

## Summary Tabulation 10-05-2021

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	33	10	43
	Leukocytosis	2	0	2
	Lymph node pain	1	3	4
	Lymphadenitis	0	1	1
	Lymphadenopathy	30	28	58
	Microangiopathic haemolytic anaemia	1	0	1
	Neutropenia	1	0	1
	Thrombocytopenia	7	3	10
Cardiac disorders	Angina pectoris	2	1	3
	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	9	0	9
	Cardiac disorder	4	0	4
	Cardiac failure	4	0	4
	Cardio-respiratory arrest	3	0	3
	Cardiogenic shock	2	0	2
	Cardiomegaly	2	0	2
	Cardiovascular disorder	58	17	75
	Coronary artery thrombosis	1	0	1
	Extrasystoles	1	0	1
	Myocarditis	1	0	1
	Palpitations	14	10	24
	Pericardial effusion	2	0	2
	Pericarditis	3	0	3
	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	29	16	45
	Ear and labyrinth disorders	Deafness	1	0
Deafness unilateral		1	0	1

	Dysacusis	1	0	1
	Ear discomfort	1	2	3
	Ear pain	5	3	8
	Endolymphatic hydrops	2	0	2
	Hypoacusis	1	1	2
	Meniere's disease	0	1	1
	Sudden hearing loss	1	0	1
	Tinnitus	7	3	10
	Vertigo	24	11	35
	Vertigo positional	0	2	2
	Vestibular disorder	1	0	1
Endocrine disorders	Goitre	0	1	1
	Thyroid mass	0	1	1
Eye disorders	Abnormal sensation in eye	0	1	1
	Asthenopia	1	2	3
	Blepharospasm	1	0	1
	Blindness	2	0	2
	Diplopia	2	0	2
	Endocrine ophthalmopathy	0	1	1
	Eye irritation	1	1	2
	Eye movement disorder	1	0	1
	Eye pain	4	3	7
	Eye swelling	4	1	5
	Glaucoma	1	0	1
	Iridocyclitis	0	1	1
	Lacrimation increased	1	0	1
	Mydriasis	0	1	1
	Ocular discomfort	0	2	2
	Ocular hyperaemia	1	1	2
	Photophobia	1	0	1
	Photopsia	1	1	2
	Retinal pigment epitheliopathy	1	0	1
	Retinal vein occlusion	1	0	1
	Swelling of eyelid	1	0	1
	Vision blurred	6	3	9
	Visual field defect	2	0	2
	Visual impairment	8	2	10
	Vitreous floaters	0	1	1
Gastrointestinal disorders	Abdominal discomfort	1	6	7
	Abdominal distension	1	1	2
	Abdominal pain	11	11	22
	Abdominal pain upper	9	4	13
	Anal incontinence	0	1	1
	Aphthous ulcer	2	1	3
	Breath odour	2	0	2
	Constipation	1	1	2
	Diarrhoea	36	26	62
	Diarrhoea haemorrhagic	0	1	1
	Dry mouth	3	2	5
	Dyspepsia	1	2	3

Dysphagia	5	2	7
Faecal vomiting	1	0	1
Faeces discoloured	1	0	1
Flatulence	1	2	3
Gastric dilatation	2	0	2
Gastrointestinal disorder	3	1	4
Gastrointestinal pain	4	1	5
Gastrooesophageal reflux disease	1	1	2
Gingival pain	1	0	1
Glossodynia	0	1	1
Hyperaesthesia teeth	1	0	1
Hypoaesthesia oral	0	2	2
Intestinal dilatation	1	0	1
Intestinal ischaemia	2	0	2
Intestinal obstruction	1	0	1
Lip swelling	6	1	7
Nausea	343	198	541
Oral pruritus	0	1	1
Pancreatitis	1	0	1
Paraesthesia oral	5	5	10
Parotid gland enlargement	1	1	2
Rectal haemorrhage	1	1	2
Retching	4	0	4
Salivary gland pain	1	0	1
Salivary hypersecretion	3	0	3
Stomatitis	1	1	2
Swollen tongue	6	4	10
Tongue discolouration	0	1	1
Tongue discomfort	1	0	1
Tongue oedema	1	0	1
Vomiting	46	26	72
General disorders and administration site conditions			
Application site oedema	1	0	1
Asthenia	28	25	53
Axillary pain	8	13	21
Chest discomfort	10	1	11
Chest pain	27	4	31
Chills	439	205	644
Condition aggravated	1	1	2
Crying	2	0	2
Death	14	0	14
Discomfort	2	0	2
Drug ineffective	5	0	5
Drug resistance	1	0	1
Exercise tolerance decreased	4	0	4
Extensive swelling of vaccinated limb	21	1	22
Face oedema	1	2	3
Facial pain	0	1	1
Fatigue	547	329	876
Feeling abnormal	8	4	12
Feeling cold	5	6	11

