

## Summary Tabulation 13-04-2021

Active Substance (High Level)		COVID-19 MRNA VACCINE PFIZER-BIONTECH (TOZINAMERAN)		
Reaction SOC	Reaction PT	Serious	Non Serious	Total
Blood and lymphatic system disorders	Coagulopathy	14	4	18
	Leukocytosis	1	0	1
	Lymph node pain	1	2	3
	Lymphadenitis	0	1	1
	Lymphadenopathy	25	18	43
	Neutropenia	1	0	1
	Thrombocytopenia	3	0	3
Cardiac disorders	Angina pectoris	1	1	2
	Arrhythmia	3	0	3
	Atrial fibrillation	3	0	3
	Atrioventricular block	1	0	1
	Atrioventricular block complete	1	0	1
	Bradycardia	9	1	10
	Bundle branch block left	1	0	1
	Cardiac arrest	8	0	8
	Cardiac disorder	3	0	3
	Cardiac failure	4	0	4
	Cardio-respiratory arrest	3	0	3
	Cardiogenic shock	1	0	1
	Cardiomegaly	1	0	1
	Cardiovascular disorder	51	17	68
	Coronary artery thrombosis	1	0	1
	Palpitations	8	9	17
	Pericardial effusion	1	0	1
	Pericarditis	1	0	1
	Rhythm idioventricular	1	0	1
	Sinus tachycardia	1	0	1
	Stress cardiomyopathy	0	1	1
	Supraventricular tachycardia	1	0	1
	Tachyarrhythmia	1	0	1
Tachycardia	27	16	43	
Ear and labyrinth disorders	Deafness unilateral	1	0	1
	Ear discomfort	0	2	2
	Ear pain	4	3	7
	Endolymphatic hydrops	2	0	2

	Hypoacusis	1	1	2
	Sudden hearing loss	1	0	1
	Tinnitus	5	1	6
	Vertigo	23	7	30
	Vertigo positional	0	1	1
Endocrine disorders	Goitre	0	1	1
Eye disorders	Abnormal sensation in eye	0	1	1
	Asthenopia	0	2	2
	Blindness	2	0	2
	Diplopia	1	0	1
	Endocrine ophthalmopathy	0	1	1
	Eye irritation	1	1	2
	Eye movement disorder	1	0	1
	Eye pain	2	1	3
	Eye swelling	3	1	4
	Glaucoma	1	0	1
	Lacrimation increased	1	0	1
	Mydriasis	0	1	1
	Ocular hyperaemia	1	0	1
	Photophobia	1	0	1
	Photopsia	1	1	2
	Swelling of eyelid	1	0	1
	Vision blurred	5	2	7
	Visual impairment	2	2	4
	Vitreous floaters	0	1	1
Gastrointestinal disorders	Abdominal discomfort	1	2	3
	Abdominal distension	1	0	1
	Abdominal pain	8	9	17
	Abdominal pain upper	4	3	7
	Anal incontinence	0	1	1
	Aphthous ulcer	2	1	3
	Breath odour	2	0	2
	Constipation	1	1	2
	Diarrhoea	24	25	49
	Diarrhoea haemorrhagic	0	1	1
	Dry mouth	3	1	4
	Dyspepsia	1	2	3
	Dysphagia	4	2	6
	Faecal vomiting	1	0	1
	Faeces discoloured	1	0	1
	Gastric dilatation	1	0	1
	Gastrointestinal disorder	2	0	2
	Gastrointestinal pain	2	1	3
	Gastroesophageal reflux disease	1	1	2
	Gingival pain	1	0	1
	Glossodynia	0	1	1
	Hyperaesthesia teeth	1	0	1
	Hypoaesthesia oral	0	1	1
	Intestinal dilatation	1	0	1
	Intestinal ischaemia	2	0	2

