

## Summary Tabulation 14-12-2021

Active Substance (High Level)		COVID-19 MRNA VACCINE MODERNA (CX-024414)		
Reaction SOC	Reaction PT	Serious	Non Serious	Total
Blood and lymphatic system disorders	Blood disorder	1	0	1
	Coagulopathy	8	1	9
	Increased tendency to bruise	1	6	7
	Lymph node pain	0	1	1
	Lymphadenitis	3	0	3
	Lymphadenopathy	36	14	50
	Platelet disorder	1	0	1
	Splenic infarction	1	0	1
	Thrombocytopenia	5	1	6
Cardiac disorders	Acute myocardial infarction	3	0	3
	Angina pectoris	2	0	2
	Arrhythmia	5	1	6
	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 disorder	1	0	1
	Cardiac failure	2	0	2
	Cardiac fibrillation	0	1	1
	Cardiac tamponade	1	0	1
	Cardiovascular disorder	29	3	32
	Coronary artery occlusion	2	0	2
	Extrasystoles	5	0	5
	Heart alternation	1	0	1
	Myocardial injury	1	0	1
	Myocardial ischaemia	1	0	1
	Myocarditis	6	0	6
	Palpitations	26	10	36
	Pericarditis	8	1	9
	Sinus bradycardia	1	0	1
	Supraventricular extrasystoles	1	0	1
	Tachycardia	13	9	22
	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	5	1	6	
	Hypoacusis	1	0	1	
	Inner ear disorder	0	1	1	
	Tinnitus	10	8	18	
	Vertigo	16	19	35	
Endocrine disorders	Goitre	2	0	2	
	Hyperthyroidism	1	0	1	
	Hypothyroidism	1	0	1	
	Ovulation delayed	0	1	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 irritation	0	1	1	
	Eye oedema	0	1	1	
	Eye pain	4	2	6	
	Eye pruritus	0	1	1	
	Eye swelling	1	2	3	
	Eyelid pain	0	1	1	
	Eyelids pruritus	1	0	1	
	Iridocyclitis	0	1	1	
	Lacrimation increased	0	3	3	
	Ocular discomfort	1	0	1	
	Ocular hyperaemia	0	2	2	
	Photophobia	4	2	6	
	Retinal detachment	1	0	1	
	Retinal vein thrombosis	0	1	1	
	Scleritis	1	0	1	
	Strabismus	1	0	1	
	Swelling of eyelid	0	2	2	
	Uveitis	0	1	1	
	Vision blurred	6	0	6	
	Visual impairment	6	6	12	
	Gastrointestinal disorders	Abdominal discomfort	6	3	9
		Abdominal distension	0	3	3
		Abdominal pain	19	9	28
		Abdominal pain lower	1	0	1
Abdominal pain upper		14	6	20	
Abdominal rigidity		0	1	1	
Acute abdomen		1	0	1	

Aphthous ulcer	2	1	3
Constipation	2	0	2
Diarrhoea	30	11	41
Dry mouth	2	0	2
Dyspepsia	4	0	4
Dysphagia	3	0	3
Enteritis	1	0	1
Eructation	1	0	1
Faeces discoloured	1	0	1
Gastrointestinal disorder	0	2	2
Gastrointestinal pain	1	1	2
Haematemesis	1	0	1
Haematochezia	1	0	1
Haemorrhoids	1	1	2
Hypoaesthesia oral	0	1	1
Intestinal haemorrhage	1	0	1
Lip swelling	4	1	5
Mouth swelling	0	1	1
Nausea	478	143	621
Odynophagia	1	0	1
Oesophageal spasm	1	0	1
Oral pruritus	1	0	1
Pancreatitis acute	1	0	1
Paraesthesia oral	2	1	3
Retching	1	2	3
Swollen tongue	3	2	5
Tongue oedema	0	1	1
Toothache	2	0	2
Vomiting	74	26	100
General disorders and administration site conditions			
Asthenia	34	18	52
Axillary pain	11	17	28
Chest discomfort	12	8	20
Chest pain	21	12	33
Chills	639	218	857
Condition aggravated	3	1	4
Cyst	0	1	1
Death	11	0	11
Decreased activity	1	0	1
Discomfort	7	3	10
Disease recurrence	2	0	2
Exercise tolerance decreased	1	1	2
Extensive swelling of vaccinated limb	178	70	248
Face oedema	1	1	2
Facial pain	1	0	1
Fatigue	802	310	1.112
Feeling abnormal	8	11	19
Feeling cold	22	6	28