Feeling drunk	0	1	1
Feeling hot	4	10	14
Feeling of body temperature change	5	12	17
Gait disturbance	2	0	2
Gait inability	1	3	4
General physical health deterioration	19	0	19
Hangover	1	1	2
Hunger	0	1	1
Hyperthermia	0	6	6
Hypothermia	3	1	4
Illness	1	1	2
Induration	0	1	1
Inflammation	3	4	7
Influenza like illness	63	40	103
Injection site bruising	1	1	2
Injection site discomfort	0	3	3
Injection site erythema	13	64	77
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	5	26	31
Injection site inflammation	0	1	1
Injection site movement impairment	1	1	2
Injection site oedema	0	2	2
Injection site pain	43	108	151
Injection site paraesthesia	0	1	1
Injection site pruritus	1	5	6
Injection site rash	0	3	3
Injection site reaction	272	155	427
Injection site swelling	10	28	38
Injection site warmth	5	15	20
Malaise	320	180	500
Multiple organ dysfunction syndrome	2	0	2
Oedema	0	1	1
Oedema peripheral	1	0	1
Pain	8	9	17
Peripheral swelling	37	58	95
Pyrexia	415	304	719
Secretion discharge	0	1	1
Sensation of foreign body	2	0	2
Sense of oppression	3	8	11
Sudden death	23	0	23
Swelling	2	6	8
Swelling face	5	2	7
Therapeutic response unexpected	1	0	1
Thirst	2	2	4
Vaccination failure	3	0	3
Vaccination site discolouration	0	1	1
Vaccination site discomfort	0	1	1

	Vaccination site erythema	1	4	5
	Vaccination site induration	1	0	1
	Vaccination site movement impairment	0	1	1
	Vaccination site pain	2	21	23
	Vaccination site pruritus	0	1	1
	Vaccination site reaction	0	1	1
	Vaccination site swelling	1	2	3
	Vaccination site warmth	0	2	2
Hepatobiliary disorders	Hepatic failure	1	0	1
	Hepatitis	2	1	3
	Liver disorder	7	0	7
Immune system disorders	Allergic reaction to excipient	0	1	1
	Anaphylactic reaction	28	3	31
	Anaphylactic shock	5	0	5
	Anaphylactoid reaction	1	0	1
	Autoimmune disorder	5	3	8
	Food allergy	1	0	1
	Hypersensitivity	17	8	25
Infections and infestations	Abscess	1	0	1
	Appendicitis	2	0	2
	Asymptomatic COVID-19	1	0	1
	COVID-19	38	14	52
	COVID-19 pneumonia	2	0	2
	Diverticulitis	0	1	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	3	9	12
	Hordeolum	1	0	1
	Infection	1	0	1
	Influenza	2	11	13
	Laryngitis	1	0	1
	Localised infection	1	0	1
	Nasopharyngitis	3	3	6
	Ophthalmic herpes zoster	1	0	1
	Oral herpes	5	0	5
	Parapharyngeal space infection	1	0	1
	Pharyngitis	1	2	3
	Pneumonia	6	0	6
	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	2	0	2
	Sinusitis	0	2	2

	Tonsillitis	0	1	1
	Urosepsis	1	0	1
	Vaginal abscess	1	0	1
	Vestibular neuronitis	1	0	1
Injury, poisoning and procedural complications	Brain contusion	1	0	1
	Chest injury	1	0	1
	Chillblains	1	0	1
	Contusion	0	2	2
	Drug administered in wrong device	0	1	1
	Eschar	1	0	1
	Facial bones fracture	1	0	1
	Fall	11	0	11
	Inappropriate schedule of product administration	0	1	1
	Incorrect dose administered	0	1	1
	Incorrect route of product administration	0	1	1
	Subdural haematoma	1	0	1
	Wrong product administered	1	0	1
Investigations	Alanine aminotransferase increased	0	1	1
	Aspartate aminotransferase increased	0	1	1
	Blood alkaline phosphatase increased	1	0	1
	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	4	14
	Blood pressure increased	9	2	11
	Blood test abnormal	1	0	1
	Blood urine present	1	0	1
	Body temperature fluctuation	1	0	1
	Body temperature increased	7	9	16
	C-reactive protein increased	3	1	4
	Fibrin D dimer increased	4	0	4
	Gamma-glutamyltransferase increased	0	1	1
	Haemoglobin decreased	1	0	1
	Heart rate decreased	2	0	2
	Heart rate increased	7	2	9
	Heart rate irregular	0	1	1
	Hepatic enzyme increased	0	1	1
	International normalised ratio increased	1	0	1
	Liver function test abnormal	3	1	4
	N-terminal prohormone brain natriuretic peptide	1	0	1
	Oxygen saturation abnormal	1	0	1
	Oxygen saturation decreased	29	4	33
	Platelet count decreased	1	0	1
	Prohormone brain natriuretic peptide increased	1	0	1
	Respiratory rate increased	1	0	1
	SARS-CoV-2 antibody test negative	1	0	1
	SARS-CoV-2 test positive	3	0	3
	Troponin T increased	1	0	1