	Intestinal obstruction	1	0	1
	Lip swelling	6	1	7
	Nausea	272	173	445
	Oral pruritus	0	1	1
	Paraesthesia oral	4	4	8
	Parotid gland enlargement	0	1	1
	Rectal haemorrhage	1	0	1
	Retching	4	0	4
	Salivary hypersecretion	2	0	2
	Stomatitis	1	1	2
	Swollen tongue	6	4	10
	Tongue discolouration	0	1	1
	Tongue discomfort	1	0	1
	Vomiting	35	23	58
General disorders and administration site conditions	Application site oedema	1	0	1
	Asthenia	21	19	40
	Axillary pain	5	9	14
	Chest discomfort	8	1	9
	Chest pain	17	3	20
	Chills	349	189	538
	Condition aggravated	0	1	1
	Crying	2	0	2
	Death	3	0	3
	Drug ineffective	3	0	3
	Drug resistance	1	0	1
	Exercise tolerance decreased	4	0	4
	Extensive swelling of vaccinated limb	6	1	7
	Face oedema	1	2	3
	Facial pain	0	1	1
	Fatigue	413	294	707
	Feeling abnormal	4	0	4
	Feeling cold	4	3	7
	Feeling drunk	0	1	1
	Feeling hot	2	7	9
	Feeling of body temperature change	4	10	14
	Gait disturbance	2	0	2
	Gait inability	0	3	3
	General physical health deterioration	13	0	13
	Hyperthermia	0	6	6
	Hypothermia	2	1	3
	Illness	2	0	2
	Inflammation	1	3	4
	Influenza like illness	52	24	76
	Injection site bruising	0	1	1
	Injection site discomfort	0	2	2
	Injection site erythema	12	64	76
	Injection site haematoma	1	7	8
	Injection site haemorrhage	0	1	1
	Injection site hypersensitivity	1	0	1
	Injection site hypoaesthesia	0	1	1

	Injection site induration	4	26	30
	Injection site inflammation	0	1	1
	Injection site movement impairment	1	1	2
	Injection site oedema	0	2	2
	Injection site pain	36	107	143
	Injection site paraesthesia	0	1	1
	Injection site pruritus	1	5	6
	Injection site rash	0	3	3
	Injection site reaction	203	150	353
	Injection site swelling	9	28	37
	Injection site warmth	5	15	20
	Malaise	264	168	432
	Multiple organ dysfunction syndrome	1	0	1
	Oedema	0	1	1
	Oedema peripheral	1	0	1
	Pain	4	6	10
	Peripheral swelling	36	57	93
	Pyrexia	335	259	594
	Secretion discharge	0	1	1
	Sensation of foreign body	2	0	2
	Sense of oppression	3	8	11
	Sudden death	18	0	18
	Swelling	1	6	7
	Swelling face	5	2	7
	Thirst	1	1	2
	Vaccination site erythema	1	2	3
	Vaccination site induration	1	0	1
	Vaccination site pain	2	4	6
	Vaccination site pruritus	0	1	1
	Vaccination site swelling	1	1	2
	Vaccination site warmth	0	1	1
Hepatobiliary disorders	Hepatitis	1	1	2
	Liver disorder	3	0	3
Immune system disorders	Anaphylactic reaction	28	3	31
	Anaphylactic shock	4	0	4
	Anaphylactoid reaction	1	0	1
	Autoimmune disorder	3	3	6
	Food allergy	1	0	1
	Hypersensitivity	17	7	24
Infections and infestations	Appendicitis	2	0	2
	Asymptomatic COVID-19	1	0	1
	COVID-19	23	13	36
	COVID-19 pneumonia	1	0	1
	Ear infection	0	1	1
	Erysipelas	1	0	1
	Herpes ophthalmic	2	1	3
	Herpes simplex	1	0	1
	Herpes virus infection	1	1	2
	Herpes zoster	1	9	10
	Influenza	1	9	10

	Laryngitis	1	0	1
	Localised infection	1	0	1
	Nasopharyngitis	2	2	4
	Oral herpes	4	0	4
	Parapharyngeal space infection	1	0	1
	Pharyngitis	0	2	2
	Pneumonia	4	0	4
	Pneumonia bacterial	1	0	1
	Pyelonephritis	2	0	2
	Respiratory tract infection	2	0	2
	Rhinitis	1	2	3
	Rhinolaryngitis	0	1	1
	Scarlet fever	1	0	1
	Sepsis	2	0	2
	Septic shock	1	0	1
	Sinusitis	0	2	2
	Tonsillitis	0	1	1
	Urosepsis	1	0	1
	Vestibular neuronitis	1	0	1
Injury, poisoning and procedural complications	Chillblains	1	0	1
	Contusion	0	1	1
	Drug administered in wrong device	0	1	1
	Eschar	1	0	1
	Facial bones fracture	1	0	1
	Fall	9	0	9
	Inappropriate schedule of product	0	1	1
	Incorrect dose administered	0	1	1
	Incorrect route of product	0	1	1
	Vaccination failure	2	0	2
	Wrong product administered	1	0	1
Investigations	Blood creatine phosphokinase increased	0	1	1
	Blood glucose decreased	0	1	1
	Blood glucose fluctuation	0	1	1
	Blood lactic acid increased	3	0	3
	Blood pressure abnormal	2	0	2
	Blood pressure decreased	10	3	13
	Blood pressure increased	7	2	9
	Blood test abnormal	1	0	1
	Blood urine present	1	0	1
	Body temperature fluctuation	1	0	1
	Body temperature increased	6	7	13
	Fibrin D dimer increased	1	0	1
	Haemoglobin decreased	1	0	1
	Heart rate decreased	2	0	2
	Heart rate increased	7	1	8
	Heart rate irregular	0	1	1
	Liver function test abnormal	3	0	3
	N-terminal prohormone brain	1	0	1
	Oxygen saturation abnormal	1	0	1
	Oxygen saturation decreased	26	4	30