Feeling hot	15	7	22
Feeling of body temperature change	9	1	10
Gait disturbance	8	1	9
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	3	3	6
Induration	0	1	1
Inflammation	1	2	3
Inflammatory pain	1	0	1
Influenza like illness	93	29	122
Injected limb mobility decreased	2	0	2
Injection site bruising	1	0	1
Injection site dermatitis	1	0	1
Injection site discomfort	1	0	1
Injection site erythema	43	44	87
Injection site haematoma	3	1	4
Injection site hypersensitivity	1	2	3
Injection site induration	11	11	22
Injection site inflammation	3	4	7
Injection site irritation	1	0	1
Injection site lymphadenopathy	2	4	6
Injection site macule	0	3	3
Injection site movement impairment	7	1	8
Injection site necrosis	0	1	1
Injection site oedema	1	2	3
Injection site pain	56	43	99
Injection site paraesthesia	2	0	2
Injection site plaque	2	1	3
Injection site pruritus	11	8	19
Injection site rash	2	4	6
Injection site reaction	560	219	779
Injection site swelling	27	27	54
Injection site warmth	16	8	24
Localised oedema	0	3	3
Malaise	547	155	702
Mass	0	1	1
Mucosal inflammation	1	0	1
Oedema	1	0	1
Oedema peripheral	5	4	9
Pain	30	15	45
Peripheral swelling	33	17	50
Pyrexia	736	257	993
Sense of oppression	3	1	4
Sensitivity to weather change	0	1	1

	Sudden death	1	0	1
	Swelling	3	3	6
	Swelling face	2	2	4
	Systemic inflammatory response syndrome	1	1	2
	Tenderness	0	1	1
	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	2	5
	Ocular icterus	1	0	1
Immune system disorders	Allergy to vaccine	1	1	2
	Anaphylactic reaction	7	2	9
	Anaphylactic shock	4	1	5
	Autoimmune disorder	6	1	7
	Drug hypersensitivity	0	1	1
	Food allergy	1	0	1
	Hypersensitivity	8	4	12
	Immune system disorder	1	1	2
Infections and infestations	Bronchitis	0	1	1
	COVID-19	22	10	32
	COVID-19 pneumonia	1	0	1
	Cellulitis	2	1	3
	Erysipelas	4	0	4
	Herpes virus infection	0	1	1
	Herpes zoster	9	27	36
	Herpes zoster meningoencephalitis	1	0	1
	Infection	0	1	1
	Influenza	5	0	5
	Localised infection	1	0	1
	Meningitis viral	1	0	1
	Mucosal infection	2	0	2
	Myelitis	1	0	1
	Nasopharyngitis	3	6	9