	Troponin increased	4	0	4
	Weight decreased	2	0	2
	White blood cell count decreased	1	0	1
Metabolism and nutrition disorders	Decreased appetite	14	9	23
	Dehydration	1	0	1
	Diabetic complication	1	0	1
	Hyperferritinaemia	1	0	1
	Hyperglycaemia	2	0	2
	Hypoglycaemia	5	2	7
	Ketoacidosis	3	0	3
	Lactic acidosis	2	0	2
	Metabolic acidosis	1	0	1
	Tetany	1	0	1
	Vitamin D deficiency	1	0	1
Musculoskeletal and connective tissue disorders	Arthralgia	212	105	317
	Arthritis	3	2	5
	Axillary mass	1	0	1
	Back pain	13	9	22
	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	11	1	12
	Mastication disorder	1	0	1
	Muscle disorder	1	0	1
	Muscle spasms	1	2	3
	Muscular weakness	4	8	12
	Musculoskeletal chest pain	0	2	2
	Musculoskeletal discomfort	0	1	1
	Musculoskeletal stiffness	21	51	72
	Myalgia	443	313	756
	Myosclerosis	0	1	1
	Neck pain	13	13	26
	Neuropathic muscular atrophy	1	0	1
	Pain in extremity	31	74	105
	Pain in jaw	1	0	1
	Posture abnormal	0	1	1
	SAPHO syndrome	0	1	1
	Spinal pain	1	0	1
	Tendonitis	1	0	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	6	0	6
	Balance disorder	10	2	12
	Bell's palsy	2	0	2
	Brain injury	1	0	1

Burning sensation	6	4	10
Carotid artery occlusion	2	0	2
Carotid artery thrombosis	1	0	1
Cerebral haemorrhage	1	0	1
Cerebral ischaemia	2	0	2
Cerebral thrombosis	3	0	3
Cerebrovascular accident	13	0	13
Coma	2	0	2
Depressed level of consciousness	10	0	10
Disturbance in attention	2	3	5
Dizziness	41	24	65
Dysaesthesia	1	0	1
Dysgeusia	11	10	21
Dyspraxia	1	0	1
Dysstasia	1	0	1
Dystonia	1	0	1
Electric shock sensation	2	0	2
Epilepsy	9	1	10
Facial nerve disorder	1	0	1
Facial paralysis	15	0	15
Facial paresis	10	0	10
Facial spasm	0	2	2
Formication	1	0	1
Generalised tonic-clonic seizure	3	0	3
Haemorrhage intracranial	1	0	1
Haemorrhagic stroke	1	0	1
Haemorrhagic transformation stroke	1	0	1
Head discomfort	2	1	3
Headache	558	363	921
Hemianaesthesia	2	0	2
Hemiparaesthesia	1	0	1
Hemiparesis	1	0	1
Hemiplegia	8	0	8
Hyperaesthesia	2	0	2
Hypersomnia	1	1	2
Hypoaesthesia	9	11	20
Hyporesponsive to stimuli	1	0	1
Ischaemic cerebral infarction	1	0	1
Ischaemic stroke	3	0	3
Lethargy	1	0	1
Loss of consciousness	8	0	8
Memory impairment	2	0	2
Migraine	16	7	23
Migraine with aura	2	0	2
Monoplegia	1	0	1
Motor dysfunction	1	0	1
Muscle contractions involuntary	1	0	1
Nerve compression	1	0	1
Nervous system disorder	46	26	72
Neuralgia	1	0	1



