

## FOI 22-817 COVID-19 mRNA Pfizer-BioNTech Vaccine Analysis Print

Report Run Date: 08-Aug-2022  
Data Lock Date: 27-Jul-2022 18:30:04

All suspected spontaneous reports from Isle of Man received up to and including 27/07/2022 for the COVID-19 mRNA Pfizer-BioNTech vaccine.

A report of a suspected ADR to the Yellow Card scheme does not necessarily mean that it was caused by the vaccine, only that the reporter has a suspicion it may have. Underlying or previously undiagnosed illness unrelated to vaccination can also be factors in such reports. The relative number and nature of reports should therefore not be used to compare the safety of the different vaccines. All reports are kept under continual review in order to identify possible new risks.

# Case Series Drug Analysis Print

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Report Run Date: 08-Aug-2022

Data Lock Date: 27-Jul-2022 18:30:04

Earliest Reaction Date: 27-Apr-2020

MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
<b>Blood disorders</b>		
<i>Anaemias NEC</i>		
Normocytic anaemia	1	0
<i>Haematological disorders</i>		
Blood disorder	1	0
<i>Lymphatic system disorders NEC</i>		
Lymph node pain	4	0
Lymphadenitis	2	0
Lymphadenopathy	21	0
<b>Blood disorders SOC TOTAL</b>	<b>29</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Cardiac disorders</b>		
<i>Cardiac signs and symptoms NEC</i>		
Palpitations	16	0
<i>Ischaemic coronary artery disorders</i>		
Acute coronary syndrome	1	0
Angina pectoris	2	1
Myocardial infarction	2	1
<i>Noninfectious myocarditis</i>		
Myocarditis	2	0
<i>Noninfectious pericarditis</i>		
Pericarditis	1	0
<i>Rate and rhythm disorders NEC</i>		
Cardiac flutter	1	0
Extrasystoles	1	0
Tachycardia	5	0
<i>Supraventricular arrhythmias</i>		
Atrial fibrillation	1	0
Atrial flutter	1	0
Sinus tachycardia	1	0
Supraventricular tachycardia	1	0
<b>Cardiac disorders SOC TOTAL</b>	<b>35</b>	<b>2</b>

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Reaction Name	Total	Fatal
<b>Ear disorders</b>		
<i>Ear disorders NEC</i>		
Ear pain	5	0
<i>Hyperacusia</i>		
Hyperacusis	1	0
<i>Inner ear signs and symptoms</i>		
Tinnitus	3	0
Vertigo	1	0
<b>Ear disorders SOC TOTAL</b>	<b>10</b>	<b>0</b>

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<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b>Endocrine disorders</b>		
<i>Thyroid disorders NEC</i>		
Thyroid disorder	1	0
<i>Thyroid hyperfunction disorders</i>		
Hyperthyroidism	1	0
<i>Thyroid hypofunction disorders</i>		
Hypothyroidism	1	0
<b>Endocrine disorders SOC TOTAL</b>	<b>3</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Eye disorders</b>		
<i>Lacrimation disorders</i>		
Dry eye	1	0
<i>Ocular disorders NEC</i>		
Eye pain	2	0
Eye swelling	1	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye pruritus	1	0
<i>Ocular nerve and muscle disorders</i>		
Ophthalmoplegia	1	0
<i>Ocular sensation disorders</i>		
Photophobia	2	0
<i>Visual disorders NEC</i>		
Photopsia	1	0
Vision blurred	3	0
<i>Visual impairment and blindness (excl colour blindness)</i>		
Blindness	1	0
Visual impairment	2	0
<b>Eye disorders SOC TOTAL</b>	<b>15</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i>Colitis (excl infective)</i>		
Colitis	1	0
<i>Dental pain and sensation disorders</i>		
Toothache	1	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	11	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	1	0
<i>Flatulence, bloating and distension</i>		
Flatulence	1	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	9	0
Abdominal pain upper	8	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	4	0
Dysphagia	1	0
<i>Gingival disorders, signs and symptoms NEC</i>		
Gingival pain	1	0
<i>Nausea and vomiting symptoms</i>		
Nausea	25	0
Vomiting	14	0
<i>Oral soft tissue signs and symptoms</i>		
Paraesthesia oral	3	0
<b>Gastrointestinal disorders SOC TOTAL</b>	<b>80</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>General disorders</b>		
<i><b>Asthenic conditions</b></i>		
Asthenia	3	0
Decreased activity	1	0
Fatigue	46	0
Malaise	9	0
<i><b>Death and sudden death</b></i>		
Sudden death	1	1
<i><b>Febrile disorders</b></i>		
Hyperpyrexia	1	0
Pyrexia	28	0
<i><b>Feelings and sensations NEC</b></i>		
Chills	15	0
Feeling abnormal	4	0
Feeling cold	3	0
Feeling of body temperature change	2	0
Hangover	1	0
Sensation of foreign body	1	0
Thirst	1	0
<i><b>Gait disturbances</b></i>		
Gait disturbance	1	0
<i><b>General signs and symptoms NEC</b></i>		
Illness	2	0
Influenza like illness	8	0
Local reaction	1	0
Peripheral swelling	4	0
Swelling	1	0
<i><b>Injection site reactions</b></i>		
Injection site mass	1	0
Injection site pain	6	0
Injection site swelling	2	0
<i><b>Oedema NEC</b></i>		
Oedema peripheral	1	0
<i><b>Pain and discomfort NEC</b></i>		
Axillary pain	9	0
Chest discomfort	2	0
Chest pain	9	0
Facial pain	1	0
Pain	14	0
Tenderness	1	0
<i><b>Vaccination site reactions</b></i>		
Vaccination site pain	2	0
Vaccination site warmth	1	0
<b>General disorders SOC TOTAL</b>	<b>182</b>	<b>1</b>