	Ophthalmic herpes zoster	1	0	1
	Oral herpes	2	2	4
	Peritonsillar abscess	1	0	1
	Pneumonia	3	0	3
	Respiratory tract infection viral	1	0	1
	Sinusitis	1	0	1
	Skin infection	1	0	1
	Vaccination site joint infection	1	0	1
	Vaccination site pustule	0	1	1
	Viral infection	1	0	1
Injury, poisoning and procedural complications	Airway burns	1	0	1
	Cartilage injury	1	0	1
	Contusion	2	4	6
	Exposure via breast milk	1	1	2
	Fall	8	1	9
	Heat stroke	0	1	1
	Inappropriate schedule of product administration	0	32	32
	Incorrect dose administered	0	1	1
	Joint injury	1	1	2
	Limb injury	0	1	1
	Maternal exposure during pregnancy	0	1	1
	Muscle rupture	0	1	1
	Musculoskeletal injury	1	0	1
	Off label use	0	2	2
	Product administered to patient of inappropriate	0	1	1
	Product dose omission issue	2	3	5
	Tracheal injury	1	0	1
	Vaccination complication	4	5	9
	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
	Blood fibrinogen increased	1	0	1
	Blood glucose increased	0	1	1
	Blood pressure abnormal	1	0	1
	Blood pressure decreased	6	3	9
	Blood pressure increased	2	4	6
	Blood prolactin decreased	1	0	1
	Blood prolactin increased	0	1	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	7	2	9
	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	6	0	6
	Heart rate decreased	1	0	1
	Heart rate increased	13	6	19
	Heart rate irregular	2	1	3
	Hormone level abnormal	2	4	6
	Liver function test abnormal	2	0	2
	Oxygen saturation decreased	5	1	6
	Platelet count decreased	2	0	2
	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	3	6
	Serum ferritin increased	1	0	1
	Troponin increased	4	0	4
	Weight decreased	5	4	9
	Weight increased	3	0	3
	White blood cell count decreased	1	0	1
Metabolism and nutrition disorders	Decreased appetite	32	8	40
	Dehydration	1	3	4
	Fluid retention	1	0	1
	Folate deficiency	1	0	1
	Hypercholesterolaemia	0	1	1
	Hyperglycaemia	1	0	1
	Lactic acidosis	1	0	1
	Vitamin B12 deficiency	1	0	1
Musculoskeletal and connective tissue disorders	Ankylosing spondylitis	1	0	1
	Arthralgia	412	138	550
	Axillary mass	4	5	9
	Back pain	22	10	32
	Bone pain	3	0	3
	Groin pain	1	1	2
	Hand deformity	0	1	1
	Joint stiffness	1	0	1
	Joint swelling	3	3	6
	Limb discomfort	15	14	29
	Muscle fatigue	0	1	1
	Muscle rigidity	3	0	3
	Muscle spasms	6	5	11
	Muscle twitching	1	0	1
	Muscular weakness	13	4	17
	Musculoskeletal chest pain	0	2	2
	Musculoskeletal discomfort	2	0	2
	Musculoskeletal stiffness	25	11	36
	Myalgia	705	288	993
	Neck pain	9	9	18

	Pain in extremity	78	45	123
	Pain in jaw	1	0	1
	Periarthritis	1	2	3
	Polyarthritis	1	0	1
	Polymyalgia rheumatica	0	1	1
	Rheumatic disorder	1	0	1
	Rheumatoid arthritis	0	1	1
	Tendon pain	1	0	1
	Tendonitis	1	1	2
	Torticollis	2	0	2
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	1	0	1
	Chronic lymphocytic leukaemia	1	0	1
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	6	3	9
	Bell's palsy	0	1	1
	Burning sensation	4	7	11
	Central pain syndrome	1	0	1
	Cerebral artery thrombosis	1	0	1
	Cerebral haemorrhage	1	0	1
	Cerebral thrombosis	1	0	1
	Cerebrovascular accident	7	1	8
	Cervicobrachial syndrome	0	1	1
	Cognitive disorder	1	0	1
	Coordination abnormal	3	0	3
	Diplegia	1	1	2
	Disturbance in attention	8	2	10
	Dizziness	44	17	61
	Dizziness postural	1	0	1
	Dysarthria	1	0	1
	Dysgeusia	2	0	2
	Dysstasia	4	1	5
	Dystonia	1	0	1
	Electric shock sensation	0	1	1
	Epilepsy	2	0	2
	Facial paralysis	5	4	9
	Formication	1	0	1
	Guillain-Barre syndrome	2	0	2
	Haemorrhagic transformation stroke	1	0	1
	Head discomfort	6	2	8
	Headache	740	265	1.005
	Hemianopia	0	1	1
	Hemiparesis	1	0	1
	Hemiplegia	2	0	2



