1	0	1
Hyporeflexia	1	0	1
Intention tremor	1	0	1
Intercostal neuralgia	1	0	1
Ischaemic stroke	1	0	1
Lethargy	1	0	1
Loss of consciousness	9	2	11
Memory impairment	2	0	2
Meningism	1	0	1
Migraine	17	6	23
Migraine with aura	1	0	1
Monoparesis	1	0	1
Monoplegia	1	0	1
Motor dysfunction	1	0	1
Movement disorder	3	0	3
Multiple sclerosis	1	0	1
Muscle contractions involuntary	3	0	3
Nervous system disorder	16	2	18
Neuralgia	3	2	5
Neuropathy peripheral	0	1	1
Paraesthesia	15	12	27
Paralysis	2	0	2
Paraplegia	1	0	1
Paresis	2	0	2
Parosmia	2	0	2
Post herpetic neuralgia	0	2	2
Presyncope	7	5	12
Radiculopathy	1	0	1
Retinal migraine	0	1	1
Seizure	1	2	3
Sensorimotor disorder	1	0	1
Sensory disturbance	1	1	2
Sensory loss	1	0	1
Sleep deficit	2	0	2
Somnolence	7	3	10
Speech disorder	0	1	1
Spinal artery embolism	1	0	1
Spinal cord infarction	1	0	1
Syncope	18	5	23
Taste disorder	3	1	4
Tension headache	0	1	1
Transient ischaemic attack	1	0	1
Tremor	13	2	15
Trigeminal neuralgia	2	1	3
Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous	3	1	4

	Morning sickness	1	1	2
	Premature baby	1	0	1
	Uterine hypertonus	1	0	1
Psychiatric disorders	Abnormal dreams	3	0	3
	Agoraphobia	1	0	1
	Anxiety	0	4	4
	Apathy	1	1	2
	Confusional state	4	1	5
	Delirium	2	0	2
	Depressed mood	0	1	1
	Disorientation	0	1	1
	Eating disorder	1	0	1
	Emotional disorder	1	1	2
	Fear	1	1	2
	Head banging	3	0	3
	Illusion	1	0	1
	Insomnia	20	6	26
	Mental disorder	1	0	1
	Mental fatigue	0	1	1
	Mood altered	1	0	1
	Mood swings	1	0	1
	Nervousness	3	0	3
	Nightmare	2	0	2
	Panic reaction	1	0	1
	Poor quality sleep	2	1	3
	Restlessness	3	0	3
	Sleep disorder	6	2	8
	Sleep disorder due to general medical condition, hypersomnia type	0	1	1
	Tearfulness	0	1	1
Renal and urinary disorders	Chromaturia	2	0	2
	Dysuria	2	0	2
	Incontinence	0	1	1
	Oliguria	1	0	1
	Pollakiuria	1	0	1
	Polyuria	1	0	1
	Renal disorder	2	1	3
	Renal failure	1	0	1
	Renal pain	5	1	6
	Strangury	1	0	1
	Urinary incontinence	0	1	1
Reproductive system and breast disorders	Adnexa uteri pain	2	0	2
	Amenorrhoea	4	14	18
	Breast engorgement	1	0	1
	Breast mass	1	0	1
	Breast pain	4	4	8
	Breast swelling	2	3	5
	Cervix disorder	0	1	1
	Dysmenorrhoea	12	8	20
	Heavy menstrual bleeding	10	33	43
	Hypomenorrhoea	0	1	1