	Prohormone brain natriuretic peptide	1	0	1
	Respiratory rate increased	1	0	1
	SARS-CoV-2 test positive	2	0	2
	Troponin T increased	1	0	1
	Troponin increased	3	0	3
	Weight decreased	1	0	1
Metabolism and nutrition disorders	Decreased appetite	8	9	17
	Dehydration	1	0	1
	Diabetic complication	1	0	1
	Hypoglycaemia	4	2	6
	Ketoacidosis	3	0	3
	Lactic acidosis	1	0	1
	Metabolic acidosis	1	0	1
	Tetany	1	0	1
	Vitamin D deficiency	1	0	1
Musculoskeletal and connective tissue disorders	Arthralgia	157	93	250
	Arthritis	3	2	5
	Axillary mass	1	0	1
	Back pain	6	4	10
	Bone pain	5	2	7
	Groin pain	0	1	1
	Jaw disorder	0	1	1
	Joint stiffness	1	0	1
	Joint swelling	1	1	2
	Limb discomfort	7	0	7
	Muscle spasms	1	2	3
	Muscular weakness	3	6	9
	Musculoskeletal chest pain	0	2	2
	Musculoskeletal discomfort	0	1	1
	Musculoskeletal stiffness	18	30	48
	Myalgia	344	276	620
	Myosclerosis	0	1	1
	Neck pain	12	9	21
	Pain in extremity	24	58	82
	Pain in jaw	1	0	1
	Posture abnormal	0	1	1
	SAPHO syndrome	0	1	1
Nervous system disorders	Ageusia	0	3	3
	Allodynia	1	0	1
	Altered state of consciousness	4	2	6
	Amnesia	1	0	1
	Anosmia	1	3	4
	Aphasia	1	0	1
	Balance disorder	8	1	9
	Burning sensation	4	4	8
	Cerebral haemorrhage	1	0	1
	Cerebral ischaemia	1	0	1
	Cerebral thrombosis	2	0	2
	Cerebrovascular accident	9	0	9
	Coma	2	0	2

Depressed level of consciousness	10	0	10
Disturbance in attention	1	2	3
Dizziness	34	19	53
Dysaesthesia	1	0	1
Dysgeusia	8	9	17
Dystasia	1	0	1
Dystonia	1	0	1
Epilepsy	7	0	7
Facial paralysis	10	0	10
Facial paresis	8	0	8
Facial spasm	0	2	2
Formication	1	0	1
Generalised tonic-clonic seizure	2	0	2
Haemorrhage intracranial	1	0	1
Haemorrhagic stroke	1	0	1
Head discomfort	1	1	2
Headache	434	305	739
Hemianaesthesia	1	0	1
Hemiparaesthesia	1	0	1
Hemiplegia	3	0	3
Hyperaesthesia	1	0	1
Hypersomnia	1	0	1
Hypoaesthesia	6	9	15
Hyporesponsive to stimuli	1	0	1
Lethargy	1	0	1
Loss of consciousness	5	0	5
Memory impairment	1	0	1
Migraine	14	6	20
Migraine with aura	2	0	2
Muscle contractions involuntary	1	0	1
Nervous system disorder	33	24	57
Neuralgia	1	0	1
Neuritis	1	0	1
Neuropathy peripheral	1	0	1
Orthostatic intolerance	1	0	1
Paraesthesia	10	18	28
Paralysis	1	0	1
Parkinson's disease	2	0	2
Parosmia	0	1	1
Patient elopement	1	0	1
Peripheral motor neuropathy	1	0	1
Poor quality sleep	1	1	2
Presyncope	8	14	22
Sedation	3	0	3
Seizure	8	1	9
Sensory disturbance	1	1	2
Sleep deficit	1	0	1
Somnolence	5	2	7
Speech disorder	1	2	3
Syncope	22	4	26

