Report Run Date: 01-Jul-2022

Data Lock Date: 29-Jun-2022 18:30:06

MedDRA Version: MedDRA 25.0

COVID-19

AstraZeneca Vaccine Analysis Print:

FOI 22/761 - All suspected spontaneous reports from Guernsey received up to and including 29/06/2022 for

the COVID-19 AstraZeneca 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.

Reaction Name	Total	Fatal
Blood disorders		
Coagulopathies		
Disseminated intravascular coagulation	1	0
Eosinophilic disorders		
Eosinophilia	1	0
Lymphatic system disorders NEC		
Lymphadenopathy	4	0
Thrombocytopenias		
Thrombocytopenia	1	0
Thrombocytopenic purpura	1	0
Blood disorders SOC TOTAL	8	0

Reaction Name	Total	Fatal
Cardiac disorders		
Cardiac signs and symptoms NEC		
Palpitations	8	0
Cardiomyopathies		
Cardiomyopathy	1	0
Stress cardiomyopathy	1	0
Ischaemic coronary artery disorders		
Acute coronary syndrome	1	0
Acute myocardial infarction	3	0
Myocardial infarction	6	1
Left ventricular failures		
Left ventricular failure	1	0
Mitral valvular disorders		
Ischaemic mitral regurgitation	1	0
Mitral valve incompetence	1	0
Mitral valve prolapse	1	0
Myocardial disorders NEC		
Ventricular hypokinesia	1	0
Noninfectious myocarditis		
Myocarditis	1	0
Rate and rhythm disorders NEC		
Bradycardia	1	0
Tachycardia	3	0
Supraventricular arrhythmias		
Atrial fibrillation	1	0
Sinus tachycardia	1	0
Ventricular arrhythmias and cardiac arrest		
Ventricular fibrillation	1	0
Cardiac disorders SOC TOTAL	33	1

Reaction Name	Total	Fatal
Ear disorders		
Inner ear signs and symptoms		
Tinnitus	5	0
Vertigo	3	0
Ear disorders SOC TOTAL	8	0

Report Run Date: 01-Jul-2022

Reaction Name	Total	Fatal
Eye disorders		
Ocular bleeding and vascular disorders NEC		
Eye haemorrhage	1	0
Ocular disorders NEC		
Eye pain	5	0
Ocular infections, inflammations and associated manifestations		
Eye irritation	1	0
Ocular hyperaemia	1	0
Ocular sensation disorders		
Eye paraesthesia	1	0
Photophobia	1	0
Visual disorders NEC		
Vision blurred	3	0
Visual impairment and blindness (excl colour blindness)		
Visual impairment	2	0
Eve disorders SOC TOTAL	15	0

Reaction Name	Total	Fatal
Gastrointestinal disorders		
Diarrhoea (excl infective)		
Diarrhoea	5	0
Dyspeptic signs and symptoms		
Dyspepsia	2	0
Gastrointestinal and abdominal pains (excl oral and throat)		
Abdominal pain	4	0
Abdominal pain upper	2	0
Gastrointestinal disorders NEC		
Appendix disorder	1	0
Gingival disorders, signs and symptoms NEC		
Gingival pain	1	0
Nausea and vomiting symptoms		
Nausea	17	0
Vomiting	7	0
Vomiting projectile	1	0
Oral dryness and saliva altered		
Dry mouth	1	0
Oral soft tissue swelling and oedema		
Mouth swelling	1	0
Tongue signs and symptoms		
Swollen tongue	1	0
Gastrointestinal disorders SOC TOTAL	43	0

Reaction Name	Total	Fatal
General disorders		
Asthenic conditions		
Asthenia	2	0
Chronic fatigue syndrome	2	2 0
Fatigue	35	0
Malaise	7	7 0
Death and sudden death		
Sudden death	1	1
Febrile disorders		
Pyrexia	34	۱ o
Feelings and sensations NEC		
Chills	25	5 0
Feeling abnormal	4	l o
Feeling cold	3	0
Feeling drunk	1	0
Feeling of body temperature change	2	2 0
Thirst	2	2 0
General signs and symptoms NEC		
Illness	2	2 0
Influenza like illness		
Local reaction	2	2 0
Peripheral swelling	5	0
Swelling	4	l o
Inflammations		
Inflammation	2	2 0
Injection site reactions		
Injection site mass	1	0
Injection site pain	3	3 0
Oedema NEC		
Oedema	2	0
Pain and discomfort NEC		
Chest discomfort	1	
Chest pain	8	
Discomfort	2	0
Facial pain		
Pain	10	0
Vaccination site reactions		
Vaccination site erythema	1	0
Withdrawal and rebound effects		
Withdrawal syndrome	1	0
General disorders SOC TOTAL	171	ıl 1

Reaction Name	Total	Fatal
Immune system disorders		
Anaphylactic and anaphylactoid responses		
Anaphylactic reaction	1	0
Autoimmune disorders NEC		
Autoimmune disorder	1	0
Immune system disorders SOC TOTAL	2	0