	Intermenstrual bleeding	2	18	20
	Menometrorrhagia	1	0	1
	Menopausal symptoms	0	1	1
	Menstrual disorder	7	16	23
	Menstruation delayed	1	10	11
	Menstruation irregular	12	21	33
	Oligomenorrhoea	3	12	15
	Perineal pain	1	0	1
	Polymenorrhoea	9	21	30
	Postmenopausal haemorrhage	3	0	3
	Premenstrual syndrome	0	1	1
	Uterine spasm	1	1	2
	Vaginal discharge	0	1	1
	Vaginal haemorrhage	1	5	6
	Vulval disorder	0	1	1
	Vulvovaginal discomfort	1	0	1
Respiratory, thoracic and mediastinal disorders	Acute pulmonary oedema	1	0	1
	Aphonia	1	0	1
	Apnoea	1	0	1
	Asphyxia	1	0	1
	Choking sensation	0	2	2
	Cough	9	9	18
	Dry throat	1	0	1
	Dysphonia	2	0	2
	Dyspnoea	29	14	43
	Dyspnoea at rest	1	0	1
	Dyspnoea exertional	1	2	3
	Epistaxis	0	3	3
	Hypoxia	1	0	1
	Laryngeal oedema	1	0	1
	Lung disorder	2	2	4
	Mouth breathing	1	0	1
	Nasal congestion	4	1	5
	Nasal discomfort	2	0	2
	Nocturnal dyspnoea	1	1	2
	Oropharyngeal pain	20	6	26
	Pharyngeal swelling	2	0	2
	Pleurisy	0	1	1
	Productive cough	1	1	2
	Pulmonary embolism	5	0	5
	Pulmonary infarction	1	0	1
	Pulmonary pain	2	1	3
	Respiration abnormal	1	0	1
	Respiratory depth decreased	1	0	1
	Respiratory disorder	21	5	26
	Respiratory distress	4	0	4
	Rhinalgia	1	0	1
	Rhinorrhoea	1	2	3
	Sputum discoloured	1	0	1
	Throat tightness	1	1	2

	Upper respiratory tract congestion	1	0	1
	Wheezing	1	1	2
Skin and subcutaneous tissue disorders	Angioedema	4	0	4
	Blister	2	1	3
	Cold sweat	2	1	3
	Cutaneous sarcoidosis	1	0	1
	Dry skin	2	0	2
	Erythema	10	12	22
	Erythema nodosum	1	0	1
	Hyperhidrosis	26	12	38
	Lividity	1	0	1
	Macule	1	0	1
	Night sweats	5	1	6
	Pain of skin	3	1	4
	Peau d'orange	0	1	1
	Pemphigoid	1	0	1
	Petechiae	1	0	1
	Photosensitivity reaction	1	1	2
	Pruritus	17	8	25
	Psoriasis	0	2	2
	Rash	11	8	19
	Rash erythematous	5	2	7
	Rash macular	14	7	21
	Rash maculo-papular	1	0	1
	Rash papular	0	1	1
	Rash pruritic	0	1	1
	Sensitive skin	3	4	7
	Skin burning sensation	1	1	2
	Skin discolouration	1	1	2
	Skin disorder	90	68	158
	Skin irritation	0	1	1
	Skin reaction	1	2	3
	Skin warm	0	1	1
	Urticaria	10	7	17
	Urticaria chronic	1	0	1
Social circumstances	Bedridden	0	1	1
	Housebound	2	0	2
	Impaired work ability	1	0	1
	Menopause	0	1	1
	Walking disability	2	0	2
	Water pollution	1	0	1
Surgical and medical procedures	Bed rest	6	0	6
Vascular disorders	Arteritis	1	0	1
	Artery dissection	1	0	1
	Blood pressure fluctuation	3	2	5
	Circulatory collapse	1	0	1
	Cyanosis	2	1	3
	Deep vein thrombosis	2	0	2
	Diastolic hypertension	1	0	1
	Flushing	1	0	1

Giant cell arteritis	1	0	1
Haematoma	3	3	6
Haemodynamic instability	1	0	1
Haemorrhage	2	0	2
Hot flush	4	6	10
Hypertension	5	2	7
Hypertensive crisis	2	0	2
Hypotension	10	1	11
Lymphoedema	1	0	1
Microangiopathy	0	1	1
Pallor	4	3	7
Peripheral coldness	4	0	4
Phlebitis	1	0	1
Raynaud's phenomenon	0	1	1
Shock	1	0	1
Thrombophlebitis	0	1	1
Thrombosis	4	2	6
Varicophlebitis	0	1	1
Varicose vein	1	1	2
Vasculitis	1	0	1
Vein discolouration	1	0	1
Vein disorder	1	1	2
Venous thrombosis	1	1	2
Total	7354	2888	10.242