	Taste disorder	1	1	2
	Thoracic outlet syndrome	1	0	1
	Transient ischaemic attack	1	0	1
	Tremor	7	2	9
	Unresponsive to stimuli	3	0	3
	Visual field defect	2	0	2
Psychiatric disorders	Agitation	5	2	7
	Anxiety	6	2	8
	Apathy	2	1	3
	Confusional state	4	8	12
	Depressed mood	0	1	1
	Disorientation	2	0	2
	Hallucination	3	0	3
	Hallucination, visual	0	1	1
	Insomnia	13	2	15
	Irritability	1	0	1
	Nightmare	1	0	1
	Restlessness	1	1	2
	Sleep disorder	2	1	3
	Staring	1	0	1
Renal and urinary disorders	Acute kidney injury	3	0	3
	Polyuria	0	1	1
	Renal disorder	6	0	6
	Renal failure	3	0	3
	Renal pain	3	2	5
	Urinary retention	1	0	1
Reproductive system and breast disorders	Breast pain	2	0	2
	Metrorrhagia	0	1	1
	Pelvic pain	0	1	1
	Suppressed lactation	1	0	1
	Vaginal haemorrhage	1	0	1
Respiratory, thoracic and mediastinal disorders	Acute pulmonary oedema	1	0	1
	Acute respiratory failure	3	0	3
	Asthma	2	1	3
	Asthma exercise induced	1	0	1
	Bradypnoea	1	0	1
	Bronchial disorder	1	0	1
	Bronchospasm	3	0	3
	Cheyne-Stokes respiration	1	0	1
	Cough	10	9	19
	Dry throat	1	1	2
	Dysphonia	2	2	4
	Dyspnoea	41	5	46
	Dyspnoea exertional	1	0	1
	Epistaxis	2	4	6
	Hyperventilation	3	0	3
	Hypoxia	1	0	1
	Laryngeal discomfort	0	1	1
	Laryngeal oedema	0	1	1
	Laryngospasm	1	0	1



Lower respiratory tract congestion	1	0	1
Lung infiltration	1	0	1
Nasal congestion	0	1	1
Nasal discomfort	0	1	1
Oropharyngeal pain	7	13	20
Painful respiration	1	1	2
Pharyngeal paraesthesia	1	0	1
Pharyngeal swelling	4	3	7
Pleural effusion	2	0	2
Pneumonia aspiration	1	0	1
Pneumonitis	1	0	1
Productive cough	0	1	1
Pulmonary arterial hypertension	1	0	1
Pulmonary embolism	7	0	7
Pulmonary infarction	1	0	1
Pulmonary oedema	3	0	3
Rales	2	0	2
Respiration abnormal	2	0	2
Respiratory acidosis	1	0	1
Respiratory arrest	1	0	1
Respiratory disorder	64	28	92
Respiratory distress	3	0	3
Respiratory failure	1	0	1
Rhinorrhoea	4	5	9
Sinus pain	1	0	1
Sneezing	3	1	4
Suffocation feeling	1	0	1
Tachypnoea	2	0	2
Throat tightness	3	0	3
Tonsillar inflammation	1	0	1
Upper airway obstruction	1	0	1
Wheezing	2	0	2
Skin and subcutaneous tissue disorders			
Angioedema	4	0	4
Cold sweat	1	0	1
Dermatitis	0	1	1
Dry skin	1	0	1
Eczema	0	1	1
Erythema	13	16	29
Hyperhidrosis	8	8	16
Livedo reticularis	1	0	1
Night sweats	1	0	1
Pain of skin	3	0	3
Palmoplantar pustulosis	0	1	1
Pityriasis rosea	0	1	1
Pruritus	17	17	34
Rash	7	12	19
Rash erythematous	2	8	10
Rash macular	2	0	2
Rash maculo-papular	1	0	1
Rash papular	0	2	2

	Rash pruritic	1	0	1
	Sensitive skin	3	0	3
	Skin burning sensation	1	0	1
	Skin disorder	33	24	57
	Skin reaction	0	1	1
	Skin sensitisation	1	0	1
	Urticaria	6	6	12
	Urticaria papular	0	1	1
	Yellow skin	1	0	1
Social circumstances	Bedridden	1	0	1
	Immobile	0	1	1
Surgical and medical procedures	Coronary arterial stent insertion	1	0	1
	Resuscitation	1	0	1
Vascular disorders	Cyanosis	2	1	3
	Deep vein thrombosis	5	0	5
	Flushing	2	1	3
	Haematoma	2	4	6
	Haemorrhage	1	0	1
	Hot flush	10	12	22
	Hypertension	29	10	39
	Hypertensive crisis	1	0	1
	Hypotension	14	7	21
	Hypovolaemic shock	2	0	2
	Lymphoedema	1	0	1
	Neurogenic shock	2	0	2
	Pallor	3	1	4
	Peripheral coldness	2	1	3
	Thrombophlebitis	1	0	1
	Thrombophlebitis superficial	0	1	1
	Thrombosis	2	0	2
	Vasculitis	0	1	1
	Vein rupture	1	0	1
<b>Total</b>		<b>4482</b>	<b>3136</b>	<b>7.618</b>