Reaction Name		Total	Fatal
Infections			
Bacterial infections NEC			
Cellulitis		1	0
Vaccination site cellulitis		1	0
Cardiac infections			
Acute endocarditis		1	0
Endocarditis		1	0
Coronavirus infections			
COVID-19		2	0
Fungal infections NEC			
Fungal infection		1	0
Herpes viral infections			
Herpes simplex		1	0
Herpes zoster		3	0
Infections NEC			
Infection		1	0
Influenza viral infections			
Influenza		3	0
Lower respiratory tract and le	ung infections		
Lower respiratory tract infe	ction	1	0
Upper respiratory tract infect	tions		
Laryngitis		1	0
Nasopharyngitis		1	0
Viral infections NEC			
Gastroenteritis viral		1	0
Infections SOC TOTAL		19	0

Report Run Date: 01-Jul-2022

Data Lock Date: 29-Jun-2022 18:30:06 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Injuries		
Chest and respiratory tract injuries NEC		
Chest crushing	1	0
Non-site specific injuries NEC		
Fall	1	0
Skin injuries NEC		
Contusion	2	0
Injuries SOC TOTAL	4	0

Report Run Date: 01-Jul-2022

Data Lock Date: 29-Jun-2022 18:30:06 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Investigations		
ECG investigations		
Electrocardiogram T wave inversion	1	0
Physical examination procedures and organ system status		
Respiratory rate increased	1	0
Platelet analyses		
Platelet count decreased	2	0
Plateletcrit	1	0
Red blood cell analyses		
Haemoglobin	1	0
Renal function analyses		
Glomerular filtration rate decreased	1	0
Investigations SOC TOTAL	7	0

Report Run Date: 01-Jul-2022

Reaction Name	Total	Fatal
Metabolic disorders		
Appetite disorders		
Decreased appetite	2	0
Metabolic disorders SOC TOTA	L 2	0

Report Run Date: 01-Jul-2022

Reaction Name	Total	Fatal
Muscle & tissue disorders		
Arthropathies NEC		
Arthritis	1	0
Autoimmune arthritis	1	0
Bone related signs and symptoms		
Pain in jaw	1	0
Bursal disorders		
Bursitis	1	0
Joint related disorders NEC		
Periarthritis	1	0
Joint related signs and symptoms		
Arthralgia	15	0
Joint swelling	1	0
Muscle pains		
Myalgia	20	0
Muscle related signs and symptoms NEC		
Muscle fatigue	3	0
Muscle spasms	7	0
Musculoskeletal and connective tissue conditions NEC		
Musculoskeletal stiffness	4	0
Musculoskeletal and connective tissue pain and discomfort		
Back pain	4	0
Neck pain	1	0
Pain in extremity	13	0
Muscle & tissue disorders SOC TOTAL	73	0

Reaction Name	<u>Total</u>	<u>Fatal</u>
Nervous system disorders		
Acute polyneuropathies		
Guillain-Barre syndrome	1	0
Central nervous system haemorrhages and cerebrovascular accidents		
Cerebral haemorrhage	1	0
Cerebrovascular accident	2	0
Ischaemic stroke	1	0
Thrombotic stroke	1	0
Central nervous system inflammatory disorders NEC		
Central nervous system inflammation	1	0
Disturbances in consciousness NEC		
Lethargy	4	0
Loss of consciousness	1	0
Somnolence	2	0
Dyskinesias and movement disorders NEC		
Clumsiness	1	0
Hyperkinesia	1	0
Facial cranial nerve disorders		
Bell's palsy	1	0
Headaches NEC		
Cold-stimulus headache	1	0
Drug withdrawal headache	1	0
Headache	49	0
Sinus headache	1	0
Tension headache	1	0
Lumbar spinal cord and nerve root disorders		
Sciatica	1	0
Memory loss (excl dementia)		
Amnesia	1	0
Mental impairment (excl dementia and memory loss) Disturbance in attention	1	0
Migraine headaches		
Migraine	4	0
Migraine with aura	2	0
Neurological signs and symptoms NEC		
Dizziness	18	0
Dizziness postural	3	0
Neurological symptom	1	0
Persistent postural-perceptual dizziness	1	0
Unresponsive to stimuli	1	0
Neuromuscular disorders NEC		
Muscle spasticity	1	0
Olfactory nerve disorders		_
Anosmia	2	0
Paraesthesias and dysaesthesias		0
Formication	1	0
Hypoaesthesia	4	0
Paraesthesia  Paripharal neuropathics NEC	8	0
Peripheral neuropathies NEC	4	^
Neuritis	1	0
Seizures and seizure disorders NEC	٨	^
Seizure	1	0
Status epilepticus	l 1	/ \