Hyperaesthesia	2	2	4
Hypersomnia	0	1	1
Hypoaesthesia	11	8	19
Hypokinesia	1	0	1
Hyporeflexia	1	0	1
Intention tremor	1	0	1
Intercostal neuralgia	1	0	1
Ischaemic stroke	1	0	1
Loss of consciousness	10	3	13
Memory impairment	2	0	2
Meningism	1	0	1
Migraine	23	7	30
Migraine with aura	1	0	1
Monoparesis	1	0	1
Monoplegia	1	0	1
Motor dysfunction	1	0	1
Movement disorder	3	1	4
Multiple sclerosis	1	0	1
Muscle contractions involuntary	3	0	3
Muscle spasticity	1	0	1
Narcolepsy	1	0	1
Nervous system disorder	18	2	20
Neuralgia	4	2	6
Neuropathy peripheral	2	1	3
Paraesthesia	17	14	31
Paralysis	3	0	3
Paraplegia	1	0	1
Paresis	2	0	2
Parosmia	2	0	2
Polyneuropathy	1	0	1
Post herpetic neuralgia	0	2	2
Presyncope	8	5	13
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
Sinus headache	0	1	1
Sleep deficit	2	0	2
Somnolence	7	5	12
Speech disorder	1	1	2
Spinal artery embolism	1	0	1
Spinal cord infarction	1	0	1
Syncope	24	6	30
Taste disorder	3	1	4
Tension headache	0	1	1

	Transient ischaemic attack	1	0	1
	Tremor	15	2	17
	Trigeminal neuralgia	2	1	3
Pregnancy, puerperium and perinatal conditions	Abortion spontaneous	4	1	5
	Morning sickness	1	1	2
	Pregnancy	1	0	1
	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
	Claustrophobia	0	1	1
	Confusional state	4	2	6
	Delirium	2	0	2
	Depressed mood	0	1	1
	Depression	1	0	1
	Disorientation	0	1	1
	Eating disorder	1	0	1
	Emotional disorder	1	1	2
	Fear	1	1	2
	Head banging	4	0	4
	Illusion	1	0	1
	Insomnia	23	8	31
	Laziness	0	1	1
	Listless	1	0	1
	Mental disorder	1	0	1
	Mental fatigue	0	1	1
	Mood altered	3	0	3
	Mood swings	2	0	2
	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	8	3	11
	Sleep disorder due to general medical condition, hypersomnia type	0	1	1
	Stress	0	1	1
	Suicide attempt	1	0	1
	Tearfulness	0	1	1
Renal and urinary disorders	Chromaturia	2	2	4
	Dysuria	2	0	2
	Haematuria	0	1	1
	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	1	1	2
	Urinary retention	1	0	1
Reproductive system and breast disorders	Adnexa uteri pain	2	1	3
	Amenorrhoea	5	18	23
	Breast cyst	0	1	1
	Breast discomfort	1	0	1
	Breast engorgement	1	0	1
	Breast mass	1	0	1
	Breast pain	5	4	9
	Breast swelling	2	4	6
	Breast tenderness	1	1	2
	Cervix disorder	0	1	1
	Dysmenorrhoea	17	8	25
	Endometriosis	0	1	1
	Genital disorder	1	0	1
	Heavy menstrual bleeding	18	38	56
	Hypomenorrhoea	0	6	6
	Intermenstrual bleeding	7	26	33
	Menometrorrhagia	1	0	1
	Menopausal symptoms	0	1	1
	Menstrual disorder	11	17	28
	Menstruation delayed	5	10	15
	Menstruation irregular	15	27	42
	Oligomenorrhoea	5	21	26
	Ovarian disorder	1	0	1
	Perineal pain	1	0	1
	Polymenorrhoea	12	27	39
	Postmenopausal haemorrhage	3	1	4
	Premenstrual syndrome	1	2	3
	Uterine pain	0	1	1
	Uterine spasm	1	2	3
	Vaginal discharge	0	1	1
	Vaginal haemorrhage	2	8	10
	Vulval disorder	0	1	1
	Vulvovaginal discomfort	1	0	1
	Vulvovaginal pain	0	1	1
Respiratory, thoracic and mediastinal disorders	Acute pulmonary oedema	1	0	1
	Aphonia	1	0	1
	Apnoea	1	0	1
	Asphyxia	1	0	1
	Asthma	0	1	1
	Bronchiectasis	1	0	1
	Choking sensation	0	2	2