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<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b>Immune system disorders</b>		
<i>Allergic conditions NEC</i>		
Hypersensitivity	2	0
<i>Immune and associated conditions NEC</i>		
Immunisation reaction	1	0
<b>Immune system disorders SOC TOTAL</b>	<b>3</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Infections</b>		
<i>Abdominal and gastrointestinal infections</i>		
Appendicitis	1	0
<i>Bacterial infections NEC</i>		
Cellulitis	2	0
<i>Central nervous system and spinal infections</i>		
CNS ventriculitis	1	0
<i>Coronavirus infections</i>		
COVID-19	4	0
<i>Dental and oral soft tissue infections</i>		
Pulpitis dental	1	0
<i>Herpes viral infections</i>		
Herpes zoster	4	0
Oral herpes	1	0
<i>Influenza viral infections</i>		
Influenza	6	0
<i>Lower respiratory tract and lung infections</i>		
Lower respiratory tract infection	2	0
<i>Upper respiratory tract infections</i>		
Sinusitis	2	0
<i>Viral infections NEC</i>		
Sweating fever	2	0
<b>Infections SOC TOTAL</b>	<b>26</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Injuries</b>		
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Maternal exposure during breast feeding	1	0
Maternal exposure during pregnancy	1	0
<i>Non-site specific injuries NEC</i>		
Fall	1	0
<i>Skin injuries NEC</i>		
Contusion	1	0
<b>Injuries SOC TOTAL</b>	<b>4</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Investigations</b>		
<i>Endocrine analyses and imaging NEC</i>		
Hormone level abnormal	2	0
<i>Heart rate and pulse investigations</i>		
Heart rate	2	0
Heart rate increased	1	0
Heart rate irregular	1	0
<i>Hepatobiliary function diagnostic procedures</i>		
Hepatic enzyme increased	1	0
<i>Investigations NEC</i>		
Blood test	1	0
<i>Physical examination procedures and organ system status</i>		
Body temperature	1	0
Body temperature abnormal	1	0
<i>Respiratory tract and thoracic imaging procedures</i>		
Chest X-ray	1	0
<i>Urinary tract function analyses NEC</i>		
Urine output decreased	1	0
<i>Vascular tests NEC (incl blood pressure)</i>		
Blood pressure measurement	1	0
<i>Virus identification and serology</i>		
Viral test	1	0
<b>Investigations SOC TOTAL</b>	<b>14</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Metabolic disorders</b>		
<i>Appetite disorders</i>		
Decreased appetite	3	0
Hypophagia	1	0
<i>Disorders of purine metabolism</i>		
Gout	1	0
<i>Total fluid volume decreased</i>		
Dehydration	3	0
<b>Metabolic disorders SOC TOTAL</b>	<b>8</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
<i><b>Arthropathies NEC</b></i>		
Arthritis	1	0
<i><b>Joint related disorders NEC</b></i>		
Temporomandibular joint syndrome	1	0
<i><b>Joint related signs and symptoms</b></i>		
Arthralgia	29	0
Joint swelling	2	0
<i><b>Muscle pains</b></i>		
Fibromyalgia	1	0
Myalgia	25	0
<i><b>Muscle related signs and symptoms NEC</b></i>		
Muscle fatigue	1	0
Muscle spasms	2	0
Muscle tightness	1	0
Muscle twitching	1	0
<i><b>Muscle weakness conditions</b></i>		
Muscular weakness	1	0
<i><b>Musculoskeletal and connective tissue conditions NEC</b></i>		
Musculoskeletal stiffness	4	0
<i><b>Musculoskeletal and connective tissue pain and discomfort</b></i>		
Back pain	6	0
Limb discomfort	6	0
Musculoskeletal chest pain	2	0
Musculoskeletal discomfort	1	0
Neck pain	7	0
Pain in extremity	33	0
<i><b>Soft tissue disorders NEC</b></i>		
Axillary mass	3	0
Neck mass	1	0
<b>Muscle &amp; tissue disorders SOC TOTAL</b>	<b>128</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<b><i>Central nervous system haemorrhages and cerebrovascular accidents</i></b>		
Cerebrovascular accident	2	0
<b><i>Coordination and balance disturbances</i></b>		
Balance disorder	1	0
<b><i>Disturbances in consciousness NEC</i></b>		
Lethargy	7	0
Loss of consciousness	2	0
Somnolence	3	0
Syncope	3	0
<b><i>Facial cranial nerve disorders</i></b>		
Facial spasm	2	0
<b><i>Headaches NEC</i></b>		
Cluster headache	3	0
Headache	63	0
Sinus headache	1	0
Tension headache	1	0
<b><i>Memory loss (excl dementia)</i></b>		
Amnesia	2	0
Memory impairment	1	0
<b><i>Mental impairment (excl dementia and memory loss)</i></b>		
Mental impairment	1	0
<b><i>Migraine headaches</i></b>		
Migraine	8	0
<b><i>Neurological signs and symptoms NEC</i></b>		
Dizziness	22	0
Dizziness postural	2	0
Head discomfort	1	0
Neurological symptom	1	0
Presyncope	2	0
<b><i>Neuromuscular junction dysfunction</i></b>		
Myasthenia gravis crisis	1	0
<b><i>Paraesthesias and dysaesthesias</i></b>		
Hypoaesthesia	11	0
Paraesthesia	12	0
<b><i>Paralysis and paresis (excl cranial nerve)</i></b>		
Paraplegia	1	0
<b><i>Sensory abnormalities NEC</i></b>		
Ageusia	2	0
Dysgeusia	2	0
Neuralgia	3	0
Sensory disturbance	2	0
Sensory loss	1	0
Taste disorder	2	0
<b><i>Transient cerebrovascular events</i></b>		
Transient ischaemic attack	2	0
<b><i>Tremor (excl congenital)</i></b>		
Tremor	5	0
<b><i>Trigeminal disorders</i></b>		
Trigeminal neuralgia	1	0
<b>Nervous system disorders SOC TOTAL</b>	<b>173</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b>		
<i><b>Anxiety symptoms</b></i>		
Anxiety	2	0
<i><b>Confusion and disorientation</b></i>		
Confusional state	1	0
<i><b>Deliria</b></i>		
Delirium	1	0
<i><b>Disturbances in initiating and maintaining sleep</b></i>		
Insomnia	6	0
<i><b>Dyssomnias</b></i>		
Poor quality sleep	1	0
<i><b>Emotional and mood disturbances NEC</b></i>		
Emotional disorder	1	0
Irritability	3	0
<i><b>Fluctuating mood symptoms</b></i>		
Mood swings	1	0
<i><b>Hallucinations (excl sleep-related)</b></i>		
Hallucination	1	0
<i><b>Increased physical activity levels</b></i>		
Restlessness	1	0
<i><b>Mood alterations with depressive symptoms</b></i>		
Depressed mood	1	0
<i><b>Perception disturbances NEC</b></i>		
Illusion	1	0
<i><b>Suicidal and self-injurious behaviour</b></i>		
Suicidal ideation	1	0
<b>Psychiatric disorders SOC TOTAL</b>	<b>21</b>	<b>0</b>



