Case Series Drug Analysis Print Name: FOI 22/875 - Moderna Vaccine - Guernsey

Report Run Date: 15-Aug-2022

FOI 22/875 - Moderna All UK Spontaneously received Adverse Drug Vaccine - Guernsey: Reaction (ADR) reports received upto 04/08/2022 associated with the Moderna COVID-19 Vaccine reported from within Guernsey

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.

Name: FOI 22/875 - Moderna Vaccine - Guernsey

| Reaction Name | Total | Fatal |
|--------------------------------|-------|-------|
| Blood disorders | | |
| Lymphatic system disorders NEC | | |
| Lymphadenopathy | 3 | 0 |
| Blood disorders SOC TOTAL | 3 | 0 |

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| Reaction Name | Total | Fatal |
|--|-------|-------|
| Cardiac disorders | | |
| Cardiac signs and symptoms NEC | | |
| Palpitations | 4 | 0 |
| Ischaemic coronary artery disorders | | |
| Acute myocardial infarction | 1 | 0 |
| Noninfectious myocarditis | | |
| Myocarditis | 1 | 0 |
| Rate and rhythm disorders NEC | | |
| Tachycardia | 2 | 0 |
| Supraventricular arrhythmias | | |
| Atrial fibrillation | 1 | 0 |
| Atrial flutter | 1 | 0 |
| Ventricular arrhythmias and cardiac arrest | | |
| Ventricular tachycardia | 1 | 0 |
| Cardiac disorders SOC TOTAL | 11 | 0 |

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| Total | Fatal |
|-------|-------|
| | |
| | |
| 1 | 0 |
| | |
| 1 | 0 |
| 2 | 0 |
| | 1 |

Name: FOI 22/875 - Moderna Vaccine - Guernsey

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| Reaction Name | Total | Fatal |
|--|-------|-------|
| Eye disorders | | |
| Ocular disorders NEC | | |
| Eye pain | 1 | 0 |
| Ocular sensation disorders | | |
| Photophobia | 1 | 0 |
| Retinal bleeding and vascular disorders (excl retinopathy) | | |
| Retinal vein occlusion | 1 | 0 |
| Visual impairment and blindness (excl colour blindness) | | |
| Blindness | 1 | 0 |
| Eye disorders SOC TOTAL | 4 | 0 |

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| Reaction Name | Total | Fatal |
|---|-------|-------|
| Gastrointestinal disorders | | |
| Gastrointestinal and abdominal pains (excl oral and throat) | | |
| Abdominal pain | 1 | 0 |
| Abdominal pain upper | 1 | 0 |
| Nausea and vomiting symptoms | | |
| Nausea | 6 | 0 |
| Oral soft tissue signs and symptoms | | |
| Paraesthesia oral | 1 | 0 |
| Oral soft tissue swelling and oedema | | |
| Lip swelling | 1 | 0 |
| Gastrointestinal disorders SOC TOTAL | 10 | 0 |

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| Reaction Name | Total | Fatal |
|---|-------|------------|
| General disorders | | |
| Application and instillation site reactions | | |
| Application site erythema | 1 | 0 |
| Asthenic conditions | | |
| Fatigue | 12 | 2 0 |
| Malaise | 3 | 0 |
| Febrile disorders | | |
| Pyrexia | 11 | 0 |
| Feelings and sensations NEC | | |
| Chills | | |
| Feeling cold | 1 | C |
| Feeling hot | 2 | 2 0 |
| Thirst | 1 | C |
| General signs and symptoms NEC | | |
| Illness | 1 | C |
| Influenza like illness | 3 | S C |
| Peripheral swelling | 1 | C |
| Swelling | 1 | C |
| Injection site reactions | | |
| Injection site pain | 3 | |
| Mass conditions NEC | | |
| Mass | 1 | C |
| Pain and discomfort NEC | | |
| Axillary pain | 1 | C |
| Chest discomfort | 1 | C |
| Chest pain | 3 | |
| Pain | 1 | C |
| Tenderness | 1 | 0 |
| Vaccination site reactions | | |
| Vaccination site erythema | 2 | 2 0 |
| Vaccination site pain | 2 | 2 0 |
| General disorders SOC TOTAL | 57 | <u>'</u> C |

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| MedDIXA Version. MedDIXA 23.0 | | |
|-------------------------------|-------|-------|
| Reaction Name | Total | Fatal |
| Infections | | |
| Coronavirus infections | | |
| COVID-19 | 3 | 0 |
| Influenza viral infections | | |
| Influenza | 2 | 0 |
| Viral infections NEC | | |
| Sweating fever | 1 | 0 |
| Infections SOC TOTAL | 6 | 0 |