Cough	12	9	21
Dry throat	1	0	1
Dysphonia	2	0	2
Dyspnoea	35	16	51
Dyspnoea at rest	1	0	1
Dyspnoea exertional	1	2	3
Epistaxis	1	4	5
Hypoxia	1	0	1
Laryngeal oedema	1	0	1
Lung disorder	2	2	4
Mouth breathing	1	0	1
Nasal congestion	4	2	6
Nasal discomfort	2	0	2
Nocturnal dyspnoea	1	1	2
Oropharyngeal pain	21	6	27
Painful respiration	1	0	1
Pharyngeal swelling	2	0	2
Pleurisy	0	1	1
Productive cough	1	1	2
Pulmonary embolism	7	0	7
Pulmonary infarction	2	0	2
Pulmonary pain	2	1	3
Respiration abnormal	1	0	1
Respiratory depth decreased	1	0	1
Respiratory disorder	26	6	32
Respiratory distress	5	0	5
Rhinalgia	1	0	1
Rhinorrhoea	1	3	4
Sneezing	0	1	1
Sputum discoloured	1	0	1
Throat tightness	1	1	2
Tonsillar hypertrophy	1	0	1
Upper respiratory tract congestion	1	0	1
Wheezing	1	1	2
Skin and subcutaneous tissue disorders			
Acne	1	1	2
Alopecia	0	1	1
Angioedema	6	0	6
Blister	2	2	4
Blood blister	0	1	1
Cellulite	0	1	1
Cold sweat	2	1	3
Cutaneous sarcoidosis	1	0	1
Dry skin	2	0	2
Erythema	10	17	27
Erythema nodosum	1	0	1
Hyperhidrosis	30	14	44
Lividity	1	0	1

	Macule	1	1	2
	Night sweats	5	1	6
	Pain of skin	3	1	4
	Pemphigoid	1	0	1
	Petechiae	1	0	1
	Photosensitivity reaction	1	1	2
	Pityriasis rosea	0	1	1
	Pruritus	18	13	31
	Psoriasis	0	2	2
	Rash	11	10	21
	Rash erythematous	5	6	11
	Rash macular	14	8	22
	Rash maculo-papular	1	0	1
	Rash papular	0	1	1
	Rash pruritic	0	2	2
	Sensitive skin	3	4	7
	Skin burning sensation	1	1	2
	Skin discolouration	1	2	3
	Skin disorder	98	88	186
	Skin irritation	0	1	1
	Skin reaction	1	3	4
	Skin warm	0	1	1
	Urticaria	11	12	23
	Urticaria chronic	1	0	1
Social circumstances	Bedridden	0	1	1
	Housebound	2	0	2
	Impaired work ability	1	1	2
	Loss of personal independence in daily activities	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
	COVID-19 immunisation	3	2	5
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	1	2
	Giant cell arteritis	1	0	1
	Haematoma	3	3	6
	Haemodynamic instability	1	0	1
	Haemorrhage	2	0	2
	Hot flush	5	6	11
	Hypertension	5	2	7

	Hypertensive crisis	3	0	3
	Hypotension	12	1	13
	Lymphoedema	1	0	1
	Microangiopathy	0	1	1
	Orthostatic hypotension	1	0	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	5	2	7
	Varicophlebitis	0	1	1
	Varicose vein	1	1	2
	Vasculitis	1	1	2
	Vein discolouration	1	0	1
	Vein disorder	1	1	2
	Venous thrombosis	1	1	2
<b>Total</b>		<b>8219</b>	<b>3587</b>	<b>11.806</b>