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<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b>Renal &amp; urinary disorders</b>		
<i>Bladder and urethral symptoms</i>		
Dysuria	1	0
<i>Renal disorders NEC</i>		
Renal disorder	1	0
<i>Urinary tract signs and symptoms NEC</i>		
Renal pain	1	0
<b>Renal &amp; urinary disorders SOC TOTAL</b>	<b>3</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Reproductive &amp; breast disorders</b>		
<i><b>Breast signs and symptoms</b></i>		
Breast pain	2	0
<i><b>Menopausal effects NEC</b></i>		
Premature menopause	1	0
<i><b>Menstruation and uterine bleeding NEC</b></i>		
Dysmenorrhoea	1	0
Menstrual disorder	2	0
Menstruation irregular	4	0
<i><b>Menstruation with decreased bleeding</b></i>		
Amenorrhoea	1	0
Menstruation delayed	5	0
<i><b>Menstruation with increased bleeding</b></i>		
Heavy menstrual bleeding	6	0
<i><b>Reproductive tract signs and symptoms NEC</b></i>		
Pelvic pain	1	0
<i><b>Spermatogenesis and semen disorders</b></i>		
Haemospermia	1	0
<i><b>Vulvovaginal disorders NEC</b></i>		
Vaginal haemorrhage	1	0
<b>Reproductive &amp; breast disorders SOC TOTAL</b>	<b>25</b>	<b>0</b>