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Report Run Date: 15-Aug-2022

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Injuries | | |
| Exposures associated with pregnancy, delivery and lactation | | |
| Maternal exposure during breast feeding | 1 | 0 |
| Skin injuries NEC | | |
| Contusion | 1 | 0 |
| Injuries SOC TOTAL | 2 | 0 |

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| Reaction Name | Total | Fatal |
|-------------------------------|-------|-------|
| Metabolic disorders | | |
| Appetite disorders | | |
| Decreased appetite | 1 | 0 |
| Metabolic disorders SOC TOTAL | 1 | 0 |

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| Reaction Name | Total | Fatal |
|---|-------|-------|
| Muscle & tissue disorders | | |
| Joint related signs and symptoms | | |
| Arthralgia | 5 | 0 |
| Muscle pains | | |
| Myalgia | 7 | 0 |
| Musculoskeletal and connective tissue conditions NEC | | |
| Musculoskeletal disorder | 1 | 0 |
| Musculoskeletal and connective tissue pain and discomfort | | |
| Musculoskeletal chest pain | 1 | 0 |
| Neck pain | 5 | 0 |
| Pain in extremity | 9 | 0 |
| Soft tissue disorders NEC | | |
| Neck mass | 1 | 0 |
| Muscle & tissue disorders SOC TOTAL | 29 | 0 |

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| Reaction Name | Total | Fatal |
|---|-------|-------|
| Nervous system disorders | | |
| Disturbances in consciousness NEC | | |
| Lethargy | 5 | 0 |
| Somnolence | 3 | 0 |
| Headaches NEC | | |
| Headache | 14 | 0 |
| Mental impairment (excl dementia and memory loss) | | |
| Cognitive disorder | 1 | 0 |
| Migraine headaches | | |
| Migraine | 1 | 0 |
| Neurological signs and symptoms NEC | | |
| Dizziness | 3 | 0 |
| Paraesthesias and dysaesthesias | | |
| Hypoaesthesia | 2 | 0 |
| Sensory abnormalities NEC | | |
| Sensory disturbance | 1 | 0 |
| Tremor (excl congenital) | | |
| Tremor | 1 | 0 |
| Nervous system disorders SOC TOTAL | 31 | 0 |

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|------------------------------|-------|-------|
| MedDRA Version: MedDRA 25.0 | | |
| Reaction Name | Total | Fatal |
| Psychiatric disorders | | |

| Psychiatric disorders | | |
|---------------------------------|---|---|
| Anxiety symptoms | | |
| Anxiety | 1 | 0 |
| Psychiatric disorders SOC TOTAL | 1 | 0 |

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| Reaction Name | Total | Fatal |
|---------------------------------|-------|-------|
| Respiratory disorders | | |
| Breathing abnormalities | | |
| Dysphoea | 5 | 0 |
| Nasal disorders NEC | | |
| Epistaxis | 1 | 0 |
| Pulmonary oedemas | | |
| Pulmonary congestion | 1 | 0 |
| Pulmonary oedema | 1 | 0 |
| Respiratory disorders SOC TOTAL | 8 | 0 |

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| Reaction Name | Total | Fatal |
|--------------------------------------|-------|-------|
| Skin disorders | | |
| Angioedemas | | |
| Angioedema | 2 | 0 |
| Apocrine and eccrine gland disorders | | |
| Cold sweat | 1 | 0 |
| Night sweats | 4 | 0 |
| Bullous conditions | | |
| Blister | 1 | 0 |
| Dermal and epidermal conditions NEC | | |
| Skin discolouration | 1 | 0 |
| Erythemas | | |
| Erythema | 1 | 0 |
| Pruritus NEC | | |
| Pruritus | 4 | 0 |
| Rashes, eruptions and exanthems NEC | | |
| Rash | 3 | 0 |
| Rash erythematous | 1 | 0 |
| Urticarias | | |
| Urticaria | 2 | 0 |
| Skin disorders SOC TOTAL | 20 | 0 |

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| Reaction Name | Total | Fatal |
|---|-------|-------|
| Surgical & medical procedures | | |
| Therapeutic procedures NEC | | |
| Injection | 2 | 0 |
| Surgical & medical procedures SOC TOTAL | 2 | 0 |

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|--------------------------------------|-------|-------|
| Vascular disorders | | |
| Peripheral embolism and thrombosis | | |
| Blue toe syndrome | 1 | 0 |
| Site specific vascular disorders NEC | | |
| Pallor | 1 | 0 |
| Vascular disorders SOC TOTAL | 2 | 0 |
| TOTAL REACTIONS FOR DRUG | 189 | 0 |
| | | |
| TOTAL REPORTS | 40 | |