Report Run Date: 01-Jul-2022

Data Lock Date: 29-Jun-2022 18:30:06 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Nervous system disorders us system disorders cont'd		
Ageusia	1	0
Dysgeusia	2	0
Neuralgia	1	0
Sensory disturbance	1	0
Transient cerebrovascular events		
Transient ischaemic attack	2	0
Tremor (excl congenital)		
Action tremor	1	0
Tremor	5	0
Nervous system disorders SOC TOTAL	135	0

Report Run Date: 01-Jul-2022

Reaction Name	Total	Fatal
Psychiatric disorders		
Anxiety symptoms		
Anxiety	2	0
Stress	1	0
Cognitive and attention disorders and disturbances NEC		
Mental fatigue	2	0
Confusion and disorientation		
Disorientation	2	0
Depressive disorders		
Depression	1	0
Disturbances in initiating and maintaining sleep		
Insomnia	1	0
Emotional and mood disturbances NEC		
Irritability	1	0
Hallucinations (excl sleep-related)		
Hallucination	1	0
Mood disorders NEC		
Listless	1	0
Panic attacks and disorders		
Panic attack	1	0
Parasomnias		
Nightmare	1	0
Stereotypies and automatisms		
Head banging	1	0
Psychiatric disorders SOC TOTAL	15	l o

Report Run Date: 01-Jul-2022

Data Lock Date: 29-Jun-2022 18:30:06 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Renal & urinary disorders		
Renal failure and impairment		
Renal impairment	1	0
Urinary tract signs and symptoms NEC		
Renal pain	1	0
Renal & urinary disorders SOC TOTAL	2	0

Reaction Name	Total	Fatal
Reproductive & breast disorders		
Menopausal effects on the genitourinary tract		
Postmenopausal haemorrhage	1	0
Menstruation and uterine bleeding NEC		
Dysmenorrhoea	3	0
Intermenstrual bleeding	1	0
Menstrual disorder	3	0
Menstruation irregular	3	0
Menstruation with decreased bleeding		
Hypomenorrhoea	1	0
Menstruation delayed	1	0
Menstruation with increased bleeding		
Heavy menstrual bleeding	6	0
Polymenorrhoea	3	0
Reproductive tract signs and symptoms NEC		
Pelvic pain	1	0
Uterine tone disorders		
Uterine spasm	1	0
Reproductive & breast disorders SOC TOTAL	24	0

Report Run Date: 01-Jul-2022

Reaction Name	Total	Fatal
Respiratory disorders		
Breathing abnormalities		
Dyspnoea	6	0
Conditions associated with abnormal gas exchange		
Нурохіа	1	0
Coughing and associated symptoms		
Cough	1	0
Nasal disorders NEC		
Epistaxis	2	0
Pulmonary thrombotic and embolic conditions		
Pulmonary embolism	3	0
Upper respiratory tract signs and symptoms		
Aphonia	1	0
Oropharyngeal pain	3	0
Paranasal sinus discomfort	1	0
Rhinorrhoea	1	0
Respiratory disorders SOC TOTAL	19	0

Report Run Date: 01-Jul-2022

Reaction Name	 Total	Fatal
Skin disorders		
Alopecias		
Diffuse alopecia	1	0
Angioedemas		
Angioedema	1	0
Apocrine and eccrine gland disorders		
Cold sweat	1	0
Hyperhidrosis	5	0
Night sweats	2	0
Dermal and epidermal conditions NEC		
Dry skin	1	0
Sensitive skin	1	0
Skin burning sensation	1	0
Skin warm	1	0
Erythemas		
Erythema	4	0
Pilar disorders NEC		
Piloerection	1	0
Pruritus NEC		
Pruritus	5	0
Rashes, eruptions and exanthems NEC		
Rash	5	0
Rash papular	1	0
Rash pruritic	1	0
Skin and subcutaneous tissue ulcerations		
Skin erosion	1	0
Skin ulcer	1	0
Skin vasculitides		
Nodular vasculitis	1	0
Urticarias		
Urticaria	2	0
Skin disorders SOC TOTAL	36	0

Report Run Date: 01-Jul-2022

Data Lock Date: 29-Jun-2022 18:30:06 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Vascular disorders		
Blood pressure disorders NEC		
Labile blood pressure	1	0
Circulatory collapse and shock		
Circulatory collapse	1	0
Haemorrhages NEC		
Haemorrhage	1	0
Non-site specific embolism and thrombosis		
Embolism	2	0
Thrombosis	3	0
Peripheral embolism and thrombosis		
Deep vein thrombosis	1	0
Peripheral vascular disorders NEC		
Hot flush	1	0
Peripheral vasoconstriction, necrosis and vascular insufficiency		
Raynaud's phenomenon	1	0
Vascular hypertensive disorders NEC		
Hypertension	1	0
Vascular disorders SOC TOTAL	12	0
TOTAL REACTIONS FOR DRUG	628	2
TOTAL REPORTS	182	
TOTAL FATAL OUTCOME REPORTS		2