	Neuritis	1	0	1
	Neuropathy peripheral	1	0	1
	Noninfective encephalitis	1	0	1
	Orthostatic intolerance	1	0	1
	Paraesthesia	11	20	31
	Paralysis	1	0	1
	Parkinson's disease	2	0	2
	Parosmia	1	1	2
	Patient elopement	1	0	1
	Peripheral motor neuropathy	1	0	1
	Presyncope	9	14	23
	Psychomotor hyperactivity	1	0	1
	Sedation	3	0	3
	Seizure	11	2	13
	Sensory disturbance	1	1	2
	Sleep deficit	1	0	1
	Somnolence	7	2	9
	Speech disorder	4	3	7
	Syncope	24	5	29
	Taste disorder	3	1	4
	Thoracic outlet syndrome	1	0	1
	Transient ischaemic attack	1	0	1
	Tremor	8	3	11
	Trigeminal neuralgia	1	0	1
	Unresponsive to stimuli	3	0	3
Pregnancy, puerperium and perinatal conditions	Abortion spontaneous	1	0	1
Psychiatric disorders	Abnormal dreams	1	0	1
	Acute psychosis	1	0	1
	Aggression	1	0	1
	Agitation	5	2	7
	Anxiety	6	2	8
	Apathy	2	1	3
	Attention deficit hyperactivity disorder	1	0	1
	Aversion	0	1	1
	Confusional state	5	9	14
	Delirium	1	0	1
	Delusion	0	1	1
	Depressed mood	0	1	1
	Disorientation	2	0	2
	Hallucination	4	1	5
	Hallucination, visual	0	1	1
	Insomnia	18	6	24
	Irritability	1	0	1
	Middle insomnia	0	2	2
	Nightmare	1	0	1
	Poor quality sleep	1	2	3
	Restlessness	1	1	2
	Sleep disorder	2	2	4
	Staring	1	0	1
Renal and urinary disorders	Acute kidney injury	5	0	5

	Haematuria	1	1	2
	Polyuria	1	1	2
	Renal disorder	8	0	8
	Renal failure	3	0	3
	Renal pain	4	2	6
	Urinary retention	1	0	1
Reproductive system and breast disorders	Breast pain	2	0	2
	Intermenstrual bleeding	0	1	1
	Pelvic pain	0	1	1
	Suppressed lactation	1	0	1
	Vaginal haemorrhage	1	1	2
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	17	10	27
	Dry throat	1	1	2
	Dysphonia	3	3	6
	Dyspnoea	50	7	57
	Dyspnoea exertional	3	0	3
	Epistaxis	2	8	10
	Haemoptysis	2	0	2
	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	1	1	2
	Nasal discomfort	0	1	1
	Oropharyngeal pain	9	14	23
	Painful respiration	1	1	2
	Pharyngeal paraesthesia	1	0	1
	Pharyngeal swelling	4	3	7
	Pleural effusion	2	0	2
	Pneumonia aspiration	2	0	2
	Pneumonitis	1	0	1
	Productive cough	2	1	3
	Pulmonary arterial hypertension	1	0	1
	Pulmonary embolism	20	0	20
	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	2	0	2
	Respiratory disorder	69	28	97
	Respiratory distress	3	0	3
	Respiratory failure	2	0	2
	Rhinitis allergic	1	0	1
	Rhinorrhoea	7	6	13
	Sinus pain	1	0	1
	Sneezing	4	2	6
	Suffocation feeling	1	0	1
	Tachypnoea	3	0	3
	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	5	0	5
	Cold sweat	1	0	1
	Cutaneous vasculitis	2	0	2
	Dermatitis	0	1	1
	Dry skin	1	0	1
	Eczema	0	2	2
	Erythema	17	19	36
	Hyperhidrosis	13	12	25
	Livedo reticularis	1	0	1
	Night sweats	2	1	3
	Pain of skin	3	1	4
	Palmoplantar pustulosis	0	1	1
	Papule	0	1	1
	Petechiae	1	1	2
	Pityriasis rosea	0	1	1
	Pruritus	21	18	39
	Rash	9	14	23
	Rash erythematous	2	9	11
	Rash macular	2	0	2
	Rash maculo-papular	1	0	1
	Rash papular	0	2	2
	Rash pruritic	1	0	1
	Sensitive skin	3	2	5
	Skin burning sensation	1	0	1
	Skin disorder	48	25	73
	Skin haemorrhage	0	1	1
	Skin reaction	0	1	1
	Skin sensitisation	1	0	1
	Urticaria	8	7	15
	Urticaria papular	0	1	1
	Yellow skin	1	0	1
Social circumstances	Bedridden	2	0	2
	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	9	1	10
Flushing	2	1	3
Haematoma	3	5	8
Haemorrhage	1	0	1
Hot flush	13	12	25
Hypertension	34	10	44
Hypertensive crisis	1	0	1
Hypotension	16	7	23
Hypovolaemic shock	2	0	2
Lymphoedema	1	0	1
Neurogenic shock	2	0	2
Pallor	3	1	4
Peripheral coldness	3	1	4
Phlebitis	0	1	1
Phlebitis superficial	2	1	3
Thrombophlebitis	1	1	2
Thrombophlebitis superficial	0	1	1
Thrombosis	7	0	7
Vasculitis	0	1	1
Vasodilatation	1	1	2
Vein disorder	1	0	1
Vein rupture	1	0	1
Venous thrombosis	0	1	1
<b>Total</b>	<b>5832</b>	<b>3654</b>	<b>9 486</b>