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<b>Respiratory disorders</b>		
<i>Breathing abnormalities</i>		
Dyspnoea	14	0
Mouth breathing	1	0
<i>Bronchospasm and obstruction</i>		
Asthma	1	0
Wheezing	1	0
<i>Coughing and associated symptoms</i>		
Cough	4	0
<i>Lower respiratory tract signs and symptoms</i>		
Pulmonary pain	1	0
<i>Nasal disorders NEC</i>		
Epistaxis	1	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Pharyngeal swelling	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Aphonia	1	0
Dry throat	1	0
Dysphonia	1	0
Oropharyngeal pain	4	0
Sinus pain	1	0
Yawning	1	0
<b>Respiratory disorders SOC TOTAL</b>	<b>33</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Skin disorders</b>		
<i><b>Alopecias</b></i>		
Alopecia	2	0
<i><b>Angioedemas</b></i>		
Angioedema	1	0
<i><b>Apocrine and eccrine gland disorders</b></i>		
Cold sweat	2	0
Hyperhidrosis	9	0
<i><b>Bullous conditions</b></i>		
Blister	1	0
<i><b>Dermal and epidermal conditions NEC</b></i>		
Dry skin	1	0
Pain of skin	2	0
Sensitive skin	1	0
Skin burning sensation	1	0
Skin discolouration	1	0
Skin plaque	1	0
<i><b>Dermatitis and eczema</b></i>		
Dermatitis contact	1	0
Eczema	3	0
Eczema asteatotic	1	0
<i><b>Erythemas</b></i>		
Erythema	3	0
<i><b>Papulosquamous conditions</b></i>		
Pityriasis rosea	1	0
<i><b>Photosensitivity and photodermatosis conditions</b></i>		
Photosensitivity reaction	2	0
<i><b>Pilar disorders NEC</b></i>		
Hair colour changes	1	0
Hair texture abnormal	1	0
<i><b>Pruritus NEC</b></i>		
Pruritus	12	0
<i><b>Psoriatic conditions</b></i>		
Psoriasis	2	0
<i><b>Rashes, eruptions and exanthems NEC</b></i>		
Rash	13	0
Rash erythematous	1	0
Rash macular	1	0
Rash papular	1	0
Rash pruritic	2	0
<i><b>Scaly conditions</b></i>		
Dandruff	1	0
<i><b>Skin cysts and polyps</b></i>		
Dermal cyst	1	0
<i><b>Urticarias</b></i>		
Urticaria	4	0
<b>Skin disorders SOC TOTAL</b>	<b>73</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Social circumstances</b>		
<i>Age related issues</i>		
Menopause	2	0
<b>Social circumstances SOC TOTAL</b>	<b>2</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Surgical &amp; medical procedures</b>		
<i>Therapeutic procedures NEC</i>		
Injection	1	0
<b>Surgical &amp; medical procedures SOC TOTAL</b>	<b>1</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Vascular disorders</b>		
<i>Accelerated and malignant hypertension</i>		
Hypertensive crisis	1	0
<i>Haemorrhages NEC</i>		
Haemorrhage	3	0
<i>Peripheral embolism and thrombosis</i>		
Deep vein thrombosis	1	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	1	0
Hot flush	6	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	1	0
<i>Site specific vascular disorders NEC</i>		
Pallor	3	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	1	0
<i>Vascular hypotensive disorders</i>		
Hypotension	2	0
<b>Vascular disorders SOC TOTAL</b>	<b>19</b>	<b>0</b>
<b>TOTAL REACTIONS FOR DRUG</b>	<b>887</b>	<b>3</b>
<b>TOTAL REPORTS</b>	<b>309</b>	
<b>TOTAL FATAL OUTCOME REPORTS</b>		<b>3</b>